Innovation, Technology, and Knowledge Management

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Responsible Product Innovation

Putting Safety First

Springer

Innovation, Technology, and Knowledge Management

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Series Foreword

The Springer book series *Innovation, Technology, and Knowledge Management* was launched in March 2008 as a forum and intellectual, scholarly "podium" for global/local, transdisciplinary, transsectoral, public–private, and leading/"bleeding"-edge ideas, theories, and perspectives on these topics.

The book series is accompanied by the Springer *Journal of the Knowledge Economy,* which was launched in 2009 with the same editorial leadership.

The series showcases provocative views that diverge from the current "conventional wisdom," that are properly grounded in theory and practice, and that consider the concepts of ***robust competitiveness,***[1] ***sustainable entrepreneurship***,[2] and ***democratic capitalism,***[3] central to its philosophy and objectives. More specifically, the aim of this series is to highlight emerging research and practice at the dynamic intersection of these fields, where individuals, organizations, industries, regions, and nations are harnessing creativity and invention to achieve and sustain growth.

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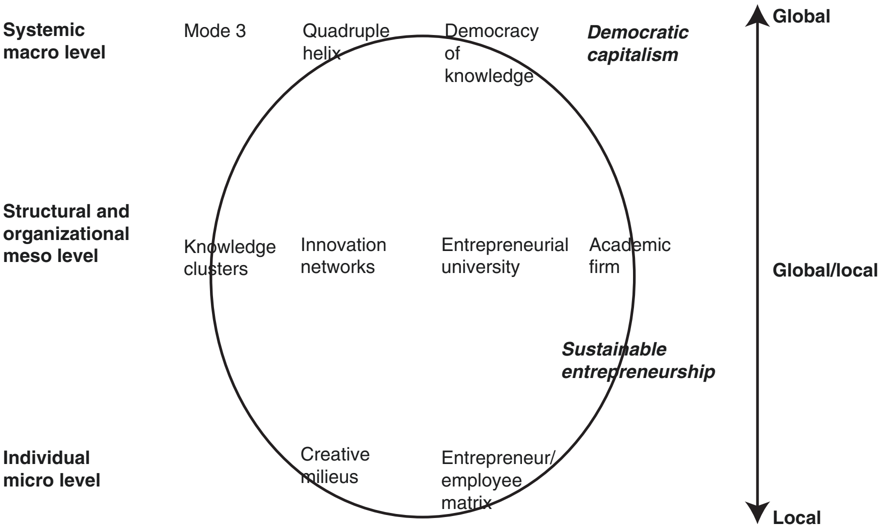
[1] We define *sustainable entrepreneurship* as the creation of viable, profitable, and scalable firms. Such firms engender the formation of self-replicating and mutually enhancing innovation networks and knowledge clusters (innovation ecosystems), leading toward robust competitiveness (E.G. Carayannis, *International Journal of Innovation and Regional Development* 1(3). 235–254, 2009).

[2] We understand *robust competitiveness* to be a state of economic being and becoming that avails systematic and defensible "unfair advantages" to the entities that are part of the economy. Such competitiveness is built on mutually complementary and reinforcing low-, medium- and high-technology and public and private sector entities (government agencies, private firms, universities, and nongovernmental organizations) (E.G. Carayannis, *International Journal of Innovation and Regional Development* 1(3). 235–254. 2009).

[3] The concepts of *robust competitiveness* and *sustainable entrepreneurship* are pillars of a regime that we call *"democratic capitalism"* (as opposed to "popular or casino capitalism"), in which real opportunities for education and economic prosperity are available to all. Especially – but not only – younger people. These are the direct derivative of a collection of top-down policies as well as bottom-up initiatives (including strong research and development policies and funding, but going beyond these to include the development of innovation networks and knowledge clusters across regions and sectors) (E.G. Carayannis and A. Kaloudis. *Japan Economic Currents,* p. 6–10 January 2009).

Books that are part of the series explore the impact of innovation at the "macro" (economies, markets), "meso" (industries, firms), and "micro" levels (teams, individuals), drawing from such related disciplines as finance, organizational psychology, research and development, science policy, information systems, and strategy, with the underlying theme that for innovation to be useful it must involve the sharing and application of knowledge.

Some of the key anchoring concepts of the series are outlined in the figure below and the definitions that follow (all definitions are from E.G. Carayannis and D.F.J. Campbell, *International Journal of Technology Management*, 46, 3–4, 2009).



Conceptual profile of the series *Innovation, Technology, and knowledge Management*

Conceptual profile of the series Innovation, Technology, and Knowledge Management

- The "Mode 3" Systems Approach for Knowledge Creation, Diffusion, and Use: "Mode 3" is a multilateral, multinodal, multimodal, and multilevel systems approach to the conceptualization, design, and management of real and virtual, "knowledge-stock" and "knowledge-flow," modalities that catalyze, accelerate, and support the creation, diffusion, sharing, absorption, and use of cospecialized knowledge assets. "Mode 3" is based on a system-theoretic perspective of socioeconomic, political, technological, and cultural trends and conditions that shape the coevolution of knowledge with the "knowledge-based and knowledge-driven, global/local economy and society."

- Quadruple Helix: Quadruple helix, in this context, means to add to the triple helix of government, university, and industry a "fourth helix" that we identify as the "media-based and culture-based public." This fourth helix associates with "media," "creative industries," "culture," "values," "life styles," "art," and perhaps also the notion of the "creative class."
- Innovation Networks: Innovation networks are real and virtual infrastructures and infratechnologies that serve to nurture creativity, trigger invention, and catalyze innovation in a public and/or private domain context (for instance, government–*university–industry public–private research and technology development coopetitive partnerships).*
- *Knowledge Clusters: Knowledge clusters are agglomerations of cospecialized, mutually complementary, and reinforcing knowledge assets in the form of "knowledge stocks" and "knowledge flows" that exhibit self-organizing, learning-driven, dynamically adaptive competences and trends in the context of an open systems perspective.*
- *Twenty-First Century Innovation Ecosystem: A twenty-first century innovation ecosystem is a multilevel, multimodal, multinodal, and multiagent system of systems. The constituent systems consist of innovation metanetworks (networks of innovation networks and knowledge clusters) and knowledge metaclusters (clusters of innovation networks and knowledge clusters) as building blocks and organized in a self-referential or chaotic fractal knowledge and innovation architecture (Carayannis 2001), which in turn constitute agglomerations of human, social, intellectual, and financial capital stocks and flows as well as cultural and technological artifacts and modalities, continually coevolving, cospecializing, and cooperating. These innovation networks and knowledge clusters also form, reform, and dissolve within diverse institutional, political, technological, and socioeconomic domains, including government, university, industry, and nongovernmental organizations and involving information and communication technologies, biotechnologies, advanced materials, nanotechnologies, and next- Generation energy technologies.*

Who is this book series published for? The book series addresses a diversity of audiences in different settings:

1. *Academic communities:* Academic communities worldwide represent a core group of readers. This follows from the theoretical/conceptual interest of the book series to influence academic discourses in the fields of knowledge, also carried by the claim of a certain saturation of academia with the current concepts and the postulate of a window of opportunity for new or at least additional concepts. Thus, it represents a key challenge for the series to exercise a certain impact on discourses in academia. In principle, all academic communities that are interested in knowledge (knowledge and innovation) could be tackled by the book series. The interdisciplinary (transdisciplinary) nature of the book series underscores that the scope of the book series is not limited a priori to a specific basket of disciplines. From a radical viewpoint, one could create the hypothesis that there is no discipline where knowledge is of no importance.

2. *Decision makers – private/academic entrepreneurs and public (governmental, subgovernmental) actors:* Two different groups of decision makers are being addressed simultaneously: (1) private entrepreneurs (firms, commercial firms, academic firms) and academic entrepreneurs (universities), interested in optimizing knowledge management and in developing heterogeneously composed knowledge-based research networks; and (2) public (governmental, subgovernmental) actors that are interested in optimizing and further developing their policies and policy strategies that target knowledge and innovation. One purpose of public *knowledge and innovation policy* is to enhance the performance and competitiveness of advanced economies.
3. *Decision makers in general:* Decision makers are systematically being supplied with crucial information, for how to optimize knowledge-referring and knowledge-enhancing decision-making. The nature of this "crucial information" is conceptual as well as empirical (case-study-based). Empirical information highlights practical examples and points toward practical solutions (perhaps remedies), conceptual information offers the advantage of further-driving and further-carrying tools of understanding. Different groups of addressed decision makers could be decision makers in private firms and multinational corporations, responsible for the knowledge portfolio of companies; knowledge and knowledge management consultants; globalization experts, focusing on the internationalization of research and development, science and technology, and innovation; experts in university/business research networks; and political scientists, economists, and business professionals.
4. *Interested global readership:* Finally, the Springer book series addresses a whole global readership, composed of members who are generally interested in knowledge and innovation. The global readership could partially coincide with the communities as described above ("academic communities," "decision makers"), but could also refer to other constituencies and groups.

Washington, DC, USA
Elias G. Carayannis

Preface

Product safety affects everybody and should not just be a responsibility of government certification bodies, corporate litigation lawyers, and product manufacturers. Research on responsible innovation is gaining traction with scholars, managers, and entrepreneurs alike, as increasingly the benefits of improved safety in products outweigh the economic costs of achieving them. The problem to date has been that the benefits of product safety were not only not easy to measure and quantify, but they were also difficult to attribute and appropriate by beneficiaries. For a long time, it was unclear who would benefit from product safety and how much and hence who would be obligated (or mandated) to contribute to it and what.

Several large-scale trends have made clarifying the role of product safety in its socioeconomic context difficult. One was the rise of consumerism and the shift in the balance of power from manufacturers and brand owners to customers and regulators. Another was the internationalization of value chains and the fragmentation of markets worldwide. A third was technological change leading to a sophistication of products that rendered average consumers increasingly unaware of risk and potential accidents. These trends continue to change our economies and our societies, and they are far from concluded. But it is paramount to introduce a new voice into the orchestra of profit and cost, scale and scope, utility and liability, and expectation and demand. This is the voice of advocating responsible innovation, which calls for greater attention to product safety in and from product innovation.

This book is the result of ongoing research on product safety and responsible product innovation, one puzzle piece in a much bigger picture that is still being laid out by scholars and researchers worldwide. In this book, we focus on product safety and innovation in the durable juvenile product industry. Its consumers are close to our hearts: they are our children, most vulnerable to faulty and unsafe products, and largely unprotectable by its defects. Most of the products are made in China, a country which has a poor reputation for manufacturing quality, although much of it is undeserved and many product defects are design- rather than manufacturing-related.

We only have indirect means to improve product safety from the outside, but in our research, we looked inside the black box of product innovation in firms—the design processes, the innovation climate, the safety culture, and the R&D processes and practices—to identify antecedents of products that not only do well in markets but also remain safe over their lifetime for its consumers. We needed to deep-dive into Chinese manufacturing firms, but we also investigated design practices in brand owners worldwide. In the course of our research, we crafted a product innovation and product safety model that we used to sample the innovation practices of the 126 companies we investigated. In addition to solid quantitative research based on structural equation modeling, we also conducted many interviews with people in charge of product safety and innovation, both in firms and those observing and controlling it, asking the ever-important why, how, and so-what questions, to create qualitative data-rich case studies that explain what really is going on in some of the best companies (in terms of consistently and reliably delivering safe products) of the world. The results of this research have been published in leading international journals and conferences or are under final review there and thus have also been scrutinized by the critical gatekeepers of scientific and academic quality.

In sum, some of the main results of this research support what we already suspected but were unable to state with statistically informed conviction, for instance, that top management involvement is paramount in setting the right context and strategy for safety to flourish in firms or that a strong safety-first culture impacts R&D processes such that they deliver more reliably safe and innovative products. But there are also a few surprises that we did not expect, for instance, that concurrent engineering is not connected to product safety, even though cross-functional communication in innovation should lead to greater awareness of product features and its effects on eventual users. We were also a bit disappointed that product safety cannot be tied to the use of a particular tool, skill, or practice, as this would have made it so much easier for manufacturers to amend and improve their own R&D processes quickly. But those findings reflect the greater insight that responsible innovation is a systemic challenge, a grand challenge as it is often called when multiple stakeholders need to coordinate their actions against great odds, and a challenge that requires purposeful orchestration at the firm level as well as far-sighted coordination with external stakeholders in the government, markets, and industry bodies. This is no easy task and will surely challenge manufacturers in many industries for many years to come.

We wish to recognize the many R&D managers, entrepreneurs, and quality experts—in China and elsewhere—who volunteered information on how they manage product innovation and product safety in their companies, providing insights for the benefit of everybody and not just their own companies. We also would like to thank the team at Springer, our publisher, for their assistance in transforming the original research (a doctoral thesis by the first author under the supervision of the second and third author) into a product that you will surely enjoy holding in your hands, and—last but not least—our editor Elias Carayannis, who made room in his series “Innovation, Technology, and Knowledge Management” to host our work.

This book is for them, but primarily it is for the many children and their families who are affected daily by products that could be designed safer and better.

Singapore	Andy Yunlong Zhu
Kaunas, Lithuania	Max von Zedtwitz
Ecully, France	Dimitris G. Assimakopoulos

Advance Praise for *Responsible Product Innovation*

"An eye-opening read for those wanting to fathom the challenges and opportunities of responsible product innovation."

Paolo Salvaterra
Head of Section Design and Production, Swiss Federal Office of Civil Aviation

"Product safety nowadays draws more and more concerns, especially for children's products which are designed with increasing sophistication. This issue is addressed intensively in this book; the most valuable insights are provided for managing safety of innovative products. I highly recommend reading this book."

Zhuohui Liu
Former Chief Engineer of the Chinese Administration
of Quality Supervision, Inspection and Quarantine and Academician
at the International Academy for Quality

"It is refreshing to read a book based upon actual experience rather than theory. This book is co-written by a member of one of the most successful, high-quality organizations in China. He really understands the situation because he had to make it work."

Dr. H. James Harrington
CEO of Harrington Management Systems,
Quality Guru and Author of 35 Books

"A comprehensive review on strategic product safety and innovation models, a useful reference for product developers."

Ong Mei Horng, PhD
Chief Scientific Officer, Corporate Research Development,
Food & Beverage Company

“This book vividly presents the business case and good practices for integrating safety in the new product development process. It is a cogent contribution, compellingly filling a gap in the field of innovation.”

Dr. Georges Haour
Professor at IMD, Switzerland

“I am delighted to endorse this forthcoming book “*Responsible Product Innovation*”. This book will provide academics and decision makers (including specialists, organisations and policy makers) with the necessary tools and techniques to meet all stakeholders’ demands for safe innovative products, together with the reassurance that they have been developed by the world-leading authors of this important new publication.”

Terry Wilkins
Yorkshire Forward Professor of Nanomanufacturing Innovation,
Leeds University
Fellow of the Royal Academy of Engineering, UK
Chair of the European Commission’s Expert Advisory Group
for Nano-, Advanced Materials- & Production- Technologies

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Author Biographies

Andy Yunlong Zhu is a senior vice president of Goodbaby International Holdings Limited, the co-chairman of ISO/PC 310 (a committee to establish international standards for juvenile products), and an adjunct professor at the Nanjing University MBA Center and Jiangsu Science and Technology University. He has held various executive leadership positions in MNCs in different industries in R&D, quality, and operations and general management. His research focuses on R&D and innovation management, quality and product safety management, and operations management. He has published in academic and practitioner journals, such as the *International Journal of Production Economics*.

Max von Zedtwitz is a professor of strategy and innovation at Kaunas University of Technology in Lithuania and a director of the GLORAD Center for Global R&D and Innovation, a research organization with centers in China, the USA, Brazil, and Europe. He was previously on the faculty of Tsinghua University, Peking University, Skoltech, and International Institute for Management Development (IMD) and also held positions as a vice president of PRTM Management Consultants (now part of PwC) and as president of AsiaCompete Ltd. He has published widely in academic and practitioner journals, including 12 books, and was recognized by IAMOT as one of the 50 most influential innovation scholars worldwide in 2009. A frequent public speaker, he has appeared on radio and television and has been cited in *The Economist*, *China Daily*, the *South China Morning Post*, and *The New York Times*.

Dimitris G. Assimakopoulos is a professor of technology and innovation management at EMLYON (EML) Business School in France and founding director of the EML Global DBA. He also serves as the president of the European Doctoral Programmes Association in Management and Business Administration (EDAMBA), a faculty at the European Institute for Advanced Studies in Management (EIASM), and a board member for the EFMD European Quality Link (EQUAL). Prior to joining EML, he worked as a professor, associate dean for research, and DBA director at Grenoble Ecole de Management. Dimitris has been educated in civil engineering, architecture, planning, and economic sociology in Greece, the UK, France, and the

USA. He has also been a European Commission "Marie Curie" ESR and principal investigator, a visiting scholar in sociology and the Asia-Pacific Research Center at Stanford University (USA), as well as a visiting professor at universities in the UK (Durham, Newcastle) and China (Sun Yat-sen, Tongji). Dimitris has led or participated in several multi-million-euro projects with world-class organizations such as CERN, Fraunhofer ISI, and Airbus. He has published more than a hundred publications including 12 books and special issues and articles in scholarly and professional journals such as *Computers & Operations Research*, *Environment and Planning B*, the *International Journal of Information Management*, the *International Journal of Production Economics*, the *International Journal of Technology Management*, the *International Small Business Journal*, *Organizational Dynamics*, *R&D Management*, *Science and Public Policy*, and *MIT Sloan Management Review*. His teaching has varied focusing initially on business geographics and MIS and more recently on doctoral studies; he also supervised the successful completion of 18 PhD and DBA theses. He also initiated the EIASM Eden SNA (Social Network Analysis) doctoral seminar with colleagues from Bocconi University, UC London, and MIT Sloan.

Glossary

Product Innovation and Safety-Related Section

Administration for Quality Supervision, Inspection and Quarantine of China (AQSIQ) AQSIQ is a ministerial-level department under the State Council of the People's Republic of China that is in charge of national quality, metrology, entry-exit commodity inspection, entry-exit health quarantine, entry-exit animal and plant quarantine, import-export food safety, certification and accreditation, standardization, as well as administrative law enforcement.

American Society for Quality (ASQ) ASQ is a knowledge-based global community of quality professionals, with nearly 80,000 members dedicated to promoting and advancing quality tools, principles, and practices in their workplaces and communities.

American Society for Testing and Materials (ASTM) ASTM is a standard organization that develops and publishes voluntary consensus technical standards for a wide range of materials, products, systems, and services in the USA.

China Inspection and Quarantine (CIQ) CIQ directly operates under AQSIQ to secure the quality of products imported to China.

China Toy and Juvenile Products Association (TJPA) TJPA is the not-for-profit trade association representing the interests of the Chinese toy and juvenile product industry. The government, the trade, media, and consumers recognize CTJPA as the authoritative voice of our industry.

Concurrent Engineering (CE) Concurrent engineering is a systematic approach to the integrated, concurrent design of products and their related processes, including manufacture and support. In CE, different stages run simultaneously, rather than consecutively. This approach is intended to cause the developers to consider all elements of the product life cycles from conception through disposal, including quality, cost, schedule, and user requirements (Pennel and Winner 1989).

Cross-functional Team (CFT) A CFT is a group of people with different functional expertise working toward a common goal.

Design for Safety (DFS) DFS is a process of defining the need for safety, identifying, estimating and evaluating risks, and conducting design reviews in order to reduce risks to an acceptable level.

Design Quality Engineer (DQE) A DQE is a quality engineer tasked to ensure product quality in the design or R&D stages.

Design-Manufacturing Integration (DMI) DMI aims to improve the way that design and manufacturing work together and, ultimately, improve NPD effectiveness.

DFMEA Design FMEA (DFMEA) explores the possibility of product malfunctions, reduced product life, and safety and regulatory concerns derived from material properties, geometry, tolerances, interfaces with other components and/or systems, and engineering noise.

Engineering Pilot (EP) EP refers to a pilot production run with first off tool components to verify the product design performance.

European Foundation of Quality Management (EFQM) EFQM is a not-for-profit membership foundation in Brussels, established in 1989 to increase the competitiveness of the European economy. The initial impetus for forming EFQM was a response to the work of W. Edwards Deming and the development of the concepts of total quality management.

Failure Mode and Effect Analysis (FMEA) FMEA is a highly structured approach for discovering potential failures that may exist within the design of a product or process.

Fault Tree Analysis (FTA) FTA is a top-down, deductive failure analysis in which an undesired state of a system is analyzed using Boolean logic to combine a series of lower-level events.

Final Engineering Pilot (FEP) FEP refers to a pilot production run set up to validate the final product design.

Good Manufacturing Practices (GMP) GMP are the practices required in order to conform to the guidelines recommended by agencies that control authorization and licensing for manufacture and sale of food, drug products, and active pharmaceutical products. These guidelines provide minimum requirements that a pharmaceutical or a food product manufacturer must meet to assure that the products are of high quality and do not pose any risk to the consumer or public.

Good Laboratory Practice (GLP) GLP specifically refers to a quality system of management controls for research laboratories and organizations to ensure the uniformity, consistency, reliability, reproducibility, quality, and integrity of chemical (including pharmaceuticals) nonclinical safety tests, from physiochemical properties through acute to chronic toxicity tests.

Hazard Analysis and Critical Control Point (HACCP) HACCP is a systematic preventive approach to food safety, addressing the risks from biological, chemical, and physical hazards in production processes that can cause the finished product to be unsafe, and designs measurements to reduce these risks to a safe level.

High Price Point (HPP) HPP refers to high-price range products.

ICE Ideal concurrent engineering practices, a dependent variable in our ideal model representing manager perceptions.

International Academy for Quality (IAQ) IAQ is a community of the world's leading executives, practitioners, and academics dedicated to promoting the cause of quality.

International Electrotechnical Commission (IEC) IEC is the world's leading organization for preparing and publishing international standards for all electrical, electronic, and related technologies.

INPP Ideal new product development process practices, a dependent variable in our ideal model representing manager perceptions.

IPSC Ideal product safety culture practices, a dependent variable in our ideal model representing manager perceptions.

IPSS Ideal product safety strategy practices, a dependent variable in our ideal model representing manager perceptions.

Juvenile Product Juvenile product refers to a consumer product designed or intended primarily for children 12 years of age or younger (CPSA 2008). In this research, it includes products such as toys, strollers, child restraint system (children's car seats), walkers, cribs, play yards, high chairs, safety gates, bouncers, swings, ride-ons, bicycles, tricycles, and nursery articles (such as milk bottles).

Key Performance Indicator (KPI) KPI is a type of performance measurement. KPIs evaluate the success of an organization or of a particular activity (such as projects, programs, products, and other initiatives) in which it engages.

Malcolm Baldrige National Quality Award (MBNQA) The MBNQA recognizes US organizations in the business, health care, education, and nonprofit sectors for performance excellence. The Baldrige Award is the only formal recognition of the performance excellence of both public and private US organizations given by the president of the USA.

Management Commitment to Safety (MCS) Top management commitment to safety practices.

Medium Price Point (MPP) MPP refers to medium price range products.

Multinational Corporation (MNC) MNC is a company that owns or controls production of goods or services in two or more countries other than its home country.

National Electronic Injury Surveillance System (NEISS) The CPSC's National Electronic Injury Surveillance System is a national probability sample of hospitals in the USA and its territories. The primary purpose of NEISS is to collect data on consumer product-related injuries occurring in the USA.

National Highway Traffic Safety Administration (NHTSA) The NHTSA is an agency of the executive branch of the US government, part of the Department of Transportation. Its mission is "to save lives, prevent injuries, and reduce vehicle-related crashes."

New Product Development (NPD) NPD is the transformation of a marketing opportunity into a product available for sale. It includes all processes of bringing a new product to the market.

NPD Process (NPP) The new product development process covers the set of all activities used to develop and print a product to market, especially stages, stage activities, gates, deliverables, gate reviews, and gate criteria that typically constitute a well-defined NPD process.

Open Price Point (OPP) OPP refers to low price end products.

Original Equipment Manufacturer (OEM) An original equipment manufacturer (OEM) is a company that produces parts and equipments that may be marketed by another manufacturer. For example, if company A makes strollers that are sold by company B under company B's brand, company A is an OEM.

Post-launch Review (PLR) PLR refer to reviews conducted after a new product is commercialized to evaluate whether the product performs as predefined expectations.

PFMEA Process FMEA (PFMEA) discovers failure that impacts product quality, reduced reliability of the process, customer dissatisfaction, and safety or environmental hazards derived from human factors, methods followed while processing, materials used, machines utilized, measurement systems impact on acceptance, and environment factors on process performance.

Preliminary Hazard Analysis (PHA) PHA is a semiquantitative analysis to identify all potential hazards and accident events that may lead to accident.

Product Safety (PS) Product safety is defined as whether the operation or use of a product, under normal or reasonably foreseeable condition of use, including duration, involves risk of injury or damage to health of users or damage to property or environment. A product is considered safe if the risk involved is considered acceptable and consistent with a high-level protection for health and safety of consumers (European Union Directive 2001/95/EU). We consider product safety as the ninth dimension of product quality along with the eight dimensions of quality (performance, features, reliability, conformance, durability, serviceability, aesthetics and perceived quality) defined by Garvin (1984).

Product Safety Culture (PSC) Product safety culture refers to the attitudes, values, perceptions and beliefs shared by an organization or a sub-unit of an organization as defining norms and values, which determine how they act and react in relation to product safety (Hale 2000). Product safety climate refers to shared perceptions on product safety policies, procedures, and practices (Zohar 2008). Product safety climate is a snapshot of product safety culture.

Product Safety Performance (PSP) Product safety performance refers to how a product performs in terms of product safety. Internal PSP can be measured by a quality team at the outgoing product audit, i.e., product safety issues detected at the outgoing product audit, and external PSP can be measured by customer satisfaction in terms of product safety.

Product Safety Strategy (PSS) Product safety strategy refers to how a company positions or approaches product safety, that is, what to do and what not to do in terms of product safety management. In this research, product safety strategy is evaluated from the following aspects: (1) the role of the top management in product safety, (2) top management commitment to product safety, (3) product safety policies and procedure, and (4) use of product safety as a core competency.

Production Pilot (PP) PP refers to a manufacturing or engineering production line, set up during development for testing new methods, processes, and systems.

Qualification Plan (QP) QP is a document that defines a test/inspection matrix at each stage of NPD process to qualify the product.

Quality Function Deployment (QFD) QFD is a method developed in Japan in the 1960s to help transform the voice of the customer (VOC) into engineering characteristics for a product.

Quality Requirements (QR) QR is a document that defines all quality requirements for a product, including functionalities, performance, reliability, durability, safety, fit, feel, finish, etc.

Release to Production (RTP) RTP is a formal document to approve the mass production of a new product.

Responsible Product Innovation (RPI) RPI is an NPP process that takes into account effects and potential impacts on the environment and society. RPI requires organizations to take a holistic view on product innovation and to manage product safety risk properly in the product innovation process. The organization should not only consider the benefits that the product brings to customers but also take into account its inherent potential risks to customers, society, and environment.

Responsible Research and Innovation (RRI) RRI is defined as "the comprehensive approach of proceeding in research and innovation in ways that allow all stakeholders that are involved in the processes of research and innovation at an early stage (A) to obtain relevant knowledge on the consequences of the outcomes of their actions and on the range of options open to them and (B) to effectively evaluate both outcomes and options in terms of societal needs and moral values and (C) to use these considerations (under A and B) as functional requirements for design and development of new research, products and services" (EC 2013).

Voice of Customer (VOC) VOC is a term used to describe the in-depth process of capturing customer's expectations, preferences, and aversions.

US Consumer Product Safety Commission (CPSC) The CPSC is an independent agency of the US government that promotes the safety of consumer products by addressing "unreasonable risks" of injury though coordinating recalls, evaluating products that are the subject of consumer complaints or industry reports, developing uniform safety standards, and conducting research into product-related illness and injury.

Statistics-Related Section

Average Interscale Correlations (AIC) AIC is used to assess construct discriminant validity. Adequate discriminant validity is established if the Cronbach reliability coefficient of each scale is larger than its average interscale correlations.

Average Variance Extracted (AVE) AVE is a measure to assess convergent validity. A statistic that states how much variance captured by the latent variable in a structural equation model is shared among other variables.

Confirmative Factor Analysis (CFA) CFA is a special form of factor analysis factor, most commonly used in social research. It is used to test whether measures of a construct are consistent with a researcher's understanding of the nature of that construct (or factor).

Comparative Fit Index (CFI) CFI analyzes the model fit by examining the discrepancy between the data and the hypothesized model, while adjusting for the issues of sample size inherent in the chi-squared test of model fit and the normed fit index. CFI values range from 0 to 1, with larger values indicating better fit.

Critical Ratio (CR) CR is a ratio associated with the probability of a sample, usually the ratio of the deviation from the mean to the standard deviation.

General Linear Modeling (GLM) GLM is a flexible generalization of ordinary linear regression that allows for response variables that have error distribution models other than a normal distribution.

Goodness-of-Fit Index (GFI) GFI is a measure of fit between the hypothesized model and the observed covariance matrix. The GFI ranges between 0 and 1, with a value of over 0.90 generally indicating acceptable model fit.

Multivariate Analysis of Variance (MANOVA) MANOVA is a procedure for comparing multivariate sample means. It is used when there are two or more dependent variables and is typically followed by significance tests involving individual dependent variables separately.

Non-normed Fit Index (NNFI) NNFI is also known as Tucker-Lewis index (TLI), as it was built on an index formed by Tucker and Lewis to resolve some of the issues of negative bias. Values for the NNFI should range between 0 and 1, with a cutoff of 0.90 or greater indicating an acceptable model fit.

Normed Fit Index (NFI) NFI analyzes the discrepancy between the chi-squared value of the hypothesized model and the chi-squared value of the null model. Values for both the NNFI should range between 0 and 1, with a cutoff of 0.90 or greater indicating an acceptable model fit.

Root Mean Square Error of Approximation (RMSEA) RMSEA addresses issues of sample size by analyzing the discrepancy between the hypothesized model, with optimally chosen parameter estimates, and the population covariance matrix. The RMSEA ranges from 0 to 1, with smaller values indicating better model fit. A value of 0.06 or less is indicative of acceptable model fit.

Standardized Root Mean Square Residual (SRMR) SRMR is the square root of the discrepancy between the sample covariance matrix and the model covariance matrix.

Structural Equation Modeling (SEM) SEM is a diverse set of mathematical models, computer algorithms, and statistical methods that fit networks of constructs to data. SEM includes confirmatory factor analysis, path analysis, partial least squares path modeling, and latent growth modeling. It is commonly used in the social sciences because of its ability to impute relationships between unobserved constructs (latent variables) from observable variables.

Totally Free Multiple Group Model (TF model) The TF model is the baseline model for comparison. It is a model with all free parameters being estimated separately and therefore free to take on different values in each group.

Variation Inflation Factors (VIF) VIF quantifies the severity of multicollinearity in an ordinary least squares regression analysis. It provides an index that measures how much the variance (the square of the estimate's standard deviation) of an estimated regression coefficient is increased because of collinearity.

Chapter 1
Introduction: Better Safe than Sorry

1.1 What Is Product Safety?

Product safety is defined as whether the use of a product, under normal or reasonably foreseeable condition of use, including duration, involves any risk of injury or damage to health of users or damage to property or environment. Too often this becomes a matter of life and death: not only for the unlucky consumers who are exposed to the product and risk their well-being but also for the companies that design, manufacture, and sell these products. Insufficient product safety has grave implications for individuals, companies, and occasionally society as we know it. In 2017, the US Consumer Product Safety Commission (CPSC) estimated that in the USA alone, "deaths, injuries and property damage from consumer product incidents cost [the U.S.] more than $1 trillion annually."

In this book, we focus on what companies that design, develop, and manufacture products can do to improve product safety. Of course, companies have both legal and ethical responsibilities to make sure their products are safe. Product safety is carefully monitored by consumer organizations and regulatory bodies. According to Article 2b of the European Union Directive 2001/95/EU, a "safe product shall mean any product, under normal or reasonably foreseeable condition of use including duration, and, where applicable, putting into service, installation and maintenance requirements, does not present any risk or only the minimum risks compatible with the product's use, considered as acceptable and consistent with a high level of protection for the safety and health and of persons..." Product safety is also at the heart of industry regulations focusing on internal processes, such as GMP ("good manufacturing practice") or GLP ("good laboratory practice") in the pharmaceutical industry. And perhaps too often, the safety of a product is addressed and improved only through open-market mechanisms such as customer feedback, organized consumer intervention, liability lawsuits, and political lobbying. Frequently, the degree of product safety in these instances is determined only by the voluntary action of the manufacturer, either in anticipation of possible unfavorable economic consequences

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or in response to pressure from consumer groups. Therefore, strategic product safety management is central to the emerging field of "responsible innovation" (von Schomberg 2013), especially responsible *product* innovation, and the main focus of our work.

1.2 Public Perceptions of Product Safety and Consequences for Management

In the past decade, global attention generated from several high-profile product quality-related failures and accidents has led to a heightened public awareness of product safety. The issue spans from the toy industry to automobile and food industries, from developing countries to developed countries, and from small original equipment manufacturers (OEMs) to world-renowned multinational companies (MNCs): nobody is immune to product safety risk. Product recalls not only cost companies billions of dollars but also damages their brand image and reputation and may even lead to criminal charges for their top executives.

For instance, on August 14, 2007, Mattel (the world's largest toy company) recalled 18.2 million toys that contained small, powerful magnets that could harm children if detached and swallowed. Although the toys followed Mattel's design specification, they were manufactured in China. Consequently, "Made in China" and Chinese manufacturers were widely criticized in the media. Four hundred thirty six thousand of them were die-cast toy cars that contained excessive levels of lead paint. The manufacturer that produced the toy cars in the first recall was Lee Der Industrial, a contract manufacturer from southern China. Following the recall, Mattel immediately terminated the contract with Lee Der, and Lee Der's export license was revoked by the Chinese government. The owner of Lee Der, Zhang Shuhong, committed suicide by hanging himself in a factory warehouse (Story and Barboza 2007). Mattel CEO Bob Eckert later apologized for the recalls and promised to enforce highest standard in the industry and test every production batch (CNN 2007).

Another high-profile case involving China was melamine-tainted powdered milk formula. Such formula could cause watered-down milk to appear richer in protein content. Overconsumption of melamine-tainted milk formula increases health risk and can cause death. By November 2008, China reported about 300,000 victims. Six infants died from kidney damage and 860 babies were hospitalized. Several people involved in this scandal were prosecuted and convicted: Two criminals were executed: one given a suspended death penalty, three received life sentences, two received 15-year prison terms, and seven local government officials, as well as the Chief of the Administration of Quality Supervision, Inspection and Quarantine (AQSIQ), were either dismissed or forced to resign (Wikipedia 2010)

Company top executives facing criminal charges as a result of marketing unsafe product are not uncommon. On January 6, 2017, a South Korean court sentenced the former CEO of Oxy Reckitt Benckiser and the company's research and development officials to 7 and 5 years in prison after the company's disinfectant for humidifiers killed scores of people and left hundreds with permanent lung damage. Choi Chang-young, chief judge of the case, said the disaster could have been prevented if top executives in the company, a subsidiary of the British consumer goods company Reckitt Benckiser Group Plc, had tried to ensure the chemicals' safety. Executives at Lotte Mart, Homeplus, and other retailers were also found guilty and sentenced to prison terms of 3–5 years for selling the toxic product without assuring its safety (Fox News 2017).

Automotive leaders Toyota, General Motors, and Volkswagen all suffered from product safety issues over the past few years. Toyota recalled 12.8 million cars between 2008 and 2010 as a result of unintended acceleration due to flawed pedal design, costing the company billions of dollars. By the time Toyota president Akio Toyoda apologized in his testimony to the US Congress, Toyota's stock price had dropped by about 20%—a $35 billion loss of market value within just 1 month. In March 2014, Toyota was fined $1.2 billion for its attempt to conceal the problem and protect its corporate image, leading a number of fatalities that could otherwise have been prevented. This constitutes the largest criminal penalty ever imposed on a car company in the US history. Toyota also faced 400 wrongful death and personal injury lawsuits (Douglas and Fletcher 2014).

In 2014, General Motors (GM) recalled nearly 30 million cars worldwide due to faulty ignition switches linked to at least 124 deaths. GM acknowledged the ignition switches were known to have been faulty for at least a decade, but had decided not to recall the cars prior to 2014. As part of a deferred prosecution agreement, GM agreed to forfeit $900 million to the USA. The *National Highway Traffic Safety Administration* (NHTSA) imposed a $35 million fine on GM for delaying the recall of defective cars, which is the highest fine that the NHTSA is allowed to levy (Wikipedia 2017a). The total cost for the recall reached $4.1 billion with several unsettled lawsuits still pending (Isidore 2015). Mary Barra, the new CEO of GM, fired 15 GM executives, appeared, and apologized before the congress four times, promising to change the company culture on product safety (Stock 2014).

Volkswagen's credibility as a reliable car manufacturer took a huge hit when on September 18, 2015, the US Environmental Protection Agency found Volkswagen's "clean diesel" vehicles to violate the Clean Air Act. The German car maker had installed "defeat devices," a software that allowed cars to cheat in emissions tests, thus making them appear cleaner than they actually were. But once on the road, these cars would pump out the pollutant nitrogen oxide (NOx) at up to 40 times the legal limit. The software "knew" when it was being tested, allowing it to switch emissions controls on and off. This installation affected Volkswagen, Audi, SEAT, and Skoda cars around the world. About 580,000 Volkswagen vehicles in the USA—and almost 10.5 million more worldwide—were not really "green" at all. Within 5 days of the revelations, CEO Martin Winterkorn resigned, top executives apologized, and several engineers were suspended. The company set aside $7.3 billion to deal with upcoming the penalties, with some estimating those fines to reach $45 billion in total (Smith and Parloff 2015; Spence 2015).

Another more recent case is the Galaxy Note 7, one of Samsung's most high-profile smartphones. Launched on August 19, 2016, Samsung suspended sales of the phone within 2 weeks and announced an informal recall after it received complaints that the phone generated excessive heat and caught fire. A formal US recall was announced on September 15, 2016, by the US CPSC (Consumer Product Safety Commission, 2017) after 92 reports of the phone overheating, including 25 reports of burns and 55 reports of property damage. Samsung exchanged the affected phones for an updated version using batteries from a different supplier. However, after some of these replacement phones were reported to catch fire as well, Samsung recalled the Galaxy Note 7 phones worldwide on October 10, 2016, and permanently ceased production of this device on October 11. Samsung eventually recalled all 2.5 million Galaxy Note 7 phones worldwide. It was reported that at least 112 Galaxy Note 7 phones had caught fire in the first month of sale. Credit Suisse estimated that Samsung would lose at least $17 billion in revenue as a result of the recall (Wikipedia 2017b).

1.3 Too Many Recalls, Too Little Research

While a few multibillion dollar cases get most of the public attention, there are many more often less-noticed incidents that undermine consumer trust in brands, cause physical or emotional pain, and incur financial losses. As far back as 2003, White and Pomponi estimated the cost to consumer product manufacturers for every recall at about $8 million and total recall cost at about $6 billion per year in the US consumer product industry. The impact of faulty product design is huge, both in terms of economic losses and human hardship. As a matter of fact, a large number of consumers are injured or die because of unsafe products every year. Among the most vulnerable consumers are children. In accordance with CPSC's National Electronic Injury Surveillance System (NEISS), which collects current injury data associated with consumer products from US hospital emergency departments, there were an average of 110 toy and juvenile product-related deaths for children under 5 years old and 250,000 toy-related injuries in the USA every year (Chewdhury 2016; Tu 2016; see Fig. 1.1).

Hundreds of millions of products are recalled from their markets every year for safety reasons. Among all recalled products, juvenile goods such as children's toys, articles, and equipment form the largest percentage in both regions. Figure 1.2 indicates the US CPSC recalls (as per the CPSC website) for consumer products, excluding automobiles and food. Figure 1.3 represents European nonfood consumer product (including automobiles) recalls announced in the Rapid Alert System for nonfood consumer products (RAPEX 2015).

Due to the record number of recalled cases, the year 2007 was named "The Year of the Recall" by *Consumer Reports* magazine (KID 2008). According to CPSC,

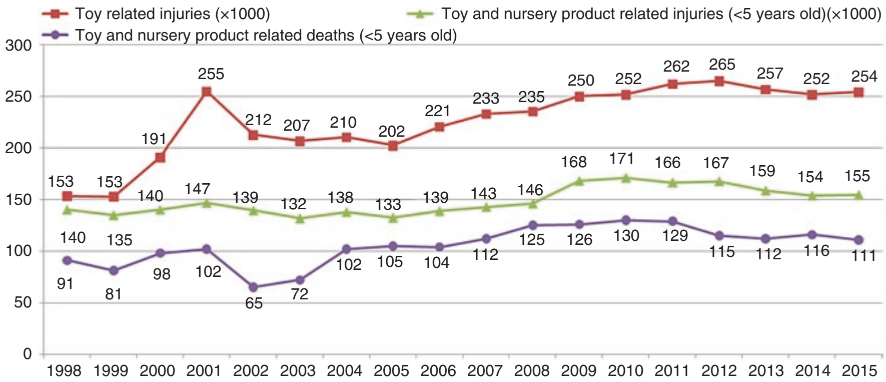

Fig. 1.1 Toy and nursery product related injuries and deaths in the US

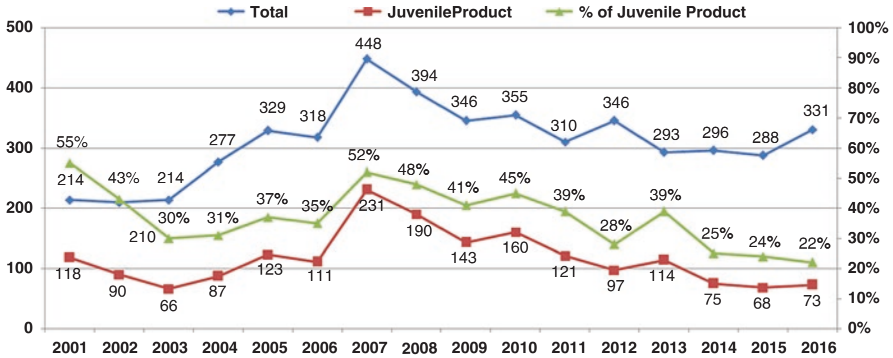

Fig. 1.2 US CPSC recalls

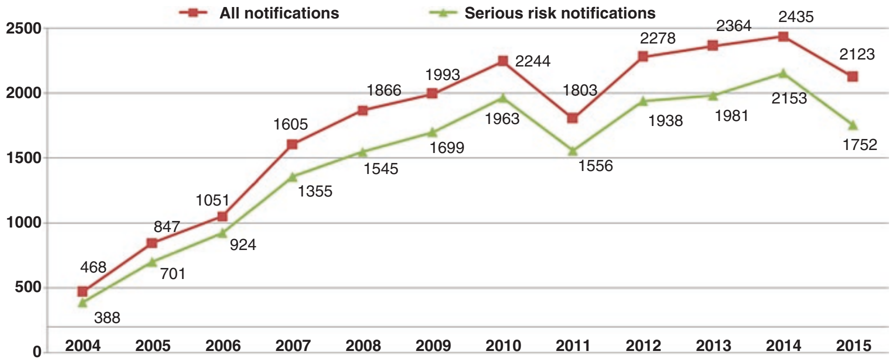

Fig. 1.3 Total number of notifications and serious risk notifications in Europe

there were 448 recalls for consumer products in 2007 in the USA, 231 recalls of those were for juvenile products (see Fig. 1.2). Since then, the US government implemented the Consumer Product Safety Improvement Act (CPSIA) and increased CPSC's resources and budget. The CPSC converted a large number of voluntary product safety standards into mandatory standards, especially for toys and juvenile products. The heightened attention in regulation has led to a significant decrease of unsafe product recalls in the USA, from its peak of 448 recalls in 2007 to 331 recalls in 2016. The number of recalls for toys and juvenile products dropped dramatically from 231 (52% of total recalls) in 2007 to 73 (22% of total recalls) in 2016 (see the CPSC website). In response to growing concerns about product safety issues, in 2009 the Chinese government established product safety recall policy for toys and juvenile products. RAPEX (2015) reported that the total number of recalls rose from 468 in 2004 to 2123 in 2015, with 30% toy and juvenile products accounting for the biggest share among all product categories in 2015 (see Fig. 1.2).

China figures prominently in public opinion about product safety, as it is one of the centers of global manufacturing. Indeed, among the products recalled in both the USA and Europe, most of them were manufactured in China. In 2015, 60% of products recalled in Europe in the RAPEX system originated from China (RAPEX 2015). According to the study of Beamish and Bapuji (2008), at the end of the third quarter of 2007, Chinese-made toy accounted for 88.2% of toy imports to the USA, and 95% of the toys recalled in the USA were made in China. The European percentages are similar. A report on "Evaluating Business Safety Measures in the Toy Supply Chain" by the European Commission (2008) found that some 85% of all toys were made in China.

As China manufactures a large share of consumer goods sold globally, it is often the Chinese OEM manufacturers that are being accused for underlying product defects. But product failure can be due to a variety of causes, among them are defective design, manufacturing error, and failure of information (Abbott and Tyler 1997). According to a PRTM study on consumer products, 75% of recalls can be traced to shortcomings in product development (White and Pomponi 2003). Bapuji and Beamish (2008) studied toy recalls in the USA for the year 2006 and discovered that 68% of all toy recalls in the USA were due to design flaws. In another study carried out by the same authors (Beamish and Bapuji 2008) covering toy recalls in the USA for the period of 1988–2007, 76.4% of all recalls were attributed to design flaws. These numbers show that—in addition to the manufacturing process—it is product development and product innovation that are responsible for faulty products.

In response to the large number of product recalls in Europe in the 2007, the European Commission (2008) established an independent expert group to evaluate business safety measures in the toy supply chain. The members of the expert group were represented by major stakeholders such as manufacturers, importers, retailers, test laboratories, consumers, and EU member states. The group conducted desk research, interviews, and fact-finding visits to 30 organizations in both Europe and China. One of the study's most important conclusions is that product safety cannot be guaranteed by final product testing only. Nonetheless, it has to be embedded in the entire product development and production process. Establishing a strong quality and safety culture was found to be a critical element in ensuring continuous attention to product safety issues.

Traditionally, the responsibility of managing product safety resides in the quality function. In quality management research literature, the most widely used definition for product quality is Garvin's eight critical dimensions of quality (Garvin 1984). They are performance, features, reliability, conformance, durability, serviceability, aesthetics, and perceived quality. Product safety is not explicitly mentioned here and is quite generally overlooked as an independent variable in the quality management literature.

Only a handful of studies on NPD even include product safety when measuring product quality (Koufteros et al. 2001, 2002; Koufteros and Marcoulides 2006; Sethi 2000). Product safety has never been included as an independent variable, and product safety management practices and tools are not explicitly explored in any of the studies on NPD and product quality (Calantone and Benedetto 1988; McDonough 2000; Millson and Wilemon 2008; Rusinko 1997; Song et al. 1997; Song and Parry 1997; Takikonda and Montoya-Weiss 2001).

The past 20 years have seen a growing number of studies on safety culture and climate in the safety management literature. Despite that, most of studies focus on occupational health and safety culture instead of product safety culture. Only a handful of studies investigated product safety culture (Rollenhagen 2010; Svenson 1984; Van Vuuren 2000). If product safety is addressed, it mainly focuses on the technical aspect of safety management, for example, FTA (fault tree analysis), FMEA (failure mode effect analysis), PHA (preliminary hazard analysis), HACCP (hazard analysis and critical control point), and safety management principles (Abbott and Tyler 1997; Main and Frantz 1994; Main and McMurphy 1998; Moller and Hansson 2008; Wang and Ruxton 1997). Furthermore, much of the literature on this topic appears to be anecdotal and prescriptive. Product safety culture is not well integrated in this stream of research.

In view of so many product recalls around the world every year, it is surprising that so little attention has been paid in the academic studies. Only a handful of empirical studies on product safety exist at all. A thorough conceptual understanding of how product innovation affects product safety (rather than just product quality) is still largely missing. There is a conceptual and empirical gap with respect to product innovation and product safety performance:

- Regulators and policy makers increase product safety expectations in consequence of greater demands on economic and social attention to lifestyle and quality. Management in manufacturing firms increasingly focus on and search for better models and tools to achieve greater product safety performance.
- Literature on new product development did not specify how product safety is best achieved as a result of optimized NPD policy and practice.
- The literature on product safety management is largely descriptive and mainly focuses on technical solutions. It fails to incorporate organizational and cultural context.

- The literature on safety culture mainly focuses on occupational health, and safety and very little attention is paid to product safety culture.
- The literature on product quality largely overlooks the significance of product safety as an independent dimension.

1.4 Toward Responsible Product Innovation (RPI)

The past few years have seen an emerging discussion on Responsible Research and Innovation (RRI), which refers to research and innovation processes taking into account effects and potential impacts on the environment and society. RRI is defined as “the comprehensive approach of proceeding in research and innovation in ways that allow all stakeholders that are involved in the processes of research and innovation at an early stage (A) to obtain relevant knowledge on the consequences of the outcomes of their actions and on the range of options open to them and (B) to effectively evaluate both outcomes and options in terms of societal needs and moral values and (C) to use these considerations (under A and B) as functional requirements for design and development of new research, products and services” (EC 2013). RRI is also defined as “a transparent, interactive process by which societal actors and innovators become mutually responsive to each other with a view to the (ethical) acceptability, sustainability and societal desirability of the innovation process and its marketable products in order to allow a proper embedding of scientific and technological advances in our society” (von Schomberg 2013).

RRI has three main features (Owen et al. 2012):

1. Democratic governance of the purposes of research and innovation and their orientation toward the “right impacts.”
2. Responsiveness, emphasizing the integration and institutionalization of established approaches of anticipation, reflection and deliberation in and around research and innovation, influencing the direction of these and associated policy.
3. Framing of responsibility itself in the context of research and innovation as collective activities with uncertain and unpredictable consequences. Stilgoe et al. (2013) presents it in four dimensions: anticipation, reflexivity, inclusion, and responsiveness.

The concept of RRI is applied mainly to science and technology-based research and innovation, especially for emerging technologies, such as nanotechnologies, information and communication technology, artificial intelligence, genomics, synthetic biology, and geo-engineering. However, some authors argue that RRI should also include financial instruments, public policy or community innovation, distribution, and service or system innovations RRI has been developed as an approach to governing research and innovation at the European Union level and has been included in European Framework Programs.

While RRI focuses more on emerging science and technologies and the process of technology creation, responsible product innovation (RPI) deals with the process of product innovation. In the product innovation process, the organization and the innovator should not only consider the benefits that the product brings to customers but also take into account its inherent potential risks to customers and the needs of society and the environment. We define RPI as an organization to take responsibility for the product that it develops, and to ensure that the product is safe, which means the use of the product, under normal or reasonably foreseeable condition of use including duration, does not present any risk of injury or damage to health of users or damage to property or environment, or only the minimum risks compatible with the product use, considered as acceptable and consistent with a high-level protection for health and safety of persons. RPI requires organizations to take a holistic view on product innovation and to manage product safety risk properly in the product innovation process.

1.5 Research Questions and Research Methods Underlying This Book

The purpose of this book is to fill a gap in the literature on innovation and science policy by identifying, analyzing, and quantifying relevant relationships between product innovation and product safety performance and by providing actionable insights to academics, managers, and regulators. Specifically, we investigate how internal context such as product safety strategy and product safety culture affects concurrent engineering and the NPD process and how a firm structures NPD processes and supporting functions and activities (practices) such that it achieves the desired level of product safety. The main research question is therefore as follows:

> *How does product innovation influence product safety? What are the relationships between product safety strategy, product safety culture, concurrent engineering, the NPD process, and product safety performance?*

The research followed standard procedures for empirical-/fact-based inductive investigations of a socioeconomic phenomenon. We started the research by conducting an in-depth review of the literature in the product innovation community, the safety community, and the quality community that are related to product innovation and product safety. Exploratory research interviews with key stakeholders and experts revealed many managerial practices and economic/policy challenges. Combining inputs from quality/R&D managers and existing concepts about product innovation and product quality, conceptual models, and hypotheses were developed and validated in field studies. After models and hypotheses were sufficiently refined, the project entered the main quantitative empirical phase. A survey instrument was developed for establishing the necessary proprietary fact base. About 70% of the data were collected from China and 30% from non-Chinese manufacturers in Europe, the USA, Australia, and Japan in the durable juvenile product industry, largely in line with the actual representation of Chinese participation in this industry. One of the authors was deeply embedded in the juvenile products industry in China, and as a senior vice president of one of its companies (with 15,000 employees worldwide), the cochairman of ISO/PC 310 wheeled child conveyances (a technical commit to lead experts from ISO member countries to develop international standard for children's products such as strollers and accessories), and a senior member of the expert group in industry association and quality associations, he had unparalleled access to product development and product safety related information in this industry.

Data collection covered all identified aspects on product innovation and product safety and was conducted globally. We received 255 usable responses from 126 firms in the survey worldwide. In-depth interviews were carried out with 19 senior managers in 15 best performing firms, leading to case studies and a managerial toolbox of successful practices, gathered from both Chinese and non-Chinese firms. Interviews were also conducted with 21 senior managers in 19 less performing firms to determine context and behavior associated with poor product safety performance, allowing firms and regulators to identify and eliminate in situ NPD practice in existing firms. Data analysis was carried out with appropriate tools such as SEM (structure equation modeling) and correlation with SPSS software and content analysis with Nvivo software. Triangulation analysis was performed between quantitative and qualitative findings. Particular attention was given to ensure dissemination of the results in both academic communities and managerial practice.

1.6 Contributions of the Research

The principal goal of this research is to identify and describe product innovation practices and contextual factors that lead to greater product safety and to develop an empirical model for investigating product safety in product innovation. This research is unique in several ways. It focuses on a crucial but poorly understood component of industrial activity—product safety—and is a world-first attempt at investigating key success factors in a most rigorous fact-base fashion (using e.g., structural equation modeling). It also advances scientific thinking and understanding of product innovation.

Academically, this research improves our understanding of the impact of product innovation on product safety, as well as various relationships between key factors of the underlying model. It also introduces a solid research framework which has been tested empirically. Managerially, the immediate benefit will be gaining a better understanding on how to develop products that are safe and which will also generate obvious benefits for manufacturing firms and their consumers worldwide. It will provide empirical guidance for governments to regulating industries properly and effectively.

From a societal perspective, safer products means improved lives and communities. Once implications from this research (which empirically focuses on the durable juvenile products/toy industry) are introduced in other industries, such as the coal and mining industry and food or transportation industries, an immediate impact on lives saved and lives improved is expected.

1.7 Organization and Presentation of the Book

This book consists of eight chapters. Chapter 1 presents the background information to motivate the reasons for this research and discusses the research objectives and questions, research methods, and organization of the research.

Chapter 2 reviews the academic literature related to the definitions of product quality and safety, product safety context, product safety strategy, product safety culture, concurrent engineering, the NPD process, and product safety performance. Conceptual and empirical gaps in the literature are also identified.

Chapter 3 explains the conceptual model and hypotheses that are motivated by the relevant literature. The conceptual model for product innovation and product safety is developed and grounded on Schein's conceptualization of culture, Cooper and Kleinschmidt's innovation diamond, and various national quality award models, for instance, the Malcolm Baldrige National Quality Award (MBNQA) framework and the European Foundation of Quality Management (EFQM) excellence framework. The proposed relationships between product safety strategy, product safety culture, concurrent engineering, the NPD process, and product safety performance are presented and clarified. Hypotheses derived from the research questions defined in Chap. 1 are presented.

Chapter 4 describes the research design applied in this study: both quantitative and qualitative methods. Data collection procedures, survey instrument development, structural equation modeling, in-depth interview, means of hypothesis tests, and other aspects of the methodology are discussed.

Chapter 5 discusses the quantitative data analysis and the research results. The measurement model and structural model are examined, and hypothesis tests are carried out by means of structural equation modeling. The causal relationships between the constructs in the underlying model are presented.

Chapter 6 presents the qualitative findings through analyzing 40 in-depth interviews. The results are presented in four constructs: product safety strategy, product safety culture, concurrent engineering, and NPD process. Comparisons between the best performers and the rest are also discussed for each construct. The critical-to-safety NPD practices identified in the interview are also presented.

Chapter 7 summarizes and discusses the results from quantitative and qualitative analysis. Triangulation analysis was carried out between quantitative and qualitative findings in each area of the four constructs. The contributions and limitations of the research are explained, and suggestions for future studies in the areas of NPD practices and product safety are proposed.

Chapter 8 proposes and examines implications of the research findings for regulatory bodies, managers, and academic researchers in the fields of product safety in

NPD. The results are discussed both in terms of the NPD process (the stage gate model) and at the level of strategy of companies with respect to product safety, outlining four different paths how companies typically deal with product safety as part of their innovation process.

Chapter 9 presents the conclusions, the academic contributions, and limitations of the research and proposes future research directions.

Chapter 2
Literature Review

2.1 Introduction

This literature review aims to establish an overview of the research on the relationship between product innovation (especially new product development or NPD) and product safety performance.

There are numerous studies on NPD practices in the product innovation literature. However, very few empirical studies investigated the issue of product safety in product innovation. Considering product safety management literature, most of it is prescriptive and focuses on the technical aspects of safety management such as hazard analysis and risk analysis. There are only few empirical studies that investigate product safety from a systematic and holistic perspective, combing firm strategy, organizational culture, NPD practices, and technical aspects for safety management.

In response to a large number of product recalls in Europe in the year 2007, the European Commission (2008) formed an independent expert group to evaluate business safety measures in the toy supply chain. The group conducted desk research, interviews, and fact-finding visits to over 30 organizations in Europe and China. One of the most important conclusions from this research is that product safety cannot be guaranteed by final product testing alone. Instead, product safety enhancing activities have to be embedded in the entire product development and production process. Building a strong quality and safety culture was found to be a critical element in ensuring continuous attention to product safety issues.

In this research, we incorporate context, culture, NPD practices, and safety management tools to investigate their effects on product safety. Specifically, we examine the relationships between product safety strategy, product safety culture, concurrent engineering (CE), the new product development (NPD) process, and product safety performance. Before proceeding with the literature review on these concepts, it is useful to examine the definitions of product safety and product quality as both terms are multidimensional and elusive. We will further offer definitions for both terms that will be employed in this study.

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Table 2.1 Summary of influential safety definitions

Year	Advocate	Definition
1976	Lowrance	Safety is an adjustment of the acceptability of risk… A thing is safe if its risks are judged to be acceptable
1983	OECD	Safety is seldom absolute and may be deemed to include an acceptable degree of risk. (p. 13)
1984	Gloss and Wardle	Safety is the measure of the relative freedom from risks of dangers. Safety is the degree of freedom from risks and hazards in any environment
1985	Hammer	Safety is a matter of relative protection from exposure to hazards; the antonym to danger
1999	ISO/IEC	Safety is "freedom from unacceptable risk"; risk is "combination of the probability of occurrence of harm and the severity of that harm"; harm refers to "physical injury or damage to the health of people, or damage to property or the environment"; hazard is a "potential source of harm" (Guide 51: 2)
2000	MIL-STD-882D	Safety is "freedom from those conditions that can cause death, injury, occupational illness, damage to or loss of equipment or property, or damage to environment"; hazard refers to "any real or potential condition that can cause injury, illness, or death to personnel; damage to or loss of a system, equipment or property; or damage to the environment." (pp. 1–2)
2005	Ericson	"Safety is the state of zero or minimal risk, and safe is a condition of zero or minimal risk. Risk is the possibility of danger, a possibility of incurring loss or misfortune." (p. XX)
2009	National Safety Council	Safety is the control and elimination of recognized hazards to attain an acceptable level of risk
2009	Wikipedia	Safety is "the state of being 'safe' (from French *sauf*), the condition of being protected against physical, social, spiritual, financial, political, emotional, occupational, psychological, educational or other types or consequences of failure, damage, error, accidents, harm or any other event which could be considered non-desirable"

2.2 Defining Product Safety and Product Quality

2.2.1 *Defining "Product Safety"*

There is no uniformly accepted definition for safety in the literature (see Table 2.1 for a summary of safety definitions). In general, there are two schools of definition widely used. The first school defines "safety" as an absolute term. For example, in dictionaries, the word "safety" is defined as "the state of being 'safe' (from French *sauf*); the condition of being protected against physical, social, spiritual, financial, political, emotional, occupational, psychological, educational or other types or consequences of failure, damage, error, accidents, harm or any other event which could be considered non-desirable" (Wikipedia 2009). A similar definition can be found in MIL-STD-882D, where safety is defined as "freedom from those conditions that can cause death, injury, occupational illness, damage to or loss of equipment or property, or damage to environment" (MIL-STD-882D 2000, pp. 1–2). Unfortunately, neither definition has much practical meaning in the context of product safety management. In reality, no product can be absolutely safe (Abbott and Tyler 1997). We do not live in a risk-free society. Many products we use and activities we enjoy present some levels of risk. But we can evaluate whether risk is reasonable, meaning whether consumers are willing to take the risk (once fully informed) to enjoy the benefits (Kitzes 2000).

The second school of definition understands safety as relative term. There can be no absolute safety: some risk will remain. Therefore, a product, process, or service can only be relatively safe (ISO/IEC 1999). Some more practical definitions by academics, practitioners, and authorities defined safety as "relative freedom of risk" or "freedom of unacceptable risk" (Lowrance 1976; OECD 1983; Gloss and Wardle 1984; Hammer 1985; ISO/IEC Guide 51:1999; Ericson 2005; National Safety Council 2009). Hence, we think the second school of definition is more applicable in practice.

Product safety is affected if the operation or use of the product involves risk of injury, either bodily harm or other sources of unintended losses in utility or money terms (Daughety and Reinganum 1995). According to Article 2b of the European Union Directive 2001/95/EU, a "safe product shall mean any product, under normal or reasonably foreseeable condition of use including duration, and, where applicable, putting into service, installation and maintenance requirements, does not present any risk or only the minimum risks compatible with the product's use, considered as acceptable and consistent with a high level of protection for the safety and health and of persons...." Product safety is concerned with failures that resulted in hazardous conditions. Problems with product safety normally lead to product recall, i.e., the product is pulled from the market. In this research, we define product safety as follows:

> *'Product safety' is defined as whether the operation or use of a product, under normal or reasonably foreseeable condition of use, including duration, involves risk of injury or damage to health of users or damage to property or environment. A product is considered safe if the risk involved is considered acceptable and consistent with a high-level protection for health and safety of consumers and for the environment.*

The above definition assumes that product safety is a relative concept, depending on the consumer's perspective. For instance, the consumer demands on safety may change, and a product considered safe today may not be acceptable tomorrow. Consumers in different markets may have different understandings of what is safe, and even the tolerance level of risk is different from person to person.

2.2.2 Defining "Product Quality"

The concept of quality is equally elusive but it has been given considerable attention in management literature, to the extent that there is a self-sustaining quality management discipline. Many quality experts and scholars have been trying to search for a universal definition of quality. However, they were not successful due to the multidimensionality of quality (Reeves and Bednar 1994), and different definitions appear to be appropriate in different contexts.

One of the most well-respected quality management scholars, Garvin (1984), classified various quality definitions into five approaches:

1. The transcendental approach
2. The product-based approach
3. The user-based approach
4. The manufacturing-based approach
5. The value-based approach

Definitions offered by some of the most prominent quality experts are presented in Table 2.2 according to these five approaches.

In the quality management literature, the most widely used definition for product quality is based on Garvin's eight critical dimensions of quality (Garvin 1984, 1987, 1988): performance, features, reliability, conformance, durability, serviceability, aesthetics, and perceived quality. Not all of the dimensions are equally important or even present in a particular product or service at any given time. Based on Kano's model (Kano et al. 1984) for product quality attributes, product safety may well have to be classified into a "must have" category, meaning customers will normally not specify it, but they will be very dissatisfied if this need is not met. However, as we can see from the above definitions, product safety is not explicitly mentioned.

We take product safety for granted, and for this reason, it is often overlooked. Product safety probably deserves to be a ninth dimension alongside Garvin's eight other dimensions of product quality (see Table 2.3). "Quality is not a synonym for safety and consequently the respective roles of quality and of safety should not be confused. However, it may be necessary to consider quality requirements in standards to ensure that safety requirements are consistently met." (ISO/IEC Guide 51 1999).

2.3 Product Safety Context

The context for product safety encompasses both internal and external aspects of a firm's product safety environment. The external product safety context includes product safety regulatory requirements (such as mandatory product safety standards and certification, product recall policy, government surveillance inspection, etc.), degree of competition and consumer demanding on product safety, etc. There is a positive relationship between external contextual factors and product safety performance, as reported by Svenson (1984), Zick et al. (1986), Litan (1991), Chirinko and Harper (1993), Magat and Moore (1996), and Zhu (2009). Our focus for this research is on the internal context. The internal product safety context includes product safety strategy (top management commitment to product safety), product safety culture, company type and size, etc.

Table 2.2 Five approaches to define quality

Approach	Discipline	Year	Advocate	Definition
Transcendental: Innate excellence	Philosophy	1974	R.M. Pirsig	"Quality is neither mind nor matter, but a third entity independent of the two…even though quality cannot be defined, you know what it is." (p. 185–213)
		1980	B.W. Tuchman	"…quality, as I understand it, means investment of the best skill and effort possible to produce the finest and most admirable results possible…you do it well or do it half well…it doesn't allow compromise with the second rate." (p. 38)
Manufacturing-based: Conformance to requirements	Operations	1974	H.L. Gilmore	"The degree to which a specific product conforms to a design or specification"
		1985	P. Crosby	"Conformance to requirements" (p. 17)
Product based: Quantity of desired attributes	Economics	1987	ANSI/ASQC	"The totality of a product's or service's features that are relevant to user needs"
		1955	L. Abbott	"Differences in quality amount to differences in quantity of some desired ingredient or contribute" (p. 126–127)
		1982	K.B. Leiffler	"The amounts of the unprimed attributes contained in each unit of the priced attribute." (p. 956)
User based: Meet and/or exceed customer expectations	Marketing	1986	W. Deming	"How well a good or service meets customers' needs"
	Economics	1988	J. Juran et al.	"Fitness to use" (p. 28)
	Operations	1968	C.D. Edwards	"Quality consists of the capacity to satisfy wants." (p. 37)
	Management	1974	H.L. Gilmore	"The degree to which a specific product satisfies the wants of a specific consumer" (p. 16)
		1962	A.A. Kuehn and R.L. Day	"…The quality of a product depends on how well it fits patterns of consumer preferences." (p. 831)
		1985	K. Ishikawa	"Quality does not only mean the quality of the product, but also of after sales service, quality of management, the company itself and human life"
		1987	H. Gitlow and S. Gitlow	"Quality must be thought of as a customer-oriented philosophy. Quality should be defined as 'surpassing customer needs and expectations throughout the life of the product." (p. 35)

(continued)

Table 2.2 (continued)

Approach	Discipline	Year	Advocate	Definition
Value based: Affordable excellence	Operations	1979	G. Taguchi	"Avoidance of loss" or the loss that a product imparts society from the time it's shipped
		1982	R.A. Broh	"The degree of excellence at an acceptable price and the control of variability at an acceptable cost" (p. 3)
		1951	A.V. Feigenbaum	"Quality means best for certain customer conditions. These conditions are (a) the actual use (b) the selling price of the product" (p. 1)

Table 2.3 Nine dimensions of product quality

	Dimension	Definition
1	Performance	A product's primary characteristics
2	Features	The "bells or whistles," a product's secondary characteristics that supplement its primary functioning
3	Reliability	The probability of a product malfunctioning or failing within a specified time period
4	Conformance	The degree to which a product's design and operating characteristics meet established standards
5	Durability	The life of a product or the amount of use a customer gets from a product before it deteriorates or must be replaced
6	Serviceability	The speed, courtesy, competence, and ease of repair
7	Aesthetics	How a product looks, feels, sounds, tastes, or smells
8	Perceived	The image, reputation, brand names, or other inferences of a product's attributes
9	*Safety*	*Freedom from unacceptable risk of injury or damage to health of users and damage to property or environment involved in the use of the product*

Note: The first eight dimensions are adopted from Garvin (1984), with safety added as a ninth dimension by the authors

Benson et al. (1991) studied the relationship between organizational quality context and ideal and actual quality management practices and identified 14 organizational quality context variables such as corporate management support for quality, degree of competition, and external quality requirements. They found that manager perceptions on ideal and actual quality management practices were influenced by internal context (the degree of top management support to quality, the organization's past quality performance) and external context (the degree of competition in the industry and the extent of government regulation of quality). Company size, company type, and manager type (general or quality) did not explain the variation in ideal quality management variables. One limitation of this research is that the samples were not randomly selected and confined in a metropolitan area. The companies that participated in the study may all have been high-quality companies. On the other hand, they categorized companies with 1000–5000 employees as small companies in their research. This may explain why they did not find that company size was significantly related to company quality practices. Also, they did not separate internal context (such as top management support and managerial knowledge, etc.) and external context and address the relationship between them.

2.4 Product Safety Strategy

"Strategy is the creation of a unique and valuable position, involving a different set of activities. If there were only one ideal position, there would be no need for strategy…The essence of strategy is choosing what *not* to do. Without trade-offs, there would be no need for choice and thus no need for strategy…" (Porter 1996, p. 67–70). Product safety strategy refers to how a company positions or approaches product safety, i.e., what to do and what not to do in terms of product safety management. Product safety strategy is evaluated from the following angles:

1. The role of top management in product safety
2. Top management commitment to product safety
3. Product safety policies and procedure
4. The use of product safety as a competitive core competency

The importance of product safety strategy on product safety performance has been supported in the literature. Top management plays a critical role in setting the tone of product safety strategy. They dedicate necessary resources to product safety, establish product safety policies and objectives, commit to build a positive safety-oriented culture, and put in place incentives to promote product safety. Much has been written about the importance of company product safety policy and top management support to product safety (Kolb and Ross 1980; Roland and Moriarty 1983; Eads and Reuter 1983; Bass 1986; Kitzes 1991). However, most of this literature is anecdotal and prescriptive. As elaborated by National Safety Council (1989, p. 11–12), "the product safety program should have an important place within the organizational structure. The components of the program can include the policy statement, procedure manuals, safety committees, and a product safety coordinator... The objective of the policy statement is to communicate the company's ideals and commitment to product safety to the employees."

Eads and Reuter (1983) analyzed data from two large-scale surveys, case studies, and interviews on corporate responses to product liability laws and regulations in the USA and concluded that formal product safety efforts (such as the presence of a formal product safety function) play an important role in improving product safety and product safety organizations, if appropriately structured and effectively integrated into a firm's design activities. They can enhance product safety incentives, but they can also undercut those incentives in subtle ways. “A lean product safety organization that has the ear of the CEO and a good working relationship at various levels of the firm is likely to be much more effective than a highly visible unit that establishes procedures but lacks either the resources to impose them or, even more disastrous, the support of the firm’s top officers when such support is necessary” (Eads and Reuter 1983, p. xii).

White and Pomponi (2003) investigated product safety management in NPD in 52 consumer products companies and suppliers using the product stewardship framework, including strategy, organization, processes, and systems to avoid potential product safety issues in NPD that can lead to costly or even deadly design defects. In the area of strategy, they evaluated (1) senior leadership; (2) commitment of resources to implement safety, regulatory, environmental, and health management practices; and (3) the use of safety management as a core competency. Their findings show that best performers integrate safety, regulatory, environmental, and health initiatives into their corporate strategy and have specific goals for each area. The senior management of best performers assumes full accountability for product stewardship decision. They invest more in managing product stewardship issues than other companies. However, the authors did not evaluate the relationship between strategy, organization, processes, and systems with product safety performance and how these practices impacted product safety performance.

In safety management literature on occupational health and safety, the importance of management commitment to safety is widely studied. Top management commitment has been linked with better safety performance or lower injury rate (Cheyne et al. 1998; Dedobbeleer and Beland 1991, 1998; Flin et al. 2000; Shannon et al. 1997; Zohar 1980, 2000). In a classical study on safety climate by Zohar (1980), the author evaluated the effect of safety climate in 20 manufacturing organizations in Israel. The study found that two major factors affect safety climate: management commitment to safety and the workers’ perceptions regarding the relevance of safety in the general production process. After surveying safety climate among 384 construction workers in the USA, Dedobbeleer and Beland (1991) also reported similar results and revealed a two-factor model: (1) management’s commitment to safety and (2) workers’ involvement in safety.

Many subsequent studies on safety management supported these results. There is no question that top management sets the tone and tempo for organizational atmosphere, establishes priorities, and allocates resources. However, there is very little empirical information on how this actually works in practice.

2.5 Product Safety Culture in NPD

There are two main aspects of study in the safety management literature: the technical aspects and the cultural aspects. Traditionally, most safety management studies focus on the technical aspects, such as safety management tools (PHA, FMEA, HACCP, risk analysis, etc.) and safety management processes (e.g., design for safety). However, as the major root causes of accidents in the high reliability industries are primarily due to organizational, managerial, and human factors rather than purely technical failures (Weick et al. 1999), research on safety culture has been on the rise over the past two decades.

Since the term "safety culture" first appeared in the 1987 OECD Nuclear Agency report (INSAG 1988) on the 1986 Chernobyl disaster, its definition and content have been widely discussed in the academic literature. Safety culture has been intensively scrutinized especially in the nuclear power industry since Chernobyl, the chemical industry since Bhopal, the offshore industry since Piper Alpha, and the space industry since Challenger and Columbia. However, due to the multilevel and multidimensional nature of the concept, it has been criticized for being vague, and to date there is still no consensus on how to define and measure safety culture (Choudhry et al. 2007; Cooper 2000; Flin et al. 2000; Guldenmund 2000; Hale 2000; Richter and Koch 2004; Sorensen 2002).

According to the UK Health and Safety Executive (1993), "the safety culture of an organization is the product of the individual and group values, attitudes, competencies, and patterns of behavior that determine the commitment to, and the style and proficiency of, an organization's health and safety programs. Organizations with a positive safety culture are characterized by communications founded on mutual trust, by shared perceptions of the importance of safety, and by confidence in the efficacy of preventive measures." Hale (2000) defined safety culture as "the attitude, beliefs and perceptions shared by natural groups as defining norms and values, which determine how they act and react in relation to risk and risk control". Cooper (2000) pointed out that many definitions of safety culture have tended to focus on the way people think or behave, but most research investigating this culture construct has tended to use safety climate measures as a surrogate measure for safety culture, which mainly focus on what people think (i.e., their beliefs, values, attitudes, and perceptions) about various aspects of safety. He further defined safety culture as the "observable degree of effort by which all organizational members direct their attention and actions toward improving safety on a daily basis."

As all abovementioned definitions were developed from the context of occupational health and safety, we define product safety culture in this study as:

> *The attitudes, values, perceptions and beliefs shared by an organization or a sub-unit of an organization as defining norms and values, which determine how they act and react in relation to product safety; and product safety climate refers to shared perceptions on product safety policies, procedures, and practices.*

An organization's underlying assumptions give rise to what Schein (1992) called a company's espoused values: common beliefs shared by the members of an organization about "what ought to be" rather than "what is"—the domain of artifacts. Such a set of values also exists in the context of an organization's attitude toward product safety. A strong organizational "safety-first" philosophy impacts members' beliefs and attitudes toward product safety and, consequently, leads to its high priority and adoption of processes and practices that support the organization's commitment to product safety. Moreover, this espousal of occupational health and safety culture has been linked to safer work behaviors (Hofmann and Stetzer 1996; Varon and Mattila 2000) and fewer employee injuries (Barling et al. 2002; Hofmann and Stetzer 1996; Mearns et al. 2003; Zohar 1980).

The literature on product safety culture is still sparse. Svenson (1984) made one of the earliest contributions when he studied Volvo's accident hazard management system and the general quality and product safety attitude of its technicians. Focusing on business safety measures in the toy industry, the European Commission (2008) echoed the importance of a strong quality and product safety culture. This is especially critical in design organizations (Rollenhagen 2010).

While the literature emphasizes the value of a strong product safety culture, it is unclear how a product safety culture influences activities and practices in NPD. Consequently, one particular interesting focus of our research will be group-level product safety culture as product safety related beliefs, norms, and values shared by the employees involved in NPD, to determine how they act and react during product development in relation to product safety.

2.6 Concurrent Engineering

Concurrent engineering (CE) is a buzzword with many synonyms (Trygg 1993); it is also known as simultaneous engineering, integrated product development, design for excellence, the team approach (cross-functional teams), design-manufacturing integration, etc. One of the most widely cited definitions for concurrent engineering is from the US Institute for Defense Analysis (IDA) report by Pennel and Winner (1989): "Concurrent Engineering is a systematic approach to the integrated, concurrent design of products and their related processes, including manufacture and support. This approach is intended to cause the developers from the outset, to consider all elements of the product life cycles from conception through disposal, including quality, cost, schedule, and user requirements." In contrast with the conventional, sequential "throw it over the wall" approach, CE requires all representatives from functions such as marketing, manufacturing, design, quality, and purchasing, including suppliers and customers, to work together simultaneously (or concurrently) throughout the NPD process (Dekkers et al. 2013). CE is characterized by three main components: the cross-functional team, the concurrent workflows (or overlap), and the early involvement of participants (Koufteros et al. 2001).

The effect of CE on product quality is inconclusive (Koufteros et al. 2002; Koufteros and Marcoulides 2006; McDonough 2000; Ragatz et al. 2002; Rusinko 1997; Sethi 2000; Takikonda and Montoya-Weiss 2001). Table 2.4 presents studies that investigated the causal relationship between concurrent engineering and product quality performance. Clark and Fujimoto (1991) were among the first to demonstrate that CE used in incremental projects not only reduced product development cycle time but also decreased product quality. However, Rusinko (1997) described a positive effect on product quality by both organizational-level and group-level design-manufacturing integration, and McDonough (2000) found the use of cross-

Table 2.4 Empirical studies on CE and product quality/safety

Author (year)	Sample/method	CE characteristics	Performance measures	Relationship w/quality	Results
Koufteros et al. (2001)	244/SEM	Concurrent workflow	Quality (incl. safety)	NS	CE does not affect quality (indirect effect only). It measures quality capability instead of actual performance
		Early involvement	Product innovation, price		
		CFT			
Koufteros et al. (2002)	244/SEM	Concurrent workflow	Quality (incl. safety)	DS	CE has positive effect on quality. It measures quality capability instead of actual performance
		Early involvement	Product innovation		
		CFT	Price/profitability		
Koufteros and Marcoulides (2006)	214/SEM	CE (CFT, overlap, integration)	Quality (incl. safety)	DS	CE affects product quality. Cellular mfg. mediating the relationship. Supplier and customer involvement are not included
		IT/heavyweight mgr.	Product innovation		
McDonough (2000)	112/regression	Use of CFT	Quality, time, budget, and satisfaction	DS	Use of CFT affects team performance
Ragatz et al. (2002)	103/SEM	Supplier integrative strategy, need, and team process	Quality	DS	Integrative strategy and team process affect product quality
			Cycle time		
			Cost		
Rusinko (1997)	123/regression	Organizational-level and project-level DMI	Quality, cost, time, and performance	DS	Organizational-level DMI affect product quality. Early mfg. involvement affects product quality
Sethi (2000)	141/regression	CFT (diversity and info. integration)	Quality (incl. safety)	Mixed	Info. integration, customers, and quality orientation affect quality. Innovativeness affects quality negatively. Time pressure and CFT diversity don't affect quality
		Context			
Tatikonda et al. (2001)	120/regression	Concurrency, formality, and adaptability	Quality, cost, and time	DS	Process concurrency, formality, and adaptability affect product quality, cost, and time to market

DS direct and significant, *NS* not significant, *Mixed* mixed results, *SEM* structural equation modeling, *CFT* cross-functional team, *DMI* design-manufacturing integration functional teams significantly related to team performance, including developing high-quality products. Takikonda and Montoya-Weiss (2001) showed that process concurrency, formality, and adaptability (all of them are organizational process factors) have a positive effect on product quality, cost, and time to market.

Regarding the effects of CE on product safety, scholars and practitioners alike suggest that safety engineers should be involved in product design as early as possible and recommend using CE (Dowlatshahi 2001; Wang and Ruxton 1997; Rausand and Utne 2008). However, the analytical and empirical evidence for this claim is still weak primarily because product safety has never been examined as a standalone variable. Even if product safety is included as an aspect of product quality, the literature is inconclusive on whether a positive relationship exists between product quality and CE. For instance, Sethi (2000) revealed that quality is positively influenced by information integration in the team, customer influences on the product development process, and quality orientation in the firm, but it is negatively affected by the innovativeness of the product. Sethi did not find functional diversity to have an effect on product quality. Measuring product quality in terms of function, safety, reliability, durability, and performance, Koufteros et al. (2001) found that CE has a positive direct relationship with product innovation, but they did not find any significant direct relationship between CE and quality. In a later paper focusing on NPD practices, Koufteros et al. (2002) reported CE has a positive impact on quality, a result that Koufteros and Marcoulides (2006) qualified by demonstrating that this effect is mediated by high versus low cellular manufacturing environments.

Thus, although the literature on the interrelationship of CE, product quality, and NPD is growing, the impact of CE on product safety has not been evaluated empirically.

2.7 NPD Processes

The NPD process includes all steps and activities that guide the project from idea to launch. Cooper et al. (2004c) state that “by ‘new product process’, we mean more than just a flow chart; the term includes all process elements: the stages, stage activities, gates, deliverables, and gate criteria that constitute a well-defined new product process.” NPD processes are the primary tools to implement product-oriented safety culture and innovation. A well-defined, high-quality NPD process is generally recognized as a critical success factor for product success (Cooper et al. 2004c; Montoya-Weiss and Calantone 1994) and product quality (Calantone and Benedetto 1988; Millson and Wilemon 2008; Song and Parry 1997). However, whether the use of certain technical activities and methodologies in the NPD process affects product quality positively is less clear (see Table 2.5 for a summary of studies on NPD process and product quality).

The study of Calantone and Benedetto (1988) made the first contribution to the significant relationship between NPD process and product quality. Based on a survey of 189 industrial manufacturing firms, they built an integrative model to evalu-

Table 2.5 Empirical studies on NPD process and product quality/safety

Author (year)	Sample/ method	NPD process characteristics	Performance measure	Rel. with quality or safety	Results
Calantone and Benedetto (1988)	189/ three-stage least squares	Technical activities	Profitability	DS	Product quality is influenced by competitive and marketing intelligence and technical activities
Calantone et al. (1996)	142 (USA) and 470 (China)/SEM	Technical proficiency	Quality	NS	Technical proficiency doesn't affect product quality. Competitive marking skills affect product quality
		Marketing skills	Profitability		
Millson and Wilemon (2008)	131/ Spearman correlation	Technical proficiency	Quality	DS	Technical proficiency affects product quality
			Program risk		
Song et al. (1997)	65/SEM	Marketing proficiency	Quality	NS	Marketing proficiency and alignment of skills affect quality. Technical proficiency doesn't affect quality
		Technical proficiency	Product performance		
		Alignment of skills			
Song and Parry (1997)	788/SEM	Technical proficiency	Product advantage (quality, features, technical performance)	DS	Technical proficiency affects product advantage (quality…)

Remarks: Technical activities/proficiency include six NPD process activities: preliminary design review, preliminary manufacturing process review, the development of prototypes and pilot models, in-house product testing, trial production, and full-scale production start-up. *DS* direct and significant, *NS*, not significant

ate the interrelationships between eight variables: marketing resources and skills, competitive and market intelligence, technical resources and skills, marketing activities, launch activities, product quality, technical activities, and success or failure of commercialized product with three-stage least square analysis. They found that relative product quality was influenced by competitive and marketing intelligence as well as technical activities, which included preliminary engineering, technical, and manufacturing review, the development of prototypes, in-house product testing, trial production, and full-scale production start-up.

Song and Parry (1997) also reported similar findings in a survey of 788 new products from 404 Japanese firms. They built and tested a structural equation model with nine constructs: competition, marketing synergy, cross-functional integration, technical synergy, marketing proficiency, competitive and marketing intelligence, technical proficiency, product competitive advantage, and level of relative new product success. They found that technical proficiency impacted product competitive advantage measured by product quality, unique features, and technical performance.

Millson and Wilemon (2008) echoed the findings of Calantone and Benedetto (1988). Based on 131 survey responses from 79 R&D managers in the medical instruments, electrical equipment, and heavy construction equipment industries, they examined the relationships between new product quality and risk with new product development proficiency and new product development entry strategies. They measured new product quality with Garvin's (1984) eight dimensions of quality and NPD technical proficiency with six technical activities performed by engineering, research and development, and manufacturing during NPD. They found that new product quality was associated with the proficient performance of many NPD technical activities, whereas risk of the NPD program was associated with the proficient performance of fewer NPD technical activities. They concluded that technical activities performed during the early stages of the NPD process ware important to achieve better quality products.

Fynes and De Búrca (2005) also found that design quality had an impact on conformance quality, product cost, external quality in use, and time to market. However, Calantone et al. (1996) did not find any significant direct relationship between technical proficiency and product quality. Based on 147 projects from the USA and 470 projects from China, they developed and tested a model with seven constructs between controllable factors and NPD performance. They found that the relationship between proficiency of technical activities and product quality was not significant in either the US or Chinese samples. Song et al. (1997) also did not find a significant relationship between NPD process and product quality. In a survey of 65 completed NPD projects from 17 large Japanese firms, they developed and tested a causal model to evaluate the interrelationships of key factors leading to new product performance. They found that marketing proficiency and alignment of skills and needs impacted product quality directly. However, they did not find any significant direct relationship between technical proficiency and product quality.

In the safety management literature, DFS (design for safety) has been studied widely as a large percentage of accidents and incidents were rooted in design (Kinnersley and Roelen 2007). "Design for safety is a process of defining the need for safety; identifying, estimating and evaluating risks; and conducting design reviews in order to reduce risks to an acceptable level. It aims to minimize injury and death, product damage and destruction, and degradation of the environment and mission performance. The process provides a systematic approach to the identification and control of high-risk areas" (Wang and Ruxton 1997, p. 27). DFS encompasses the procedures, methodologies, and practices that a company implements in NPD processes to manage product safety, with a focus on the technical and engineering aspects such as safety factors, hazard analysis, and safety management tools. Although there is substantial support for methodologies integrating safety into the design process (Drogoul et al. 2007; Rausand and Utne 2008), the challenge is to identify all the relevant hazards given the increasing complexity of technology, products, and systems and to meet the safety objective under the trade-off decision between cost, schedule, and performance (Rausand and Utne 2008).

The effective use of safety management tools, such as faulty tree analysis (FTA), preliminary hazard analysis (PHA), and failure mode effect analysis (FMEA) is important in managing integration in the NPD process (Abbott and Tyler 1997). Riswadkar (2000) also pointed out that hazard analysis and critical control point (HACCP), a systematic approach to food safety, can be applied to other products and processes. However, most design engineers do not seem to receive formal training in safety methodologies (such as FTA and FMEA) common to the safety community, and many product safety tools are not systematically implemented by the design community (Main and Frantz 1994; Main and McMurphy 1998). Safety management tools and DFS were considered important, but the effectiveness of hazard analysis was still unclear (Marucheck et al. 2011).

Even though the literature has identified a high-quality NPD process as a key success factor for NPD, its implications for product safety remain unknown at best because safety management methodologies and product safety performance are not well understood. A thorough conceptual understanding of how NPD processes incorporated with DFS practices affect product safety (rather than just product quality) is still largely missing.

2.8 Product Safety Performance

There are many different measurements that researchers use to assess product safety performance in the safety community. White and Pomponi (2003) measured product safety performance with recall rate (i.e., the number of recalls divided by total sales) in their research. Rose (1990) used accident rate and incident rate in the research of airline safety performance. Other researchers (Peltzman 1975; Viscusi 1985; Zick et al. 1986; Litan 1991; Petty 1991; Chirinko and Harper 1993; Magat and Moore 1996; Viscusi and Gayer 2002) have used accident rate and/or death rate in their studies for consumer product safety. Nevertheless, using objective accident data to measure safety performance can be problematic (Cooper and Phillips 1994), as such data are insufficiently sensitive, of dubious accuracy, retrospective, ignore risk exposure (Glendon and Litherland 2001), and tend to be very unstable (DeJoy et al. 2004; Havold 2005). Considering third-party independent data such as accident/death rate and recall data is often not available or incomplete, and not all product safety issues will lead to a product recall; in this study, we measured product safety performance from two perspectives: (1) internal product safety performance measured by quality team at the outgoing product audit, i.e., product safety issues detected at outgoing product audit, and (2) external product safety performance measured by customer satisfaction in terms of product safety.

2.9 Summary

This chapter reviewed the literature related to the concept of product quality and safety, product safety strategy, product safety culture, concurrent engineering, NPD processes, and product safety performance (see Fig. 2.1). First, various definitions of quality and product safety were evaluated. Product safety as a significant dimension of product quality is overlooked in the quality literature. Next, prior research in the areas of product safety strategy, product safety culture, concurrent engineering, and the NPD process was reviewed and discussed. As indicated already on various occasions in this review, there is a conceptual and empirical gap with respect to NPD practices and product safety performance:

- Literature on safety management mainly focuses on occupational health and safety overlooks product safety.
- Literature on new product development has not specified how product safety is best achieved as a result of optimized NPD policy and practice.
- Literature on product safety management is mainly descriptive and anecdotal and mostly focuses on the technical solutions.
- Literature on product quality largely overlooks the significance of product safety as an independent dimension.

In conclusion, purely from an academic literature point of view, product safety as a result of product development and as a component of product quality research

Fig. 2.1 Summary of selected literature

has not been integrated well. Much conceptual and empirical research remains to be done to link NPD practices with product safety performance to adequately understand managerial and policy implications. Given the rising importance of product safety worldwide, our research is thus motivated by both theoretical and practical ambitions.

Based on the insights taken from this literature review, the next chapter develops a conceptual model that links product safety strategy, product safety culture, concurrent engineering, the NPD process, and product safety performance. The research question and hypotheses to be tested are also presented and discussed.

Chapter 3
Conceptual Model and Hypotheses

3.1 Introduction

This chapter develops the conceptual model that maps how the product safety context and product innovation affect product safety performance. Specifically, we investigate how internal context—such as product safety strategy and product safety culture—affects NPD practices (concurrent engineering and the NPD process) and how a firm structures NPD processes, supporting functions and activities (practices) so that the desired level of product safety can be reached. The conceptual model is based on the following theoretical models:

- The Malcolm Baldrige National Quality Award (MBNQA) framework (Fig. 3.1)
- The European Foundation for Quality Management (EFQM) excellence framework (Fig. 3.2)
- Cooper-Kleinschmidt's (2007) innovation diamond (Fig. 3.3)
- Schein's (1992) conceptualization of culture

Hypotheses regarding the following relationships are proposed based on literature review and the conceptual model for product innovation and product safety: product safety strategy, product safety culture, concurrent engineering, NPD process, and product safety performance.

3.2 The National Quality Award Model

In the last two decades, the emergence of quality award models such as the Malcolm Baldrige National Quality Award (MBNQA) framework and the European Foundation for Quality Management (EFQM) excellence framework has brought a high and universal profile to quality management practices (Sousa and Voss 2001). The quality award model has been empirically validated (Flynn and Saladin 2001)

A.Y. Zhu et al., *Responsible Product Innovation*, Innovation, Technology, and Knowledge Management, https://doi.org/10.1007/978-3-319-68451-2_3

Fig. 3.1 MBNQA model (Source: MBNQA 2010)

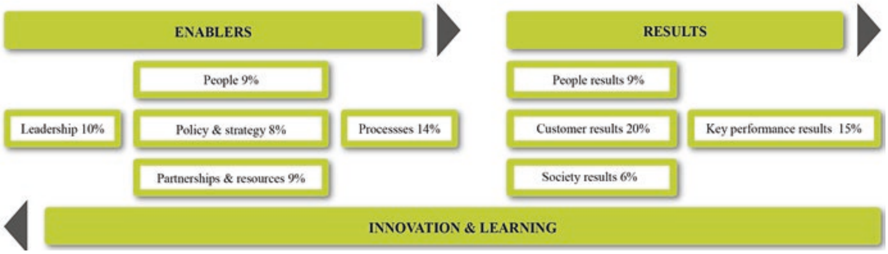

Fig. 3.2 EFQM excellence model (Source: EFQM 2009)

and adapted by thousands of organizations worldwide. Established in 1987, the MBNQA is the most influential quality award and has been widely recognized as a model of an exemplary quality management framework (Black and Porter 1996; Curkovic and Handfield 1996; Hendricks and Singhal 1997). In the MBNQA model, leadership, strategic planning, and customer focus form the "leadership triad" that emphasizes the importance of top management, strategy, and customers; workforce focus, process management, and results combine to represent the "result triad."

Top management determines strategy and customer focus. Strategy and customer focus influence workforce focus and process management. Process management and workforce focus have a direct impact on business results (MBNQA 2010). Since 1988, the MBNQA model has been revised several times to broaden its scope from customer satisfaction to embrace the results of organizational effectiveness and to include a focus on finance and marketing (Flynn and Saladin 2001).

The EFQM excellence model represents another well-recognized framework for quality (Binney 1992; Slack et al. 1995). Since its inception in 1991 by the European Foundation for Quality Management (EFQM), the framework has been used as the base reference for the European quality award and to recognize organizational excellence in European organizations. The EFQM excellence model is a non-prescriptive

Fig. 3.3 Innovation diamond (Source: Cooper and Kleinschmidt 2007)

framework based on nine criteria. Five of these are enablers and four are results. The enabler criteria (leadership, policy and strategy, people, partnerships and resources, and processes) represent what an organization does. The result criteria (people results, customer results, society results, and key performance results) cover what an organization achieves. The results are caused by enablers, and feedback from results helps improve enablers. The model is based on the premise that excellent results are achieved through leadership driving policy and strategy, and is delivered through people partnerships and resources, and processes (EFQM 2009).

In the EFQM model, leadership is described as the driver for improving people management, policy and strategy, and resources, which in turn enhance process management. On the other hand, process management is the only immediate factor leading to operational performance. Unlike the MBNQA model, customer focus and customer satisfaction are the same element in the EFQM model. In the EFQM model, customer satisfaction takes 20% of the total score and is thus considered a more important criterion than business results with 15%. Apart from the theoretical models for quality awards, various empirical models have been described in the literature. The findings of these models are rather inconsistent, and the importance of different factors and certain features in the models may depend on the type or operating characteristics of their industry sector (Anderson et al. 1995; Dow et al. 1999; Flynn et al. 1995; Powell 1995; Samson and Terziovski 1999; Zhao et al. 2004). The relative importance and interplay among leadership, cultural elements, and process management practices in determining performance outcomes under specific organizational contexts have been subject to much scholarly discussion without a unanimous conclusion (Sousa and Voss 2002).

3.3 Cooper-Kleinschmidt's Innovation Diamond

The innovation diamond is a framework derived from a major study by Cooper and Kleinschmidt into new product performance and its key success factors. It consists of four driving factors or themes (Cooper and Kleinschmidt 2007):

1. Product innovation and technology strategy for business
2. Resources: commitment and portfolio management
3. Idea-to-launch system: stage gate
4. People: climate, culture, teams, and leadership

The four major factors that drive a business's new project performance are (Cooper and Mills 2005; see also Fig. 3.3):

- Having a product innovation and technology strategy in place for the business, which is driven by the top management and its vision for the business
- Having an effective and efficient idea-to-launch process, which is well crafted, robust, and emphasizing up-front homework, voice-of-customer input, quality of execution, and performance results metrics
- Resource commitment, which focuses on the right projects—portfolio management
- People, that is, having a positive climate and culture for innovation, effective cross-functional teams, and senior management commitment to new product development

3.4 Conceptualization of Culture

Schein (1992) summarized organizational culture as a set of observed behavioral regularities, group norms, espoused values, formal philosophy, rules of the game, climate, embedded skills, habits of thinking, share meanings, and root metaphors. He aggregated these into three levels:

1. Artifact
2. Espoused values
3. Underlying assumptions

At the surface, there are observable artifacts that one sees, hears, and feels when one enters an organization (e.g., organizational structures, policies, procedures, processes, practices, rituals, language, etc.). At the second level, there are espoused values (e.g., norms, ideologies, philosophies, strategies, and goals) that govern behaviors and explain why members behave the way they do. The third level of the hierarchy is composed of underlying assumptions, such as preconscious, taken for granted, and invisible beliefs that determine perceptions, thought processes, feelings, and behaviors.

We propose that the underlying assumption of safety first (product safety strategy or management commitment to safety) affects the espoused values (group-level product safety culture at NPD) and artifacts of organizational culture (concurrent engineering and the NPD process), espoused value influences artifacts, and artifacts of impact product safety performance.

3.5 The Conceptual Model for Product Innovation and Product Safety

The national quality award frameworks, innovation diamond, and Schein's conceptualization of culture provide a good theoretical ground for the implications of product safety strategy, product safety culture, concurrent engineering, NPD process, and product safety performance. There are very few empirical studies on product safety performance in both quality and NPD management literature. Although the recall data analysis shows that about 70% of the product safety issues were rooted in NPD (White and Pomponi 2003; Bapuji and Beamish 2008; Beamish and Bapuji 2008), the relationship between NPD practices and product safety performance in the academic research is overlooked. Besides, most of the literature did not address the relationships between the context factors and NPD practices.

To fill these gaps, a conceptual framework was developed based on the literature review and in-depth interview with 40 senior managers in the industry to guide this study (see Fig. 3.4). The model consists of five blocks of variables:

1. Product safety strategy (PSS)
2. Product safety culture in NPD (PSC)
3. Concurrent engineering (CE)
4. NPD process (NPP)
5. Product safety performance (PSP)

The model proposes that a company's product safety strategy will drive its group-level product safety culture in NPD and the use of concurrent engineering and NPD process, product safety culture will influence the application of concurrent engineering and NPD process, concurrent engineering will affect the execution of NPD process and product safety performance, and NPD process will have a direct effect on product safety performance.

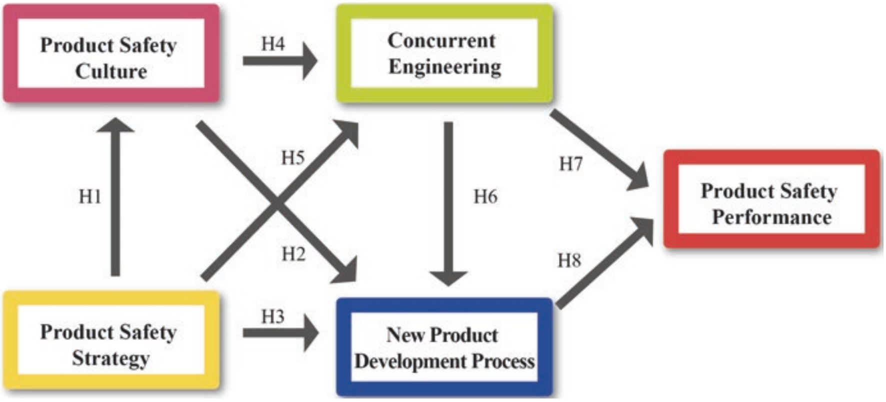

Fig. 3.4 Conceptual model: product innovation and product safety

3.5.1 Product Safety Strategy

Based on the MBNQA model, the EFQM model, and the innovation diamond, strategy—driven by the leadership and the firm's vision—will influence the workforce focus and process management practices and eventually drive product safety performance. Strategy is a key enabler that drives performance in all models. Therefore, in the case of product safety management, we propose product safety strategy (underlying assumption) as a key construct in the model for product innovation and product safety, which will influence the firm's group-level product safety culture in NPD (espoused values) and the NPD practices (artifacts) that the firm adopts. It is evaluated from the following four aspects:

1. The role of top management in product safety
2. Top management commitment to product safety
3. Product safety policies and procedure
4. The use of product safety as a competitive core competency

Because product safety is considered as one dimension of product quality, we adapt and modify the elements for top management support and quality policy identified by Saraph et al. (1989) to measure product safety strategy: acceptance of responsibility on product safety by top management and relevant department heads, the degree to which that the top management supports product safety management, evaluation of department heads on product safety performance; participation of management in product safety management (such as setting product safety goals and policies, defining recall policy/procedures) and its improvement, importance attached to product safety in relation to cost and schedule, frequency to review product safety performance in management meetings, etc. The individual measurement items are listed in Table 4.1 of Chap. 4.

3.5.2 Product Safety Culture in NPD

Again based on the national quality award frameworks and the innovation diamond, positive culture is also a key success critical factor that affects firm process management and performance. Having a positive safety-oriented culture is critical to product safety (Rollenhagen 2010; Svenson 1984; Van Vuuren 2000; White and Pomponi 2003).

In this research, group-level product safety culture in NPD is also explored to investigate its implications for NPD practices and product safety performance. Product safety culture in NPD is measured from the following aspects:

1. The degree to which NPD engineers are familiar with product safety standards
2. How product safety is considered during product development
3. Whether product safety is given higher priority than cost or schedule
4. Whether an independent product safety team conducts product safety review in NPD
5. Whether the product safety team has the authority to make go/no-go decision for new products

3.5.3 Concurrent Engineering

Concurrent engineering is well recognized as a best practice that has been linked with shortened time to market, reduced cost, and improved quality (Clark and Fujimoto 1991; Droge et al. 2000; Ettlie 1995; Gerwin and Barrowman 2002; Koufteros et al. 2001; McDonough 2000; Rusinko 1997). Many researchers and safety experts suggest that safety professionals should be involved as early as possible in the design of new products and recommend using concurrent engineering as a mechanism to ensure product safety (Dowlatshahi 2001; Drogoul et al. 2007; Hodges et al. 1996; Main and Frantz 1994; Rausand and Utne 2008; Wang and Ruxton 1997). Consequently, in the product innovation and product safety model, we propose that concurrent engineering affects the execution of NPD process and product safety performance. It is assessed from three main components: the cross-functional team, current workflow, and early involvement of downstream participants (see Table 4.1 in Chap. 4 for the detailed measurement list).

3.5.4 The NPD Process

In the national quality award models and the innovation diamond, process management is a key factor with a direct relationship to performance. Although a high-quality NPD process has been identified as a key success factor for NPD in numerous studies (Cooper et al. 2004c; Cooper and Kleinschmidt 2007; Dwyer and Mellor

1991; Griffin 1997; Montoya-Weiss and Calantone 1994; Parry and Song 1994; Song and Parry 1996), its implication on product safety remains unknown at best. In the product innovation and product safety conceptual model, we propose NPD process as a key factor that affects product safety performance. The NPD process is assessed by activities identified by Cooper et al. (2004c) and practices from the safety community literature, such as product safety review, FMEA, etc. (see Table 4.1 in Chap. 4 for detailed measurement items).

3.6 Research Hypotheses

Just as a reminder, our original research questions (from which the hypotheses are derived) were:

> *What determines product safety in product innovation? What are the relationships among various internal context (Product Safety Strategy and Product Safety Culture), NPD practices (Concurrent Engineering and NPD Process) and Product Safety Performance?*

We investigate of course whether environment factors (firm size, firm origin, target market, R&D intensity) affect manager's perception on ideal and actual constructs in the conceptual model and whether the relationship in the conceptual model holds for firms with low and high R&D intensity (in both administrations of the eventual survey). To answer the research questions, a set of hypotheses that address the association in each construct of the model are formulated.

3.6.1 Hypotheses of Product Safety Strategy

The importance of visionary leadership and top management on firm culture, activities, and performance is well established (Hofstede 1997; Ogbonna and Harris 2000; Schein 1992). Although many activities critical to product safety (such as CE, NPD processes) are not part of top management's primary responsibility, product safety strategy and management commitment directly and indirectly influence attitudes and processes (in organizational culture terminology: values and artifacts) that promote a positive safety-oriented culture, often using specific safety-inducing incentives (Eads and Reuter 1983; Roland and Moriarty 1983; White and Pomponi 2003) and leading to higher product safety performance. The extent to which top management supports quality affects management perceptions (Benson et al. 1991) and product safety performance is higher in firms with a product safety strategy with demonstrated senior leadership and a commitment of resources to implement safety, regulatory, environmental, and health management practices (White and Pomponi 2003).

What is still unclear, however, is how many of these product safety-oriented values and artifacts influence each other in mediating the overall influence of top management commitment on product safety performance. Much of the established literature on these important links is anecdotal or prescriptive, and there is little empirical research on how management commitment to safety translates into practices and affects product safety.

Management commitment to safety and management's role in establishing a product safety culture are also important for NPD more directly affecting product safety. NPD processes and CE strengthen operational product innovation efficiency, but they also create well-tested and safe products (Dowlatshahi 2001; Rausand and Utne 2008; Wang and Ruxton 1997). NPD's specific focus on safety and CE's shared intra-functional design practices should encourage management to commit resources and implement well-defined NPD techniques with more predictable outcomes. However, management's ability to establish any of these attributes of organizational culture (Garvin 1987; Schein 1992) may vary significantly between the two direct NPD artifacts of NPD process and CE. In summary, the following hypotheses are proposed:

H1: *Product safety strategy has a positive effect on the group level product safety culture in new product development.*
H2: *Product safety strategy has a positive effect on the use of concurrent engineering.*
H3: *Product safety strategy has a positive effect on the use of new product development process.*

3.6.2 Hypotheses of Product Safety Culture

Safety culture, safe work behaviors, and safety performance have received scholarly attention since the term safety culture first appeared in the 1987 OECD Nuclear Agency Report (INSAG 1988). However, most research focused on occupational health and safety; only a handful of studies have looked at product safety culture. In an example of early research, Svenson (1984) identified employees' positive safety attitudes as a critical success factor of accident hazard management systems. Van Vuuren (2000) found that safety culture had considerable impact on both incident causation and risk management and concluded that the traditional focus on human and technological failure should be replaced by a comprehensive approach that includes organizational and cultural precursors. Similarly, White and Pomponi (2003) reported firms with a safety-oriented culture to have better product safety performance, an insight echoed by a report by the European Commission (2008) that found a strong quality and safety culture to be critical in ensuring continuous attention to product safety issues.

A strong product safety culture in NPD centers on safety methodologies (such as hazard analysis, FMEA) and better executed and more disciplined NPD and CE processes. This may lead to excessive risk aversion, passed down to NPD via stricter tolerances and safer work practices, which result in safe but also less differentiated products. New products might meet minimal innovation specifications and safety criteria, and perfect safety may only be achievable through absolute reliance on standard rather than novel solutions and through expensive zero-fault testing. However, this approach is not always economically viable for firms; internal mechanisms and processes such as CE and NPD processes are intermediary instruments to achieve predictable product success, of which product safety is only one of a set of related innovation outcomes. Those firm values supporting a culture favoring product safety also have an effect on NPD techniques, such as CE and the NPD process, which leads to the proposition of the following hypotheses:

H4: Group level product safety culture in new product development has a positive effect on the use of concurrent engineering.

H5: Group level product safety culture in new product development has a positive effect on the use of new product development processes.

3.6.3 Hypotheses of Concurrent Engineering

CE promotes multiple functioning so that downstream and upstream issues can be resolved at early stage in the design. Downstream functions such as manufacturing and quality can thus voice concerns early and have a say before the design is finalized. CE allows additional information sharing across different functions at all stages through face-to-face communication and discussion. Cross-functional teams provide a platform for different participants to express concerns and suggestions and present a mechanism for multidisciplinary learning. Simultaneous planning of product, process, and manufacturing allows issues of manufacturability, quality, and safety to be evaluated and incorporated in the final product design. CE techniques are used not only to speed up innovation and NPD but also require otherwise separate teams (for different functions, disciplines, or components) to coordinate better, communicate product and process-related issues, and address problems relating to product safety performance promptly. CE interaction regarding product design questions is bound to address safety concerns; however, in the multifunctional context of CE, these issues should receive more rounded and integrated consideration, and if so, we would expect NPD processes to improve with greater emphasis of CE in NPD.

Although the effect of CE on product quality is inconclusive (Clark and Fujimoto 1991; Koufteros et al. 2001, 2002; Koufteros and Marcoulides 2006; McDonough 2000; Ragatz et al. 2002; Rusinko 1997; Sethi 2000; Tatikonda and Montoya-Weiss 2001) and product safety was absent as a separate indicator in these studies, many scholars and safety experts suggest that safety professionals should be involved in the design at the earliest stage possible and recommend concurrent engineering as a mechanism to ensure product safety (Dowlatshahi 2001; Rausand and Utne 2008; Wang and Ruxton 1997). Hence, we propose the following hypotheses:

H6: The use of concurrent engineering has a positive effect on the use of new product development process.

H7: The use of concurrent engineering has a positive effect on product safety performance.

3.6.4 Hypothesis of the New Product Development Process

The NPD process means more than just a flow chart; the term includes all process elements: the stages, stage activities, gates, deliverables, gate criteria and safety management tools, and methodologies used in new product development. It has a positive causal relationship with product quality (Calantone and Benedetto 1988; Calantone et al. 1996; Millson and Wilemon 2008; Song and Parry 1997). Safety practitioners have suggested that the issue of product safety should be addressed in parallel with the design process; however, much of the literature lacks an integrated view of product safety management methodologies and tools in the NPD process.

While it seems self-evident that safety-oriented NPD activities should lead to greater product quality, the individual components constituting the artifacts of safety orientation and the direct consequence of product safety performance (rather than the more generic product quality) need to be disentangled better. Hence, we propose:

H8: The use of new product development process practices has a positive effect on product safety performance.

3.6.5 Hypotheses of Internal Contextual Factors

It is important to understand whether a manager's perceptions of actual model constructs (in our case PSS, PSC, CE, NPP, PSP) are influenced by contextual factors (such as firm size, origin of firm, firm's target market, firm's R&D intensity) and whether a manager's perceptions of ideal model constructs (IPSS, IPSC, ICE INPP) are not affected by organizational contextual variables (again, e.g., firm size, origin of firm, firm's target market, firm's R&D intensity). Benson et al. (1991) studied the relationship between organizational quality context and ideal and actual quality management practices. They found that managers' perceptions on ideal and actual quality management practices are influenced by internal context (the degree of top management support to quality, the organization's past quality performance) and external context (the degree of competition in the industry and the extent of government regulation of quality). Company size, company type, and manager type (general manager or quality manager) did not explain the variation in ideal quality management variables. Company type (service or manufacturing) was found significantly related to actual quality management practices, but company size and manager type had no effect on actual quality management practices. Similarly, we propose the following hypotheses between manager's perception of actual and ideal model constructs and contextual factors (firm size, firm origin, target market, and R&D intensity):

H9: Manager's perceptions of actual model constructs (PSS, PSC, CE, NPP, and PSP) are influenced by contextual factors (firm size, firm origin, target market, R&D intensity).

H9a: *Manager's perceptions of actual model constructs (PSS, PSC, CE, NPP, and PSP) are not affected by firm size.*

H9b: *Manager's perceptions of actual model constructs (PSS, PSC, CE, NPP, and PSP) are not affected by firm origin.*

H9c: *Manager's perceptions of actual model constructs (PSS, PSC, CE, NPP, and PSP) are not affected by firm's target market.*

H9d: *Manager's perceptions of actual model constructs (PSS, PSC, CE, NPP, and PSP) are not affected by firm's R&D intensity.*

H10: *Manager's perceptions of ideal model constructs (IPSS, IPSC, ICE, and INPP) are not affected by organizational contextual variables (firm size, firm origin, target marketing, and R&D intensity).*

H10a: *Manager's perceptions of ideal model constructs (IPSS, IPSC, ICE, and INPP) are not affected by firm size.*

H10b: *Manager's perceptions of ideal model constructs (IPSS, IPSC, ICE, and INPP) are not affected by origin of firm.*

H10c: *Manager's perceptions of ideal model constructs (IPSS, IPSC, ICE, and INPP) are not affected by target market.*

H10d: *Manager's perceptions of ideal model constructs (IPSS, IPSC, ICE, and INPP) are not affected by R&D intensity.*

3.6.6 Hypothesis of R&D Intensity

Can we assume that the relationships posited in Fig. 3.4 of those firms that have high R&D intensity will be different from those that have low R&D intensity? Adequate R&D funding is clearly a critical input into the NPD process. The relationship between R&D intensity and firm or innovation performance has been empirically researched in a number of studies (Deeds 2001; Greve 2003; Parthasarthy and Hammond 2002). However, inconsistent results were noted in the literature. Stock et al. (2001) found an inverted-U relationship between R&D intensity and NPD performance, and Bougrain and Haudeville (2002) claimed that it does not influence the future prospects of a project. On the other hand, high levels of R&D intensity are not necessarily linked to good innovation practice: they may simply mask process inefficiencies (Dodgson and Hinze 2000). Besides, R&D intensity might not be a very useful measure for small- and medium-sized enterprises (Kleinknecht 1987) or for service industries (Hipp and Grupp 2005). Based on the above insights, considering resources available for managing NPD process and product safety is different for firms with low and high R&D intensity, the following hypothesis is developed:

H11: *Firm's R&D intensity will moderate the relationships posited in* Fig. 3.4, *thereby suggesting that the relationships of those firms that have high R&D intensity will be different from those that have low R&D intensity.*

Table 3.1 summarizes the research hypotheses presented in this chapter. The next chapter explains the research methodology used to test the hypotheses.

Table 3.1 Summary of hypotheses

H1:	*Product safety strategy has a positive effect on the group level product safety culture in new product development*
H2:	*Product safety strategy has a positive effect on the use of concurrent engineering*
H3:	*Product safety strategy has a positive effect on the use of new product development process*
H4:	*Group level product safety culture in new product development has a positive effect on the use of concurrent engineering*
H5:	*Group level product safety culture in new product development has a positive effect on the use of new product development process*
H6:	*The use of concurrent engineering has a positive effect on the use of new product development process*
H7:	*The use of concurrent engineering has a positive effect on product safety performance*
H8:	*The use of new product development process has a positive effect on product safety performance*
H9:	*Manager's perceptions of actual model constructs (PSS, PSC, CE, NPP, and PSP) are influenced by contextual factors (firm size, firm origin, target market, R&D intensity)*
H9a:	*Manager's perceptions of actual model constructs (PSS, PSC, CE, NPP, and PSP) are not affected by firm size*
H9b:	*Manager's perceptions of actual model constructs (PSS, PSC, CE, NPP, and PSP) are not affected by firm origin*
H9c:	*Manager's perceptions of actual model constructs (PSS, PSC, CE, NPP, and PSP) are not affected by firm's target market*
H9d:	*Manager's perceptions of actual model constructs (PSS, PSC, CE, NPP, and PSP) are not affected by firm's R&D intensity*
H10:	*Manager's perceptions of ideal model constructs (IPSS, IPSC, ICE, and INPP) are not affected by organizational contextual variables (firm size, firm origin, target marketing, and R&D intensity)*
H10a:	*Manager's perceptions of ideal model constructs (IPSS, IPSC, ICE, and INPP) are not affected by firm size*
H10b:	*Manager's perceptions of ideal model constructs (IPSS, IPSC, ICE, and INPP) are not affected by origin of firm*
H10c:	*Manager's perceptions of ideal model constructs (IPSS, IPSC, ICE, and INPP) are not affected by target market*
H10d:	*Manager's perceptions of ideal model constructs (IPSS, IPSC, ICE, and INPP) are not affected by R&D intensity*
H11:	*Firm's R&D intensity will moderate the relationships posited in* Fig. 3.4*, thereby suggesting that the relationships of those firms that have high R&D intensity will be different from those that have low R&D intensity*

Chapter 4
Methodology

4.1 Introduction

In this chapter, we discuss the process of research design, the selection of the sample, the survey instrument development, data collection and analysis for hypotheses testing, and in-depth interviews. Because this study is both exploratory and confirmatory in nature, we considered both a large-scale survey and a series of in-depth interview. The survey data was applied to evaluate the relationships between product safety strategy, product safety culture, concurrent engineering, new product development process, and product safety performance. The in-depth interview findings helped explain the quantitative results and facilitate triangulation analysis between the quantitative and qualitative results. The data used for this research are a part of a major empirical study that investigated factors related to product safety performance. The quantitative results are presented in Chap. 5, and the findings of in-depth interviews are reported in Chap. 6.

4.2 Quantitative Methods

4.2.1 Data Collection

This study uses a sample of primary data that was collected from senior quality and R&D managers with intimate knowledge of product development and safety performance of their company's products in the toy and juvenile product industry. The first author was kindly granted access by the China Toy and Juvenile Products Association (TJPA) to interview and collect data via a predefined survey at two of the largest industry-wide conferences organized by TJPA in Beijing (September 2008) and Hangzhou (October 2008). Attendees at this conference represented companies selling about 85% of all toys and juvenile products sold worldwide,

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Table 4.1 Demographics of the sample: 255 respondents from 126 firms

Respondents	*Position of respondents*	*No. of responses (%)*
	Quality manager/director, senior quality engineer	201 (78.8%)
	Engineering manager/director	30 (11.8%)
	Product managers	8 (3.1%)
	GM/VP	16 (6.3%)
	Total	255 (100%)
Firm size	*N = No. of employees*	*No. of responses (%)*
	$N < 500$	29 (11.4%)
	$5000>N> = 500$	123 (48.2%)
	$N > 5000$	103 (40.4%)
R&D intensity	*R = Ratio of R&D expenses/sales*	*No. of responses (%)*
	$R < 3\%$	116 (45.5%)
	$R > = 3\%$	139 (54.5%)
Firm ownership	*Location*	*No. of firms (%)*
	Chinese firms or JV in China	90 (71.4%)
	Overseas firms located in the USA, EU, JP, NL, and AU	36 (28.6%)
	Total	126 (100%)

either through Chinese domestic manufacturers or foreign multinational companies (European Commission 2008). In this setting, we had structured research interviews with 40 managers from 33 companies. All interviews were recorded in writing, and feedback on the minutes was solicited from the interviewees. All the records were anonymized for later analysis, a precondition which allowed us to discuss confidential and sometimes sensitive aspects of product quality and innovation. Using a global directory of juvenile product manufacturers, we sent the same questionnaire to juvenile product manufacturers outside China, and 31 usable responses were returned.

In total, we received 255 usable responses from 126 firms in the two surveys. Table 4.1 shows the demographics of the survey sample by respondents and firms. All of the 255 managers responding via the survey had senior R&D or quality management roles. The companies' sales revenues for the target period ranged from $5 million to $5.9 billion, totaling up to $11 billion, or 43% of global sales in the industry in 2008. Among these firms, 36 were wholly owned foreign firms from the USA, Europe, Japan, Australia, and New Zealand, and 90 firms were either local Chinese firms or joint ventures. As China has 85% share of the worldwide toy trade (EC 2008), the return rates between China-based and international firms are comparable.

To ensure the comparability of the survey data used in this analysis, several preliminary tests of significance were carried out using MANOVA with the five constructs (MCS, PSC, CE, DFS, and PSP) as dependent variables and respondent manager type, firm size, country, and survey time as categorical independent variables. There were no significant mean differences of the five constructs by respondent manager type, country, and survey time. We checked for consistency of the responses by company or group and observed no significant differences.

4.2.2 The Survey Instrument

The survey instrument used in this study was developed based on extensive review of the literature and feedback from practitioners, primarily from published questions, factors, and scales, with some modifications. Although there is no measurement applicable to all organizations (Van de Ven and Ferry 1980), most of the questions and scales used here were tested and validated in other studies, which would offer more reliability and validity than untested questions. Considering the similarity between quality management and product safety management, the overall constructs are mainly adapted from the major quality management dimensions identified by Saraph et al. (1989) and Flynn et al. (1994), with modification from "quality" to product safety. It contains 114 questions and 10 sections. This instrument covers all critical dimensions of product safety management system, namely, (A) the role of top management and product safety policy, (B) the role of the quality department, (C) training, (D) contract review and regulatory environment, (E) NPD practices, (F) supplier quality management, (G) process management, (H) product safety data, (I) employee participation, and (J) product safety performance and other relevant information. In the NPD practices section (e.g., concurrent engineering, new product development process), we incorporated relevant NPD practices identified by Cooper et al. (2004a, b, c), and Koufteros et al. (2001), critical factors affecting product safety performance identified by Kitzes (1991), and major quality management dimensions identified by Saraph et al. (1989), Benson et al. (1991), and Flynn et al. (1994). We also solicited feedbacks from experts in the industry. Based on their suggestions, a few items related to product safety testing, in-house testing, and government surveillance inspection in the market are incorporated in the survey instrument. Besides, this instrument was also reviewed by two academics.

The survey instrument contains both descriptive and evaluative measures. "Descriptive measures are positive or value-free, and focus on the factual characteristics and behaviors that actually exist or occur in the organization. Evaluation measurements are normative or value-laden, and ask a respondent to provide an opinion about strengths, weaknesses, likes, or dislikes of characteristics and behaviors in the organization" (Van de Ven and Ferry 1980, p. 61). In this research, questions related to product safety strategy, product safety culture, concurrent engineering, new product development process, product safety performance, environmental factors, and company information are descriptive. Additionally, respondents were asked to provide their opinion on ideal practices ("should be") for questions in product safety strategy, product safety culture, concurrent engineering, and new product development process, which are considered as evaluative measures. For each practice or question, we solicited the respondent's rating on the company's current situation (actual) and ideal situation ("should be" in terms of its importance to product safety) for the practice with a five-point Likert scale. The purpose is to investigate the gaps between the actual and ideal practices. This structure is similar to Benson et al.'s (1991) survey instrument design investigating the relationship between actual and ideal quality management and organizational contextual factors. An example of the survey question is shown in Table 4.2.

Table 4.2 An example of one of the survey questions

Practices	Current situation	Should be (ideal)
The degree to which top management supports product safety	1 2 3 4 5	1 2 3 4 5

1 very low/strongly disagree, *2* low/disagree, *3* moderate/partially agree, *4* high/agree, *5* very high/strongly agree

The dependent variable product safety performance was measured with a scale different from the predicting variables based on the degree of satisfaction for product safety performance at outgoing product audits (internal product safety performance) and at the customer's side (external product safety performance). Respondents were required to rate the product safety performance between 1 and 10: 1 = strongly dissatisfied, 6 = acceptable, and 10 = strongly satisfied.

In this study, we only used items related to company background information and 30 items measuring the five constructs from the 114 questions (refer to Table 4.1): (1) product safety strategy, (2) product safety culture in NPD, (3) concurrent engineering, (4) new product development process, and (5) product safety performance. The first part of the survey instrument explained the purpose of the survey, ensured confidentiality, and provided instructions on how to answer the questions. Then questions on the five constructs followed: product safety strategy, product safety culture in NPD process (group level culture), concurrent engineering, new product development process, and product safety performance. The eight items measuring product safety strategy were taken from a survey developed by Saraph et al. (1989) on critical factors of quality management. Specifically, these questions were taken from the construct of "the role of management leadership and quality policy" with modification from "quality" to "product safety." Items for product safety culture in the NPD process, which include NPD team's attitude and commitment to product safety, the importance of product safety in relation to cost and speed by NPD team, and the authority and independence of product safety review team, were developed through reviewing the safety culture literature (Zohar 1980, 2000). The questions on concurrent engineering and product development process were mainly adapted from Cooper et al. (2004b, c) and Koufteros et al. (2001).

The third part of the survey asked questions about company information and environmental factors. Respondents were required to choose the firm's R&D intensity (R&D expenses over total sales), firm size (small, medium, and big) based on number of employees, the origin of firms, firm's revenue, and the firm's main target market. The reason that these factors were selected was to evaluate whether they affected the level of practices adapted by the firms and whether these factors moderated the structural model relationships. Chinese firms have been blamed for product recalls because most of the products recalled were made by Chinese firms. Consequently, ownership was selected to investigate its moderating effect. Questions on whether the firm had senior level staff in charge of product safety and product safety commit were taken from previous studies on product safety that reported that it was a commonplace that companies had senior level in charge of product safety

(Eads and Reuter 1983). To evaluate how firms motivated employees on product safety, a question on whether the firm had a product safety award was included.

In the last part of the survey, a multiple-choice question containing ten common designs and manufacturing issues were listed, and respondents were asked to select the suitable ones. This was to investigate the major root causes for product safety issues in the firms. These choices were:

(a) Lack of design experience on the product
(b) Inadequate manufacturing process capability
(c) Design engineers not familiar with the product safety standards
(d) Product not reliable
(e) Inadequate product safety test and review (such as hazard analysis)
(f) Cost considerations
(g) Foreseeable misuse not considered by engineers
(h) Materials/components from suppliers not compliant with specifications
(i) Manufacturing process out of control
(j) Product safety standards/requirements not clear
(k) Others (please specify)

This question was also used to analyze whether the major root causes for product safety issues were rooted in design or manufacturing; product recall literature had reported about 70% of products were recalled because of design defects (White and Pomponi 2003; Bapuji and Beamish 2008; Beamish and Bapuji 2008).

A professional translator translated the original English survey questionnaire from English to Chinese, and another translator translated it back from Chinese to English. The first author is bilingual in Chinese and English and verified the translation with minor changes to the questionnaire. A pilot survey was carried out with respondents from 22 juvenile product firms in Jiangsu province, China. Based on the pilot data and suggestions from experts in the industry, some items were removed from the initial survey.

The collected data were self-reported and represent the managers' perceptions within their product category or business unit. When the measures of predictors and criteria variables are rated by the same respondent, a common method bias might exist. To address this problem, we followed recommendations by Podsakoff et al. (2003):

1. Application of all procedural remedies for questionnaire design.
2. Separation of criterion and predictor variables proximally and psychologically, with criterion and predictor variables on different pages.
3. Response anonymity and confidentiality were guaranteed during the survey.
4. Different scaling formats for independent variables and dependent variables in the survey.

In single-factor analysis for independent and dependent variables, 17 factors accounted for 85% of variance yielded, and factor #1 accounted for 39% of variance. Since neither a single factor nor a general factor accounted for the majority of covariance in the measure, a common method bias is therefore unlikely in the data (Podsakoff and Organ 1986). Table 4.3 shows the CFA factor loading estimates and t-values.

Table 4.3 CFA factor loading estimates and t-value ($n = 255$)

Code	Questions/construct	Loading	*t*-value
MCS	*Top management commitment to safety (latent variable)*		
TM1	*Extent to which the top management assumes responsibility for product safety performance*		
TM2	Degree to which top management supports product safety management	0.69	–[a]
TM3	Extent to which relevant department heads are evaluated on product safety performance	0.75	10.97
TM4	Degree to which management participates in product safety improvement	0.80	11.70
TM5	Degree to which management establishes product safety policies and objectives	0.78	11.44
TM6	Specificity of firm's product safety policies and objectives	0.81	11.71
TM7	Importance attached to product safety in relation to cost and schedule by top management	0.79	11.51
TM8	Amount of review for product safety issues in top management review meetings	0.71	10.39
PSC	*Product safety culture (latent variable)*		
PSC1	Degree to which NPD engineers are familiar with relevant product safety standards and regulatory requirements	0.76	–[a]
PSC2	Product safety is more important than cost and schedule in NPD process	0.68	10.59
PSC3	Product safety review team independent of NPD project team conducts product safety review	0.73	11.15
PSC4	Product safety review team has the authority to stop or postpone the NPD project	0.72	10.94
PSC5	Degree to which product safety is considered by NPD engineers in NPD process	0.81	11.30
CE	*Concurrent engineering (latent variable)*		
CE1	Cross-functional teams are used in NPD process	0.62	–[a]
CE2	NPD project team leader and members remain on the project from beginning to end and not just for a short while or a single phase	0.83	7.59
CE3	The NPD teams are accountable for their project's end results	0.86	7.81
CE4	NPD team members share information via a central information system	0.73	6.83
CE5	*Customer is involved in NPD process*		
CE6	Degree to which major suppliers are involved in the NPD process	0.61	6.85
CE7	Degree to which product manufacturability is considered by design engineers during NPD	0.65	7.04
NPP	*New product process (latent variable)*		
NPP1	A systematic NPD process (such as stage gate, from idea generation, feasibility study, prototyping, pilot run, to mass production) is implemented	0.72	–[a]

(continued)

Table 4.3 (continued)

Code	Questions/construct	Loading	t-value
NPP2	The firm has clearly defined requirements for product safety and verification plan at each stage in the NPD process	0.75	11.68
NPP3	Degree to which comprehensive product safety tests and reliability tests (internal or external) are carried out before product launch for production	0.66	9.81
NPP4	Degree to which comprehensive product safety reviews (including hazard analysis and foreseeable misuse/abuse analysis) are carried out before product launch for production	0.78	11.86
NPP5	In NPD process, FMEA (failure mode effect analysis) is carried out for risk analysis	0.63	10.87
NPP6	*Degree to which field test/consumer use is carried out before product launch for production*		
NPP7	Design reviews are carried out before new product launch	0.71	9.53
NPP8	*Degree to which post-launch reviews are carried out systematically*		
PSP	*Product safety performance (latent variable)*		
PSP1	In outgoing product audit, firm's assessment on product safety performance is:	0.83	–[a]
PSP2	Customers' assessment on firm's product safety performance in the market is:	0.73	8.54

Note: Items underlined (TM1, CE5, NPP6, NPP8) were deleted in the analysis due to poor model fit

[a]Not estimated when loading set to fixed value of 1.0; model fit indices after deleting the four items: $P < 0.001$, $\chi2 = 2570.33$, df = 291, $\chi2/\text{df} = 1.96$, RMSEA = 0.06, CFI = 0.92, IFI = 0.92, TLI = 0.90, AIC =742.33, saturated AIC = 754.00, independent AIC = 3691.20

4.2.3 Model Analysis

There is some controversy in the SEM literature concerning how model evaluation should be conducted (Koufteros and Marcoulides 2006). Various procedures are available in the literature on whether model test should be performed in one step (estimate the measurement and structural model simultaneously, e.g., Hayduk and Glaser 2000), two steps (separate the measurement and structural model analysis, e.g., Anderson and Gerbing 1988; Bentler 2000), three steps (Carlson and Mulaik 1993), or four steps (Mulaik and Millsap 2000). Although all methods can be applied to test the proposed model, we followed the two-step approach to formulate and test the model (Anderson and Gerbing 1982; Gerbing and Anderson 1988; Hair et al. 2010), meaning the measurement model was tested prior to the testing of the structural model. This was done to avoid possible interactions between the measurement and structural models. In addition, confirmatory factor analysis (CFA) was performed on the entire set of items simultaneously (Anderson et al. 1987). Hair et al. (2010) proposed detailed six stages to develop and test structural modeling which include analyzing dimensionality; evaluating the reliability of their composition; examining the content, convergent, and discriminant validity of the scale; etc.

Principal component exploratory factor analysis with varimax rotation and confirmatory factory analysis with structural equation modeling can be performed by means of SPSS 18 and AMOS 18 software, respectively.

Dimensionality Analysis

Principal component exploratory factor analysis can be conducted by considering all items proposed for each construct. The results revealed the unidimensional nature of the constructs, namely, product safety strategy, product safety culture, concurrent engineering, new product development process, and product safety performance. Subsequently, we carried out confirmatory factor analysis on the proposed measurement model with SPSS AMOS 18.

Model Refinement

The initial measurement model with the instrument of 30 items indicated an inadequate model fit with chi-square of 803.33, degrees of freedom of 395 ($p = 0.00$), normed chi-square of 2.03, CFI of 0.89, TLI of 0.87, IFI of 0.89, and RMSEA of 0.06. It did not pass the guideline for 0.90 for CFI, TLI, and IFI. Consequently, an iterative process was carried out to improve the model fit for the measurement model (refer to the measurement model in Fig. 4.1) by means of standard CFA refinement procedures. Items contributing to poor fit were dropped systematically: items with standardized factor loading less than 0.5 cannot be qualified as a good item (Hair et al. 2010) and were systematically dropped one at a time. Various model fit indices were evaluated for each iteration. Hair et al. (2010) cautioned against statistical-driven refinement without regard to the item's relevance to theory and content validity. Therefore, we stopped the refinement once an acceptable

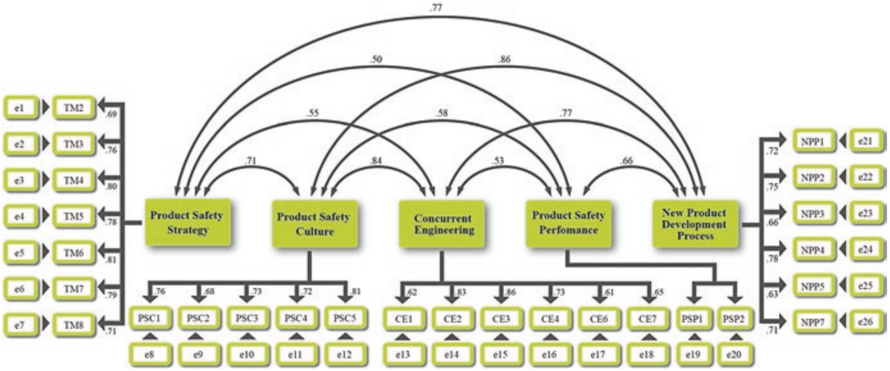


Fig. 4.1 Measurement model: CMIN = 570.32, DF = 289, $P = 0.00$, CMIN/DF = 1.97, CFI = 0.91, RMSEA = 0.06

model fit threshold was achieved without a significant reduction in the content validity of the scales. A good model fit was achieved after reducing the scale items from 30 to 26 in the five constructs (items deleted are underlined in Table 4.3). We then proceeded to evaluate the reliability and validity of the scales with the final proposed items for each of the construct.

Validity of the Measurement Model

To examine the validity of the measurement model and test the measurement theory, the theoretical measurement model was compared against the data. Both the overall model fit and criteria for construct validity were evaluated. All analyses were performed on a covariance matrix using maximum likelihood (ML) estimation and on all items simultaneously (Anderson et al. 1987). SEM requires large sample size, but if the sample size is too big (over 400), the method becomes very sensitive (Marsh et al. 1988). Consequently, various fit indices were employed to assess the overall fit of the measurement model because of their ability to adjust for model complexity and degree of freedom, and they were not sensitive to sample size (Marsh et al. 1988). The fit indices used are relative chi-square (the ratio of chi-square to degree of freedom, CMIN/DF), Bentler's (1990) comparative fit index (CFI), Bollen's (1989) incremental fit index (IFI), Tucker and Lewis (1973) index (TLI), Akaike's (1987) information criteria (AIC), and Browne and Cudeck's (1993) root mean square error of approximation (RMSEA). These indices were applied because of their widespread use in model fit assessment (Marcoulides and Hershberger 1997; Hair et al. 2010). Detailed criteria for analyzing model fit with these fit indices can be found in Byrne (1998), Hu and Bentler (1999), Raykov and Marcoulides (2000), and Hair et al. (2010). Carmines and McIver (1981) recommend relative chi-square values less than 3.0 imply an acceptable fit; a number smaller than 2.0 is considered very good. Browne and Cudeck (1993) suggest that RMSEA values of 0.08 or less indicate a reasonable model fit, and values lower than 0.05 imply a good model fit. As rules of thumb, values of CFI (Bentler 1990), IFI (Bollen 1989) and TLI (Tucker and Lewis 1973) close to 1 (e.g., >0.9) indicate a very good model fit (Raykov and Marcoulides 2000). Hair et al. (2010) recommend that fit indices should include at least one absolute fit index (i.e., GFI, RMSEA, or SRMR), one incremental fit index (i.e., CFI, TLI), one goodness-of-fit index (i.e., GFI, CFI, TLI, etc.), and one badness of fit index (RMSEA, SRMR, etc.). After achieving a good measurement model fit, the construct validity can be examined.

Construct Validity

Validity refers to the extent to which research is accurate, and the discussion centered on validating summated scales. One of the primary objectives of CFA/SEM is to assess the construct validity of a proposed measurement theory (Hair et al. 2010). The validity of a scale refers to the extent to which it measures what is intended to be measured. The validity of the scales is verified by considering the content validity, convergent, and discriminant validity. A scale has content validity if there is a general agreement among the subjects and researchers that the scale has measurement items that cover all aspects of the latent variable being measured. Therefore, content validity depends on how well the researchers create measurement items to cover the content domain of the variable being measured (Nunnally 1978). The content validity in our research was ensured through comprehensive review of the literature on the topics and detailed evaluation by professionals in the industry and scholars. The whole instrument contained 114 questions, which provided a comprehensive coverage on the research issues and theoretically related topics. The 30 items provided an adequate coverage for the five constructs. Furthermore, most of the practices adapted in this research were tested in earlier research (Saraph et al. 1989; Cooper et al. 2004b, c; Koufteros et al. 2001).

Criterion-related validity (also called predictive validity or external validity) is another important aspect of an instrument. It is concerned with the extent to which a measuring instrument is related to an independent measure of the relevant criterion (Nunnally 1978). The correlation matrix is a good start to assess the extent that the constructs are expected to relate to each other.

Convergent validity refers to the extent to which the indicators of a construct cover or share a high proportion of variance in common (Hair et al. 2010). There are several ways to estimate the convergent validity. It can be analyzed by means of factor loadings through *t*-tests or standardized factorial regression coefficients relating each indicator to the latent variable (Anderson and Gerbing 1988; Hair et al. 2010). It shows good construct validity if the standardized factor loadings are over 0.5 (ideally 0.7 or higher) and significant at a confidence level of 95%, which requires t-values over 1.96. Another way to evaluate convergent validity is through average variance extracted (AVE). AVE is calculated as the total of all squared standardized factor loadings (square multiple correlations) divided by the number of items (Hair et al. 2010). In other words, it is the average squared completely standardized factor loading or average communality. An AVE of 0.5 or higher indicates adequate convergence.

Another indicator of convergent validity is reliability. There are several alternative reliability estimates. Coefficient alpha remains a commonly used estimate. Different reliability coefficients do not produce dramatically different reliability estimates. In structural equation modeling, construct reliability (CR) value is often applied. It is computed from the squared sum of factor loadings for each construct and the sum of the error variance terms for a construct. As a rule of thumb, if construct reliability is between 0.6 and 0.7, it is acceptable. If the construct reliability is higher than 0.7, it suggests a good reliability (Hair et al. 2010).

Discriminant validity indicates the extent to which a construct is truly distinct from other constructs both in terms of how much it correlates with other constructs and how distinctly measured variables represent only this single construct (Bagozzi et al. 1991; Hair et al. 2010). Therefore, the high-scale correlations warranted a careful discriminant validity assessment for the constructs. There are several approaches how to evaluate the discriminant validity. First, discriminant validity can be verified by Anderson and Gerbing (1988) methodology, which requires estimating the confidence interval around the parameters that indicates the correlation between the five unidimensional factors. The confidence interval can be calculated based on the function correlations plus or minus twice standard errors for each pair of constructs and examine whether one is included in the interval (Anderson and Gerbing 1988; Marcoulides et al. 1988). Second, statistically different constructs exhibit interscale correlations that are adequately different from 1.0 (Bagozzi et al. 1991). Another approach to assess discriminant validity is to compare the Cronbach reliability coefficient of each scale with its average interscale correlations (AIC) with other constructs; adequate discriminant validity is established if the former is larger than the latter (Ghiselli et al. 1981).

Reliability of the Instrument

Reliability measures the degree of internal consistency between the variables that make up the scale and represents the extent to which the items of a construct measure the same concept. Using SPSS 18, reliability analysis for all the scales was performed. Traditionally, reliability coefficients of 0.70 or higher are considered satisfactory (Nunnally 1978). Based on the above analyses, if the measurement model shows a good model fit and construct validity and reliability, the structural model and hypotheses testing can be executed.

Examining the Structural Model

The structural model was developed in Chaps. 2 and 3 with the intention to test hypotheses 1–8. The structural model shown in Fig. 4.2 indicates the constructs and measured variables. PSS is an exogenous construct in this model. It is considered to be determined by factors outside of this model, which means no hypothesis predicts this construct. PSC, CE, NPP, and PSP are endogenous constructs in this model. Each is determined by constructs included in this model. Based on the hypotheses, the CFA model was transformed into a structural model. The structural model shown in Fig. 4.2 was then estimated and examined. Prior to conducting the analysis, it is necessary to evaluate the multicollinearity issue as high multicollinearity masks the effects of an individual predictor and leads to incorrect estimate of regression weight in the analysis (Neter et al. 1990). A widely used measure of multicollinearity in path analysis is variation inflation factors (VIF), which assess the portion of predictor variables explained by other predictor variables. A commonly recommended threshold value for VIF is less than 10.0 (Billings and Wroten 1978; Asher 1983; Neter et al. 1990). To assess the fit of the structural model to the data, the fit indices used to evaluate the measurement model such as normed chi-square ($\chi 2$/df), CFI, NNFI, RMSEA, and AIC are computed and evaluated for the structural model. If a model fits the data adequately, the *t*-values of the structural coefficients can be used to test the hypotheses.

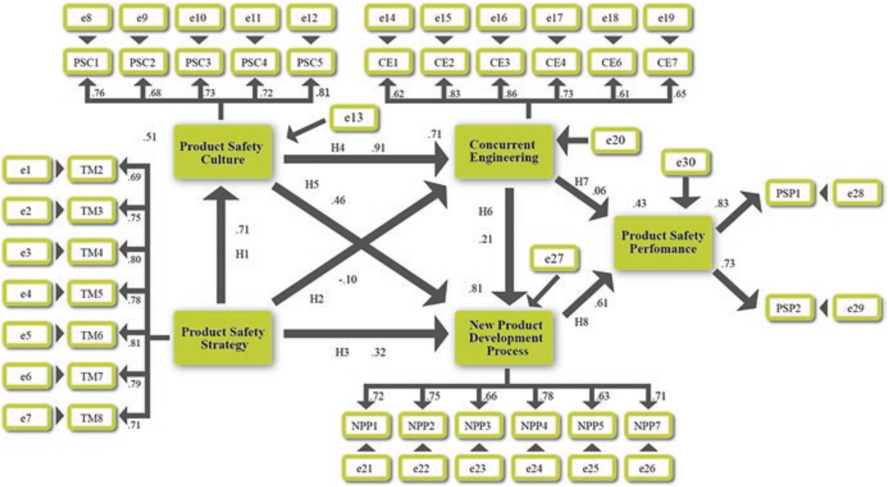


Fig. 4.2 Structural model: CMIN = 570.33, DF = 291, $P = 0.00$, CMIN/DF = 1.96, CFI = 0.92, RMSEA = 0.06

4.2.4 Multivariate Analysis of Variance (MANOVA)

Hypothesis testing for H9 and H10 was carried out by means of MANOVA (multivariate analysis of variance). MANOVA was applied because of its ability to determine if a set of categorical predictor variables can explain the variability in a set of continuous response variables. Multivariate tests provide the results of the multivariate tests of each effect in the model. These results are very difficult to interpret on their own, and so they are typically converted to an F statistic to make the determination of the p-value easier. There are four values (Pillai's trace, Wilks' lambda, Hotelling's trace, and Roy's largest root) as well as the corresponding F statistics and degrees of freedom reported in the MANOVA results. The most commonly used and accepted statistic is Wilks' lambda. More recently statisticians have used the Pillai-Bartlett trace, as research has indicated that this statistic is somewhat more robust to violations of the model assumptions than Wilk's lambda (DeCoster 2004; Olson 1974). Consequently, conclusions are based on one of these two statistics.

The GLM (general linear modeling) multivariate procedure was applied to perform MANOVA. The GLM multivariate procedure makes three assumptions:

1. The values of errors are independent of each other across observations and the independent variables in the model.
2. The covariance of dependent variables is constant across cells. This can be particularly important when there are unequal cell sizes, that is, different numbers of observations across factor-level combinations.
3. The errors for dependent variables have a multivariate normal distribution with a mean of zero.

To examine the effects of firm size, origin of firm, firm's target market, and firm's R&D intensity on the five model constructs and manager's perception on ideal model constructs, MANOVA was performed with the actual model constructs (PSS, PSC, CE, NPP, PSP) and manager's perception of ideal model constructs (IPSS, IPSC, ICE, INPP) as dependent variables, and firm size, origin of firm, firm's target market, and firm's R&D intensity as grouping factors. Firm size was classified as small (less than 500 employees, $n = 29$), medium (between 500 and 5000 employees, $n = 123$), and large (over 5000 employees, $n = 103$) based on the total number of employees. Origin of firm was categorized by the ownership of firms. Group A ($n = 219$) was denoted as local Chinese firms or joint ventures and group B ($n = 36$) as wholly owned foreign companies. Another categorical factor was the firm's major target market. Three groups were formed: group A ($n = 20$) denoted firms that sold products in China only, group B ($n = 175$) was for firms that sold products in China and overseas, and group C ($n = 60$) referred to firms that sold products in outside China in overseas markets only. The last categorical factor was R&D intensity. In this category, firms with R&D expenses over sales ratio equal to or less than 3% were classified as group A ($n = 116$); firms with R&D expenses over sales ratio above 3% were categorized as group B ($n = 139$).

4.2.5 Multiple Group Analysis

Multiple group analysis is a SEM framework used to test differences between similar models for different group of respondents (Hair et al. 2010). To evaluate whether R&D intensity moderated the relationship in the proposed model (hypothesis 11), multigroup analysis was performed by splitting the sample between firms reporting high and low levels of R&D intensity. The procedure applied here reflected the method discussed and used by Hair et al. (2010), Koufteros and Marcoulides (2006), Schumacker and Marcoulides (1998), and Byrne (1998). Measurement invariance (or measurement equivalence), considered a prerequisite prior to assessing invariance for individual path coefficients, needs to be verified. The two-group methodology was applied in our research because Koufteros and Marcoulides (2006), Calantone et al. (2003), and Ahire and Dreyfus (2000) had shown in similar studies that it is a more appropriate device to evaluate moderator effect than an approach where environmental effects are posited as direct effects. Figure 4.3 presents a flowchart for conducting a multigroup analysis, which reflects the six-stage procedure proposed by Hair et al. (2010):

Stage 1: Configural invariance (TF model). The first stage confirmed configural invariance. This was to verify that the same basic factor structure existed in all of the groups. It involved an assessment of the fit of the proposed model to the entire data set collectively. The methods for model assessment and fit were described previously in this chapter. This model is referred to as the totally free multiple group model (TF) as all free parameters were estimated separately and therefore free to

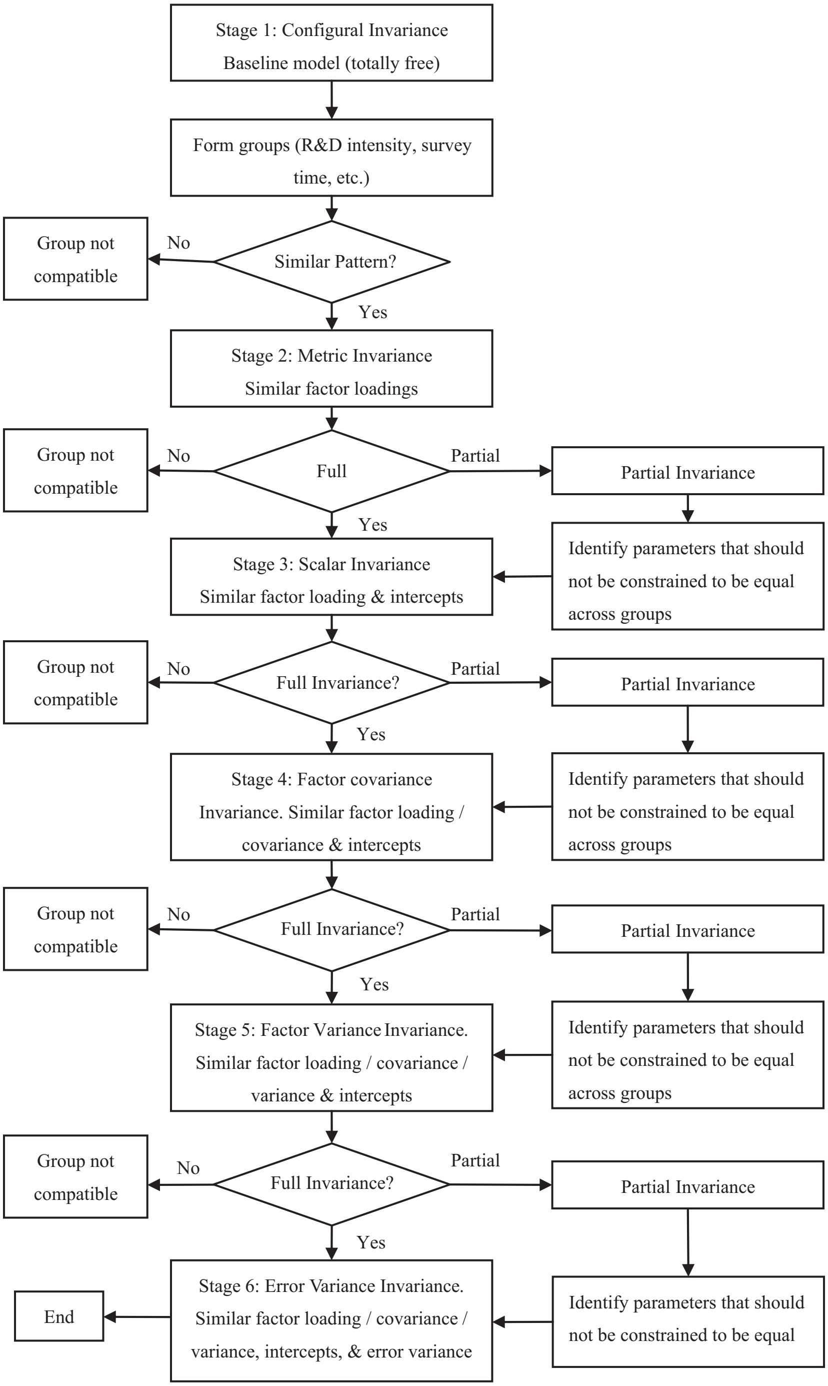


Fig. 4.3 Multigroup analysis process

take on different values in each group. No equality constraints were specified across groups. The TF model is the baseline model for comparison. The appropriateness of the posited structure depends on the overall or aggregate model fit. Only one set of model fit criteria is computed; nevertheless, adding up the chi-square of the groups yields the overall total-sample chi-square.

Stage 2: Metric invariance (factor loading). The second stage was to form groups based on particular characteristics of interest such as firm size, national origin, etc. These particular groups were formed after suspecting and postulating that the groups may indeed be different on the measurement and/or structural model parameters of the proposed model. In this study, the low and high R&D intensity groups were formed based on the ratio of R&D expenses and sales. Firms with a ratio less than 3% were classified as group A ($n = 116$), and firms with a ratio above 3% were categorized as group B ($n = 139$). This was followed by imposing equality constraints on factor loadings for the observed dependent and independent variables across groups (e.g., Lx1,group1 = Lx1,group2; Lx1,group1 = Lx2,group2, etc.). This model is referred as model 2. This is a critical test of invariance and the degree to which this is met determines cross-group validity beyond the basic factor structure. A chi-square ($\chi2$) difference between the baseline model and the model in which the equality constraints on factor loadings are imposed can indicate whether the loadings are invariant across the two groups.

Stage 3: Scalar invariance (factor loading and intercept). This stage tested for the equality of the measured variable intercepts (i.e., means) on the constructs. This model is constrained by imposing equality for factor loadings and measured variable intercepts. Scalar invariance is required if the intension is to compare means across the groups.

Stage 4: Factor covariance invariance. Equality constraints were added for the covariance between constructs. A small $\chi2$ difference is indicative of equality in the factor covariance across the groups examined.

Stage 5: Factor variance invariance. To further test for invariance of the measurement model, additional constraints of equality were placed on the factor variance. If both factor covariance and variances are equivalent across the groups, the latent construct correlations are also equal.

Stage 6: Error variance invariance. This is the final stage tests for the error term invariance for each measured variable across the group. Additional constraints of equality were imposed for error terms of the measurement models. A statistically nonsignificant $\chi2$ difference between factor variance invariance model and error variance invariance model would indicate invariance in the error terms between the two groups examined. The test evaluates whether the measures are equally reliable across the groups examined.

It was an essential prerequisite to establish measurement invariance before assessing invariance of structural coefficients or factor mean structures, as any potential differences in these parameters may otherwise be attributed to measurement non-equivalency. The chi-square difference test described earlier is a test for full invariance, which means that constraining all the parameters relative to that type of invariance to be the same in each group does not significantly worsen fit. Full variance becomes difficult to achieve as models become complex. If only some of the parameters are invariant, partial invariance is established. Full metric invariance may not be necessary for subsequent tests of invariance as long as one or more item from each latent variable is metrically invariant (Byrne et al. 1989). A general consensus is that if two parameters per construct are found to be invariant, partial invariance exists (Hair et al. 2010). Partial invariance can be achieved at each stage by freeing the equality constraints with the largest modification indices.

As our intention was to test the moderating effect of R&D intensity on the proposed model, the level of invariance needed for this type of research is full configural invariance and at least partial metric invariance (Hair et al. 2010). When measurement invariance is established, the structural model estimate is evaluated for moderation by a comparison of group models. The TF model was estimated with path estimates calculated separately for both groups. The chi-square difference test is conducted when the path estimates are constrained to be equal. If the models are statistically significant after constraining the path estimates, moderating effects exist. If the models are not significantly different, there is no support for moderation.

4.3 Qualitative Methods

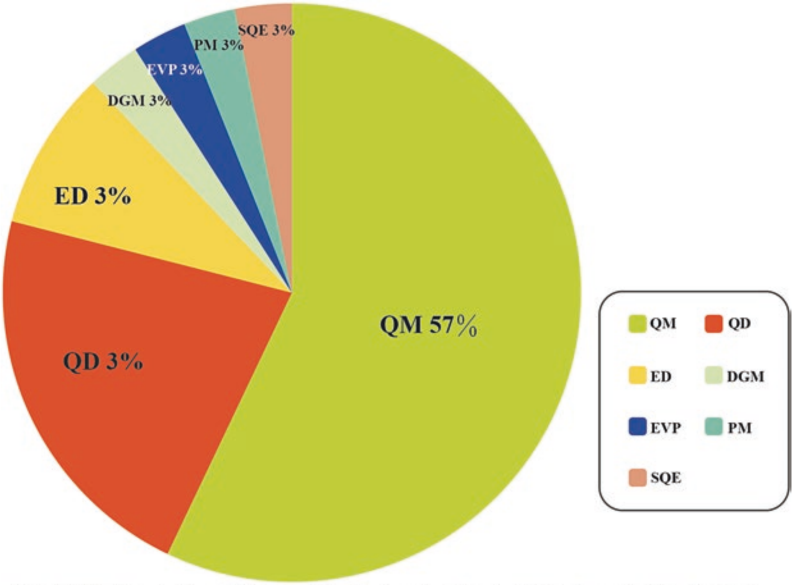
In this section, we explain the data collection for the qualitative part of the study. Traditionally, the primary way for a researcher to investigate an organization or process is through the experience of individual people (Seidman 1998). As our intention was to understand the critical safety NPD practices that firms adapt, we applied case study research, a method appropriate for exploratory research (Voss et al. 2002). Yin (1994) argued case research is based on analytical generalization rather than statistical generalization. The results should be considered exploratory and exemplary. Therefore, the intention of the qualitative part of this research was to provide evidence and explanations to support the quantitative findings and to understand the issues from a different angle. For some of the firms interviewed, we were also able to access the firm's policies and procedures, product safety standards, safety/design review records, and other official documents/records such as quality system audit reports; in some cases, one of the authors even participated in the NPD process as a senior management representative. Therefore, the findings from the records/document analysis and observations are included to identify evidence that supports the interview findings. To minimize misinterpretation or bias, various procedures such as redundancy of data gathering and triangulation (a process of using multiple perceptions to clarify meaning, see Stake (2000)) were employed. In the triangulation analysis for this research, a combination of quantitative results, interview, observation, and document review was used as different data sources to validate and cross-check the findings (Patton 1990).

4.3.1 Profile of the Firms

Based on the survey findings and with the help from four industry experts with more than 10 years of experience in the target industry, we selected two groups of firms with different external product safety performance ratings as target firms for interview. When selecting the interviewees, we intentionally chose different nationals in these firms to gain global views and valuable insights from different perspectives. Forty-four senior managers in charge of product safety management in these firms were contacted with an email introduction, 40 respondents from 33 firms accepted for the interview. The other four personnel contacted either did not reply to the introduction email or were unable to schedule the interview within the suggested time period. Among the 40 interviewees interviewed, two groups were formed based on the firm's actual performance in the market. The classification criteria included the firm's reputation in the industry and its recall history in the market. The best performers, consisting of 19 interviewees from 14 firms, formed group A. The remaining 21 interviewees from 19 firms with a product safety performance of good or lower formed group B. Most of firms in group A were well-known companies with renowned brands in their markets. Three interviewees chose to provide detailed responses in writing. Eighty-eight percent of the interviewees were senior quality managers in charge of product safety management in the company. The rest included senior managers from R&D, engineering, and product management. In terms of nationality, 57% of the interviewees were from Mainland China, and the rest were from Europe, the USA, Australia, Japan, Hong Kong, and Taiwan. In terms of origin of firms, 37% were from Mainland China, 20% from the USA, 18% from Europe, and 23% from Japan, Australia, Hong Kong, and Taiwan (see Figs. 4.4, 4.5, and 4.6 and Table 4.4 for the profile of the firms and interviewees).

4.3.2 In-Depth Interview Procedure

By adopting a semi-structure interview approach, interviewees were allowed to explain their different perceptions as they choose while centered around common questions to ensure the focus of the research. Each interview took one to one and half hour. An interview guide with 34 questions (most of them open questions) covering all aspects of product safety management was sent to each interviewee in advance to



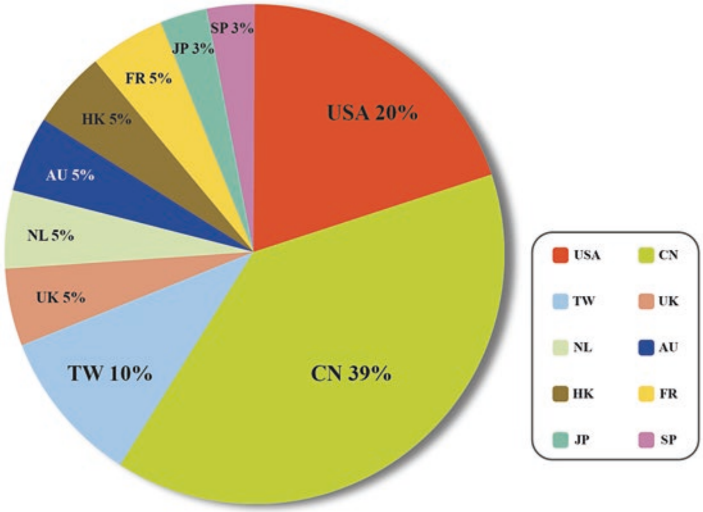
Note: DGM = Deputy General Manager, ED = Engineering Director, EVP = Executive Vice President, PM = Product Manager, QD = Quality Director, QM = Quality Manager, SQE = Senior Quality Engineer

Fig. 4.4 Positions of interviewees

ensure the interviewees were prepared before the interview. In this analysis, we only used data related to product safety strategy, product safety culture, concurrent engineering, new product development process, and product safety performance.

All interviews were conducted by the first author between July 2009 and June 2010. Four interviews were conducted by telephone, 3 were done by email, and 33 were conducted in face-to-face meetings either in the USA or in China. Twenty-seven interviews were tape-recorded and transcribed. Ten interviews were not tape-recorded but were accompanied by an assistant who took notes. We had promised confidentiality before the interview, so in the analysis, the names of the firms and interviewees did not appear. Individual interviewees were coded as "I + sequential number."

The interviews with American, European, and Australian nationals were conducted in English. The rest were done in Chinese (an interpreter helped during the interview with the Japanese). All the interviews were transcribed to facilitate data analysis. Transcripts of the interviews were sent back to the interviewees to check for the accuracy of the interpretation. For the firms that we were accessed for other sources of information, the interview data were verified with these data to ensure their validity. This is a very important step as the results and analysis are based on the responses of the interviewees. NVivo 8 software was applied to assist data analysis.



Note: AU = Australia, CN = China, FR = France, HK = Hong Kong, JP = Japan, NL = Netherlands, SP = Spain, TW = Taiwan, UK = United Kingdom, USA = United States of America

Fig. 4.5 Nationalities of interviewees

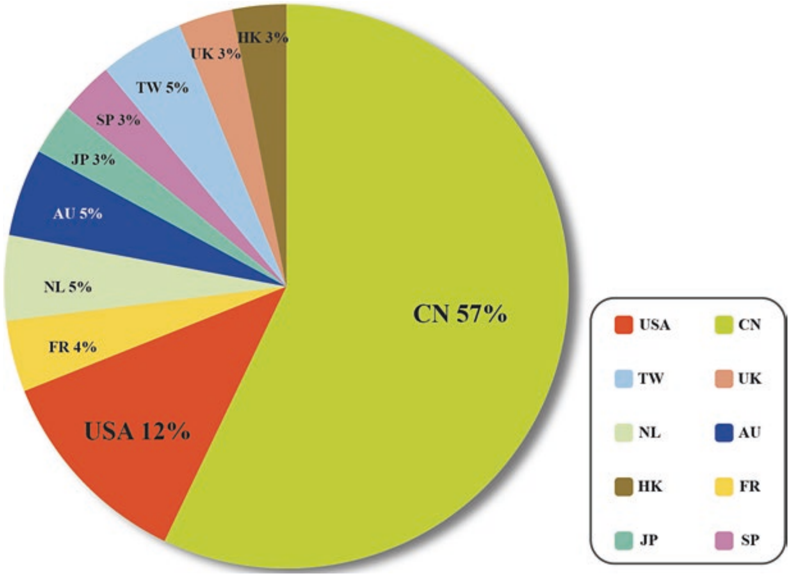


Fig. 4.6 Firm origin of interviewees

Table 4.4 Summary of in-depth interviews

Interviewee	Position	Country of origin	Date of interview	Methods	Location of the firm	Origin of the firm	Main Products
I1	Quality director	Japan	September 09, 2009	Face to face	Japan	Japan	Childcare articles and juvenile equipment
I2	Quality manager	Australia	October 11, 2009	Email	Australia	Australia	Childcare articles and juvenile equipment
I3	Quality manager	China	September 18, 2009	Telephone	China	UK	Childcare articles and juvenile equipment
I4	Vice president, R&D	USA	November 20, 2009	Face to face	USA	USA	Childcare articles and juvenile equipment
I5	Quality director	USA	October 23, 2009	Face to face	USA	USA	Childcare articles and juvenile equipment
I6	Quality manager	France	September 18, 2009	Face to face	France	France	Childcare articles and juvenile equipment
I7	Quality manager	France	August 18, 2009	Telephone	France	France	Childcare articles and juvenile equipment
I8	Quality manager	USA	November 13, 2009	Face to face	USA	USA	Childcare articles and juvenile equipment
I9	Quality manager	USA	October 20, 2009	Telephone	USA	USA	Childcare articles and juvenile equipment
I10	Executive vice president	USA	July 22, 2009	Face to face	USA	USA	Childcare articles and juvenile equipment
I11	Quality manager	Holland	August 14, 2009	Telephone	Netherlands	Netherlands	Childcare articles and juvenile equipment
I12	Senior quality engineer	Holland	July 17, 2009	Face to face	Netherlands	Netherlands	Childcare articles and juvenile equipment
I13	Deputy general manager	China	August 15, 2009	Face to face	China	China	Childcare articles and juvenile equipment

I14	Quality director	China	August 08, 2009	Face to face	China	China	Childcare articles and juvenile equipment
I15	Quality manager	China	September 03, 2009	Face to face	China	China	Childcare articles and juvenile equipment
I16	Quality manager	China	September 03, 2009	Face to face	China	China	Childcare articles and juvenile equipment
I17	Quality director	China	October 28, 2009	Face to face	China	China	Childcare articles and juvenile equipment
I18	Engineering director	Hong Kong	September 02, 2009	Face to face	China	Hong Kong	Toys
I19	Engineering director	China	September 25, 2009	Face to face	China	Hong Kong	Toys
I20	Quality manager	China	September 05, 2009	Face to face	China	Taiwan	Childcare articles and juvenile equipment
I21	Quality manager	China	September 05, 2009	Face to face	China	USA	Toys
I22	Quality manager	China	August 08, 2009	Face to face	China	USA	Toys
I23	Quality manager	China	September 02, 2009	Face to face	China	China	Childcare articles and juvenile equipment
I24	Engineering director	China	September 02, 2009	Face to face	China	China	Childcare articles and juvenile equipment
I25	Quality director	Taiwan	September 07, 2009	Face to face	China	USA	Childcare articles and juvenile equipment
I26	Quality manager	Spain	September 07, 2009	Email	Spain	Spain	Childcare articles and juvenile equipment
I27	Quality manager	UK	September 07, 2009	Face to face	UK	UK	Childcare articles and juvenile equipment
I28	Quality manager	China	September 05, 2009	Face to face	China	Taiwan	Childcare articles and juvenile equipment
I29	Quality manager	China	November 21, 2009	Face to face	China	Taiwan	Childcare articles and juvenile equipment

(continued)

Table 4.4 (continued)

Interviewee	Position	Country of origin	Date of interview	Methods	Location of the firm	Origin of the firm	Main Products
I30	Product manager	China	November 25, 209	Email	Australia	Australia	Childcare articles and juvenile equipment
I31	Quality manager	China	June 14, 2009	Telephone	China	China	Childcare articles and juvenile equipment
I32	Quality manager	China	June 17, 2010	Face to face	China	China	Childcare articles and juvenile equipment
I33	Quality manager	China	June 15, 2010	Face to face	China	China	Childcare articles and juvenile equipment
I34	Quality manager	China	June 08, 2010	Face to face	China	China	Childcare articles and juvenile equipment
I35	Quality manager	China	June 03, 2009	Face to face	China	China	Childcare articles and juvenile equipment
I36	Quality manager	Taiwan	June 03, 2009	Face to face	China	Taiwan	Childcare articles and juvenile equipment
I37	Quality manager	China	June 28, 2009	Face to face	China	China	Childcare articles and juvenile equipment
I38	Quality manager	China	June 02, 2009	Face to face	China	China	Childcare articles and juvenile equipment
I39	Quality manager	China	June 25, 2009	Face to face	China	China	Childcare articles and juvenile equipment
I40	Engineering director	China	June 05, 2009	Face to face	China	China	Childcare articles and juvenile equipment

4.3.3 Observational Studies

The qualitative part of this research falls into the class of observational studies where a researcher chooses specific observations of the subjects being examined that address the research question (Cochran 1984). The objective of observational studies is to look into “the causal effects of certain agents, procedures, treatments, or programs” (Cochran 1984, p. 1). Observational studies produce more realistic findings than other research method such as controlled experiments, as the researcher does not apply treatments to subjects and the subjects report their actual experience related to the research questions rather than respond to scenarios artificially constructed by the researcher. Our research used both primary data collected through survey and interview and secondary data such as product/process audit results, customer satisfaction results, standard operating procedures, etc. maintained by the firms during their daily operations and accessible to the authors.

We also proactively participated in several new product design and product safety reviews so as to better understand the processes and issues related to them. Generally, the information provided by the interviewees was consistent with other available data which we were able to obtain.

Chapter 5
Quantitative Results

5.1 Introduction

This chapter presents the results of our data analysis procedures detailed in Chap. 4 on methodology. Specifically, measurement model and structural model assessment was carried out to test hypotheses 1 through 8, MANOVA was performed to evaluate hypotheses 9 and 10, and multigroup analysis was conducted to test hypotheses 11 and 12.

5.2 Examining the Measurement Model

We tested the measurement theory by comparing the theoretical measurement model against the data. We looked at both the overall model fit and criteria for construct validity. The proposed measurement model was well supported by various fit indices discussed in Chap. 4. Table 5.1 shows the selected fit statistics from the CFA output. The model's chi-square was 570.32 with 289 degrees of freedom. The *p*-value associated with this result was 0.00. Given that the number of variables was 26 and the sample size was 255, a significant *p*-value was expected (Hair et al. 2010). Both the absolute fit indices indicated a good fit for the measurement model. The RMSEA was 0.06, which is well below the guideline value of 0.08 for a model with 26 observed variables and a sample size of 255 (Hair et al. 2010). Using a 90% confidence interval for RMSEA, the value of RMSEA was between 0.05 and 0.07. Even the upper limit of RMSEA was lower than the guideline in this case. Consequently, RMSEA showed a good fit between the measurement model and the data. The other obsolete fit index is normed chi-square, which was 1.97 in our case. A value of normed chi-square smaller than 2.0 is considered very good. Therefore, the normed chi-square suggests a good fit for the CFA model. In the incremental fit indices, CFI is the most widely used index. In the measurement

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Table 5.1 CFA goodness-of-fit statistics

Chi-square
Chi-square = 570.32
Degree of freedom (377–88) = 289
Number of distinct sample moments = 377
Number of distinct parameters to be estimated = 88
Probability level = 0.00
Absolute fit measures
Root mean square error of approximation (RMSEA) = 0.06
90% confidence interval for RMSEA = (0.05; 0.07)
Normed chi-square (570.32/289) = 1.97
Incremental fit indices
Comparative fit index (CFI) = 0.91
Incremental fit index (IFI) = 0.92
Non-normed fit index (NNFI or TLI) = 0.90
AIC for default model = 746.32
AIC for saturated model = 754.00
AIC for independent model = 3691.20

model, CFI, IFI, and TLI (or NNFI) were 0.91, 0.92, and 0.90, respectively, which exceeded the cutoff values of 0.90 and show an adequate model fit. The AIC was 746.32. It was much closer to the saturated model AIC (754.00) than the independence model AIC (3691.20). The CFA results suggest that the measurement model provided a reasonably good fit; therefore, we proceeded to examining the construct validity.

5.2.1 Construct Validity

Content validity was ascertained through comprehensive review of the literature on the topics and detailed evaluation by professionals in the industry and the authors. The whole instrument contained 114 questions, which provided a comprehensive coverage on the research issues and theoretically related topics. The 30 items provided an adequate coverage for the five constructs. Most of the practices adapted in this research were tested in previous literature (Saraph et al. 1989; Cooper et al. 2004b, c; Koufteros et al. 2001). The correlation matrix is a good start to assess the extent that the constructs are expected to relate to each other. Correlations between the factor scores for each construct are presented in Table 5.2. The results demonstrate that these constructs were positively related to each other. Specifically, product safety strategy, product safety culture, concurrent engineering, and the new product development process were positively related ($p < 0.001$) to product safety performance (refer to Table 5.2). Accordingly, we consider the instrument has criterion-related validity.

Table 5.2 Descriptive statistics, correlations, and Cronbach's alpha

	No. of items	Mean	SD	Cronbach's alpha	Avg IC	PSS	PSC	CE	NPP	PSP
Product safety strategy (PSS)	7	26.94	5.55	0.911	0.632	1.00				
Product safety culture (PSC)	5	18.68	3.86	0.842	0.748	0.71*	1.00			
Concurrent engineering (CE)	6	21.91	4.26	0.834	0.672	0.55*	0.84*	1.00		
New product development process (NPP)	6	32.79	4.33	0.848	0.765	0.77*	0.86*	0.77*	1.00	
Product safety performance (PSP)	2	14.97	2.51	0.754	0.568	0.50*	0.58*	0.53*	0.66*	1.00

Note: Avg IC = average interscale correlations
*Correlation is significant at $p < 0.001$ level (two-tailed)

Table 5.3 shows the CFA factor loading estimates and *t*-values, which indicate that all factor loadings are highly significant as required for convergent validity. The standardized factor loadings and average variance extracted (AVE) are reported in Table 5.4. The lowest loading is 0.61, an item (CE6) in concurrent engineering construct. The AVE is reported at the bottom of Table 5.4. The AVE estimates range from 50.8% for new product development process to 61% for product safety performance. All exceed the guideline of 50%. Therefore, the above results support the convergent validity of the measurement model. The construct reliability estimates were calculated and are shown in Table 5.4. It ranges from 0.615 for the PSP construct to 0.913 for the PSS construct, exceeding the guideline of 0.6. The reliability coefficient (Cronbach's alpha) for all scales ranged from 0.754 to 0.911 (Table 5.2). Traditionally, reliability coefficients of 0.70 or higher are considered satisfactory (Nunnally 1978). Therefore, the scales were judged to be reliable. All considered, the above calculations show strong support for the convergent validity of the measurement model.

Discriminant validity was verified with the methodology of Anderson and Gerbing (1988), which requires to estimate the confidence interval around the parameters that indicates the correlation between the five unidimensional factors. Table 5.5 shows the confidence interval for all the constructs. 1.0 is not included in any of the confidence interval for the constructs. Therefore, the results show discriminant validity for the measurement model. Second, statistically different

Table 5.3 CFA factor loading estimates and *t*-value ($n = 255$)

Indicator		Constructs	Estimated loadings	Standard error	*t*-value
TM2	←	PSS	1.00		_a
TM3	←	PSS	1.19	0.11	10.97
TM4	←	PSS	1.25	0.11	11.70
TM5	←	PSS	1.21	0.11	11.44
TM6	←	PSS	1.35	0.12	11.71
TM7	←	PSS	1.27	0.11	11.51
TM8	←	PSS	1.11	0.11	10.39
PSC1	←	PSC	1.00		_a
PSC2	←	PSC	1.09	0.10	10.59
PSC3	←	PSC	1.43	0.13	11.15
PSC4	←	PSC	1.45	0.13	10.94
PSC5	←	PSC	1.14	0.10	11.30
CE1	←	CE	1.00		_a
CE2	←	CE	1.25	0.17	7.59
CE3	←	CE	1.15	0.15	7.81
CE4	←	CE	1.06	0.15	6.83
CE6	←	CE	0.83	0.12	6.85
CE7	←	CE	0.78	0.11	7.04
NPP1	←	NPP	1.00		_a
NPP2	←	NPP	1.05	0.09	11.68
NPP3	←	NPP	0.80	0.08	9.81
NPP4	←	NPP	1.15	0.10	11.86
NPP7	←	NPP	0.98	0.09	10.87
NPP10	←	NPP	1.04	0.11	9.53
PSP1	←	PSP	1.00		_a
PSP2	←	PSP	0.86	0.10	8.54

Note: [a]Not estimated when loading set to fixed value of 1.0. *P* values for all indicators are less than 0.001

constructs exhibit interscale correlations that are adequately different from 1.0 (Bagozzi et al. 1991). Table 5.2 indicates that all interscale correlations were adequately different from 1.0. Another approach to assess discriminant validity is to compare the Cronbach reliability coefficient of each scale with its average interscale correlations (AIC) with other constructs; adequate discriminant validity is established if the former is larger than the latter (Ghiselli et al. 1981). The Cronbach reliability coefficients and average interscale correlations are presented in Table 5.2. It shows that the Cronbach reliability coefficient for each construct is larger than its corresponding average interscale correlations. Hence, it also passes the test of discriminant validity.

Based on the above analyses, the measurement model showed a good model fit, construct validity, and construct reliability. Therefore, we proceeded with assessing the structural model and hypotheses testing.

Table 5.4 Standardized factor loadings and average variance extracted

Indicator	PSS	PSC	CE	NPP	PSP
TM2	0.69				
TM3	0.75				
TM4	0.80				
TM5	0.78				
TM6	0.81				
TM7	0.79				
TM8	0.71				
PSC1		0.76			
PSC2		0.68			
PSC3		0.73			
PSC4		0.72			
PSC5		0.81			
CE1			0.62		
CE2			0.83		
CE3			0.86		
CE4			0.73		
CE6			0.61		
CE7			0.65		
NPP1				0.72	
NPP2				0.75	
NPP3				0.66	
NPP4				0.78	
NPP5				0.63	
NPP7				0.71	
PSP1					0.83
PSP2					0.73
Average variance extracted (AVE)	58.0%	54.8%	52.7%	50.8%	61%
Construct reliability	0.913	0.849	0.855	0.865	0.615

Table 5.5 Confidence interval for constructs

Construct-construct	Correlation	Standard error	Confidence interval = correlation ± two standard errors
PSS-PSC	0.71	0.04	0.63–0.79
PSS-CE	0.55	0.05	0.45–0.65
PSS-NPP	0.77	0.05	0.67–0.87
PSS-PSP	0.50	0.06	0.38–0.62
PSC-CE	0.84	0.06	0.72–0.96
PSC-NPP	0.86	0.05	0.76–0.96
PSC-PSP	0.58	0.07	0.44–0.72
CE-NPP	0.77	0.07	0.63–0.91
CE-PSP	0.53	0.08	0.37–0.69
NPP-PSP	0.66	0.08	0.50–0.84

Table 5.6 Multicollinearity analysis

Coefficients[a]								
		Unstandardized coefficients		Standardized coefficients			Collinearity statistics	
Model		*B*	Std. error	Beta	*t*-value	Sig.	Tolerance	VIF
1	(Constant)	3.812	0.369		10.317	0.000		
	PSS	0.161	0.121	0.099	1.334	0.183	0.501	1.997
	PSC	0.080	0.134	0.053	0.595	0.553	0.354	2.825
	CE	0.224	0.111	0.156	2.020	0.044	0.466	2.145
	NPP	0.536	0.151	0.320	3.539	0.000	0.340	2.941

[a] Dependent variable: PSP

5.3 Examining the Structural Model

The structural model to be examined is shown in Fig. 4.2. In the path model, the VIF values were between 1.997 and 2.941 (Table 5.6), indicating that multicollinearity is not an issue. Table 5.7 presents the overall fit statistics from testing the structural model. The chi-square was 570.33 with 291 degrees of freedom, and the normed chi-square was 1.96. The probability was 0.00. The RMSEA was 0.06 with 90% confidence interval of 0.05–0.07. The CFI, IFI, and TLI were 0.92, 0.92, and 0.90, respectively. The AIC for the default model was 742.33, which is closer to the AIC for the saturated model (754.00) than the AIC for independent model (3691.20). All these measures showed a good overall model fit. Table 5.7 also suggests that the overall model fit changed very little from the CFA model. The only substantial difference is that the degree of freedom increased by 2. Based on these results, we proceeded to test the hypotheses previously proposed with the path estimates and *t*-values.

5.4 Hypothesis Testing

The outputs of the standardized regression weights from SEM analysis are presented in Table 5.8, as are the estimates that measure the direct effect of the predictors on the independent variables and the significance value for each path. Figure 4.2 shows the estimates and significance of various hypothesized paths. The significance of individual path coefficients (direct effects) can be used to test the first eight hypotheses (H1–H8) developed in Chap. 3. A significance level of 0.05 is used to retain the path. Six out of eight hypotheses were supported. The main advantage of path analysis over conventional regression is its ability to decompose the observed empirical correlation or covariance between any two variables into three components: direct, indirect, and unexplained effects (Land 1969). The decomposed path model effects are shown in Table 5.9.

Table 5.7 Comparison of goodness-of-fit statistics for structural and measurement models

Chi-square	Structural model	CFA model
Chi-square	570.33	570.32
Degree of freedom	291	289
Probability level	0.00	0.00
Absolute fit measures		
Root mean square error of approximation (RMSEA)	0.06	0.06
90% confidence interval for RMSEA	0.05–0.07	0.05–0.07
Normed chi-square	1.96	1.97
Incremental fit indices		
Comparative fit index (CFI)	0.92	0.91
Incremental fit index (IFI)	0.92	0.92
Non-normed fit index (NNFI or TLI)	0.90	0.90
AIC for default model	742.33	746.32
AIC for saturated model	754.00	754.00
AIC for independent model	3691.20	3691.20

Table 5.8 Regression weights and hypothesis test

Structural relationship	Unstandardized parameter estimate	Standard error	*t*-value	*P*	Standardized parameter estimate	Hypothesis test
H1: PSS → PSC	0.71	0.08	8.67	***	0.71	H1: strongly supported
H2: PSS → CE	−0.12	0.11	−1.15	0.25	−0.10	H2: not supported
H3: PSS → NPP	0.36	0.09	4.19	***	0.32	H3: strongly supported
H4: PSC → CE	1.10	0.18	6.26	***	0.91	H4: strongly supported
H5: PSC → NPP	0.51	0.16	3.16	0.00	0.46	H5: strongly supported
H6: CE → NPP	0.19	0.11	1.76	0.08	0.21	H6: weakly supported
H7: CE → PSP	0.10	0.20	0.47	0.64	0.06	H7: not supported
H8: NPP → PSP	1.05	0.22	4.68	***	0.61	H8: strongly supported

Hypothesis 1

Hypothesis 1 proposed that product safety strategy has a positive effect on group-level product safety culture in new product development. With a *p*-value below 0.001 and CR of 8.67, hypothesis 1 received very strong support. Seventy-one percent of total variance in group-level product safety culture in new product development is explained by product safety strategy. This demonstrates that

Table 5.9 Summary of effects in the structural model[a]

	Direct effect	Indirect effect	Total effect	Correlation	Std. direct effect	Std. indirect effect	Std. total effect
PSC							
Effect of PSS	0.71	0.00	0.71	0.71	0.71	0.00	0.71
CE							
Effect of PSS	−0.12	0.78	0.66	0.55	−0.10	0.65	0.55
Effect of PSC	1.10	0.00	1.10	0.84	0.91	0.00	0.91
NPP							
Effect of PSS	0.36	0.49	0.86	0.77	0.32	0.45	0.77
Effect of PSC	0.51	0.21	0.73	0.86	0.46	0.19	0.65
Effect of CE	0.19	0.00	0.19	0.77	0.21	0.00	0.21
PSP							
Effect of PSS	0.00	0.96	0.96	0.50	0.00	0.50	0.50
Effect of PSC	0.00	0.87	0.87	0.58	0.00	0.45	0.45
Effect of CE	0.10	0.20	0.30	0.53	0.06	0.13	0.19
Effect of NPP	1.05	0.00	1.05	0.66	0.61	0.00	0.61

[a] Model fit indices: CMIN/DF = 1.96, CFI = 0.92, IFI = 0.92, TLI = 0.90, RMSEA = 0.06. *R*-square values: product safety culture (0.51), concurrent engineering (0.71), new product development process (0.81), product safety performance (0.43)

product safety culture in new product development is largely determined by top management's commitment to safety. If the top management pays more attention to product safety, the new product development team will care more about product safety.

Hypothesis 2

Hypothesis 2 stated that product safety strategy has a positive effect on concurrent engineering. This hypothesis was not supported as the *p*-value is 0.25. There is no statistically significant relationship between product safety strategy and the concurrent engineering. Not only was the relationship not significant, but also the effect was negative. This was not expected. The standardized direct effect was −0.10. However, the total effect that product safety strategy has on concurrent engineering is quite high at 0.50, due to a very strong and significant indirect effect (0.65) that the product safety strategy has on concurrent engineering through the mediator of product safety culture.

Hypothesis 3

Hypothesis 3 predicted that product safety strategy has a positive effect on new product development process. The relationship between product safety strategy and new product development process was significant at the 0.001 level (*p*-value less than 0.001, CR of 4.19), and H3 was strongly supported with 32% of total variance of new product development process practices explained by product safety strategy. The total effect that product safety strategy had on new product development process practices was 0.77. Product safety strategy not only has a positive direct impact on new product development process but also has a very strong and significant indirect effect (0.45) on new product development process. Therefore, top management also plays an important role in influencing the new product development process.

Hypothesis 4

Hypothesis 4 stated that group-level product safety culture in new product development has a positive effect on concurrent engineering. With a *p*-value less than 0.001 and CR of 6.26, H4 was found to be significant at the 0.001 level. Group-level product safety culture in NPD accounts for 91% of total variance for concurrent engineering.

Hypothesis 5

Hypothesis 5 proposed that group-level product safety culture in new product development has a positive effect on new product development process. This hypothesis was strongly supported, with a *p*-value less than 0.01 and CR of 3.16. With standardized direct effect of 0.46 and indirect effect of 0.19, the total effect amounted to 0.65, which means 65% of the total variance for new product development process can be explained by the group-level product safety culture in new product development.

Hypothesis 6

H6 expected that the use of concurrent engineering has a positive effect on new product development process. With a *p*-value of 0.08 and CR of 1.76, the hypothesized relationship was significant at 0.1 level and thus weakly supported. Only 21% of variance for the new product development process can be explained by the use of concurrent engineering.

Hypothesis 7

H7 predicted that the use of concurrent engineering has a positive effect on product safety performance. This hypothesis was not supported, as the *p*-value is 0.64. The use of concurrent engineering only accounted for 6% of variance for product safety performance. Therefore, concurrent engineering does not have significant impact on product safety performance. This result is unexpected and contradicts literature.

Hypothesis 8

H8 proposed that the use of new product development process has a positive effect on product safety performance. Sixty-one percent of variance for product safety performance can be explained by the use of new product development process. This hypothesis received a strong support with a *p*-value of less than 0.001 and CR of 4.68. This finding seems to be in line with literature suggesting that about 70% of product safety recalls in the market were due to design defects (White and Pomponi 2003; Bapuji and Beamish 2008; Beamish and Bapuji 2008).

Hypotheses 9 and 10

H9 proposed that manager's perceptions of actual model constructs (PSS, PSC, CE, NPP, PSP) were influenced by organizational contextual factors (firm size, origin of firm, firm's target market, firm's R&D intensity); and H10 predicted that manager's perceptions of ideal model constructs (IPSS, IPSC, ICE INPP) were not affected by organizational contextual variables (firm size, origin of firm, firm's target market, firm's R&D intensity). To test hypotheses 9 and 10, multivariate analysis of variance (MANOVA) was carried out with the actual and ideal model constructs as dependent variables and firm size, origin of firm, firm's target market, and firm's R&D intensity as factors.

The MANOVA results are summarized in Tables 5.10, 5.11, 5.12, and 5.13. The assumptions were verified prior to evaluating the significance. Table 5.10 shows Box's test of equality of covariance matrices. The *p*-value is 0.007 and significant,

Table 5.10 Between-subject factors

		N
SIZE	a	29
	b	123
	c	103
RND	a	116
	b	139
MKT	a	20
	b	175
	c	60
OWN	a	219
	b	36

Note: *SIZE* firm size, *RND* R&D intensity (R&D expenses/total sales), *MKT* target market of a firm, *OWN* origin of firm

Table 5.11 Box's test of equality of covariance matrices[a]

Box's M	255.235
F	1.311
df1	150
df2	4794.688
Sig.	0.007

Tests the null hypothesis that the observed covariance matrices of the dependent variables are equal across groups

[a]Design: intercept + SIZE + RND + MKT + OWN + SIZE * RND + SIZE * MKT + SIZE * OWN + RND * MKT + RND * OWN + MKT * OWN + SIZE * RND * MKT + SIZE * RND * OWN + SIZE * MKT * OWN + RND * MKT * OWN + SIZE * RND * MKT * OWN

Table 5.12 Levene's test of equality of error variances[a]

	F	df1	df2	Sig.
PSS	1.661	21	233	0.038
PSC	1.191	21	233	0.260
CE	1.193	21	233	0.258
NPP	1.219	21	233	0.236
PSP	1.892	21	233	0.012

Tests the null hypothesis that the error variance of the dependent variable is equal across groups

[a] Design: intercept + SIZE + RND + MKT + OWN + SIZE * RND + SIZE * MKT + SIZE * OWN + RND * MKT + RND * OWN + MKT * OWN + SIZE * RND * MKT + SIZE * RND * OWN + SIZE * MKT * OWN + RND * MKT * OWN + SIZE * RND * MKT * OWN

Table 5.13 Multivariate tests[b]

Effect		Value	F	Hypothesis df	Error df	Sig.
Intercept	Pillai's trace	0.899	405.476[a]	5.000	229.000	0.000
SIZE	Pillai's trace	0.060	1.426	10.000	460.000	0.166
RND	Pillai's trace	0.039	1.867[a]	5.000	229.000	0.101
MKT	Pillai's trace	0.071	1.691	10.000	460.000	0.080
OWN	Pillai's trace	0.025	1.193[a]	5.000	229.000	0.313
SIZE * RND	Pillai's trace	0.029	0.668	10.000	460.000	0.754
SIZE * MKT	Pillai's trace	0.117	1.400	20.000	928.000	0.113
SIZE * OWN	Pillai's trace	0.035	0.824	10.000	460.000	0.606
RND * MKT	Pillai's trace	0.013	0.613[a]	5.000	229.000	0.690
RND * OWN	Pillai's trace	0.023	1.100[a]	5.000	229.000	0.361
MKT * OWN	Pillai's trace	0.063	1.493	10.000	460.000	0.139
SIZE * RND * MKT	Pillai's trace	0.000	[a]	0.000	0.000	
SIZE * RND * OWN	Pillai's trace	0.000	[a]	0.000	0.000	
SIZE * MKT * OWN	Pillai's trace	0.013	0.580[a]	5.000	229.000	0.715
RND * MKT * OWN	Pillai's trace	0.021	0.979[a]	5.000	229.000	0.431
SIZE * RND * MKT * OWN	Pillai's trace	0.000	[a]	0.000	0.000	

[a] Exact statistic

[b] Design: intercept + SIZE + RND + MKT + OWN + SIZE * RND + SIZE * MKT + SIZE * OWN + RND * MKT + RND * OWN + MKT * OWN + SIZE * RND * MKT + SIZE * RND * OWN + SIZE * MKT * OWN + RND * MKT * OWN + SIZE * RND * MKT * OWN

meaning we cannot accept the hypothesis that the observed covariance matrices of the dependent variables are equal across groups. However, Box's M test is sensitive to large data files, i.e., if the number of cases is large, it can detect even small departures from homogeneity. Moreover, it can be sensitive to departures from the assumption of normality. As an additional check of the diagonals of the covariance matrices, Levene's tests were performed, which test equality of the error variances across the cells defined by the combination of factor levels. Table 5.12 shows the results of Levene's tests. PSS and PSP were significant at 0.05 level with p-values at 0.038 and 0.012, respectively. PSC, CE, and NPP were insignificant with *p*-values of 0.260, 0.258, and 0.230, respectively. Like Box's M tests, Levene's test is also sensitive to large data files. Overall, we think the assumptions are marginally met considering the large data size.

There are four values (Pillai's trace, Wilks' lambda, Hotelling's trace, and Roy's largest root) as well as the corresponding F statistics and degrees of freedom reported in the MANOVA results. We used the Pillai-Bartlett trace, as this statistic is somewhat more robust to violations of the model assumptions than others (DeCoster 2004; Olson 1974). Table 5.13 reports the summary of multivariate results for the four factors. Both the interaction effects and individual factors were not significant at the 0.05 level. The firm's target market ($p = 0.08$) and the firm's R&D intensity ($P = 0.10$) were significant at the 0.1 level, i.e., firm size and origin of firm had no influence on the model constructs (PSS, PSC, CE, and NPP). The firm's target market and R&D intensity had weak influence on the constructs (PSS, PSC, CE, NPP, and PSP). When examining the between-subject effects, it was observed that R&D intensity had a significant effect on CE, NPP, and PSP at the 0.05 level. No other significant effect was observed for any other factor. Consequently, hypothesis 9 is partially supported. Therefore, it can be concluded that the actual model constructs (PSS, PSC, CE, NPP, PSP) are not influenced by contextual factors firm size, origin of firm, firm's target market, and firm's R&D intensity. A firm's target market had a weak effect on the actual model constructs (PSS, PSC, CE, NPP, and PSP). R&D intensity had a significant effect on CE, NPP, and PSP.

MANOVA analysis was also carried out among the ideal model constructs (IPSS, IPSC, IEC, and INPP) and contextual factors firm size, origin of firm, firm's target market, and firm's R&D intensity. The basic assumptions are marginally met and none of the relationships were significant at 0.1 level (*p*-values > 0.3). That is, the manager's perceptions of ideal model constructs (IPSS, IPSC, IEC, and INPP) are not influenced by firm size, origin of firm, firm's target market, and firm's R&D intensity. Looking at the between-subject effect, the only significant effect observed was firm size and INPP, with a *p*-value of 0.045. Consequently, H10 is fully supported (Table 5.14).

Hypothesis 11

While six out of eight hypotheses in the structural equation model are supported, it is not clear whether the relationships hold across different environments. For example, would the model relationships vary across firms with different R&D intensity? To answer this question, hypothesis 11 predicted that R&D intensity would moderate the relationships posited in Fig. 3.4, suggesting that the relationships of those firms that have high R&D intensity would be different from those that have low R&D intensity. To ascertain whether the structural model relationships are invariant, it is essential to establish measurement model invariance through multigroup analysis.

Hypothesis 11 stated that there would be different relationships on the pattern of linkages in the structural model (Fig. 3.4) according to the level of R&D intensity. Following the procedure discussed in Chap. 4 on methodology, measurement invariance tests were carried out. Table 5.15 contains the model fit statistics for each

Table 5.14 Tests of between-subject effects

Source	Dependent variable	Type III sum of squares	df	Mean square	*F*	Sig.
Corrected model	PSS	17.391[a]	21	0.828	1.430	0.105
	PSC	22.986[b]	21	1.095	1.671	0.036
	CE	32.864[c]	21	1.565	2.256	0.002
	NPP	21.970[d]	21	1.046	2.017	0.007
	PSP	65.858[e]	21	3.136	2.179	0.003
Intercept	PSS	661.923	1	661.923	1142.751	0.000
	PSC	516.733	1	516.733	788.803	0.000
	CE	466.354	1	466.354	672.406	0.000
	NPP	557.188	1	557.188	1074.321	0.000
	PSP	2417.065	1	2417.065	1679.555	0.000
SIZE	PSS	1.549	2	0.774	1.337	0.265
	PSC	1.754	2	0.877	1.338	0.264
	CE	1.450	2	0.725	1.045	0.353
	NPP	2.791	2	1.395	2.690	0.070
	PSP	5.251	2	2.625	1.824	0.164
RND	PSS	1.585	1	1.585	2.737	0.099
	PSC	2.179	1	2.179	3.327	0.069
	CE	3.968	1	3.968	5.721	0.018
	NPP	3.398	1	3.398	6.552	0.011
	PSP	9.415	1	9.415	6.542	0.011
MKT	PSS	0.028	2	0.014	0.024	0.976
	PSC	0.674	2	0.337	0.515	0.598
	CE	0.951	2	0.475	0.685	0.505
	NPP	1.904	2	0.952	1.836	0.162
	PSP	5.061	2	2.530	1.758	0.175
OWN	PSS	0.507	1	0.507	0.875	0.351
	PSC	0.994	1	0.994	1.517	0.219
	CE	2.605	1	2.605	3.756	0.054
	NPP	0.684	1	0.684	1.319	0.252
	PSP	0.272	1	0.272	0.189	0.664

[a] *R* squared = 0.114 (adjusted *R* squared = 0.034)
[b] *R* squared = 0.131 (adjusted *R* squared = 0.053)
[c] *R* squared = 0.169 (adjusted *R* squared = 0.094)
[d] *R* squared = 0.154 (adjusted *R* squared = 0.078)
[e] *R* squared = 0.164 (adjusted *R* squared = 0.089)

model and the chi-square difference test for each model comparison. The first stage involved evaluating configural invariance, the separate models for low and high R&D intensity firms both exhibited acceptable level of model fit, with $\chi 2$/df below 2.0, RMSEA of 0.06, and CFI of 0.86. Therefore, configural invariance was verified.

The second stage involves testing metric invariance. The baseline model (model 1) with a chi-square of 1043.77 and 578 degrees of freedom was compared

Table 5.15 Measurement invariance tests for low and high R&D intensity

Model tested	$\chi2$	df	$\chi2$/df	RMSEA	CFI	Δdf	$\Delta\chi2$	*p*
Unconstrained (model 1)	1043.77	578	1.81	0.06	0.86			
Measurement weights (model 2)	1067.94	599	1.78	0.06	0.86	21	24.17	0.29
Measurement intercepts (model 3)	1124.69	625	1.80	0.06	0.86	25	56.75	0.00
Structural covariances (model 4)	1135.48	640	1.77	0.06	0.86	15	10.79	0.77
Measurement residuals (model 5)	1202.39	666	1.81	0.06	0.84	26	66.29	0.00

Table 5.16 Testing for R&D intensity as a moderator in the structural model

Model tested	$\chi2$	df	$\chi2$/df	RMSEA	CFI	$\Delta\chi2$	Δdf	*p*
Unconstrained	1043.87	582	1.79	0.06	0.87			
Equality of path estimates	1046.66	590	1.77	0.06	0.87	2.78	8	0.95

Table 5.17 Path estimates for constrained and unconstrained models

		Unconstrained				Constrained	
Path	P(a)	Estimates(a)	P (b)	Estimates(b)	*p*	Estimate(a)	Estimate(b)
PSS->PSC	***	0.64	***	0.77	***	0.64	0.77
PSS->CE	0.32	−0.12	0.52	−0.09	0.23	−0.10	−0.12
PSC->CE	***	0.92	***	0.88	***	0.90	0.91
PSS->NPP	0.02	0.26	***	0.40	***	0.30	0.35
PSC->NPP	0.04	0.47	0.01	0.46	***	0.49	0.48
CE->NPP	0.18	0.26	0.25	0.15	0.08	0.19	0.19
CE->PSP	0.94	0.02	0.49	0.12	0.58	0.08	0.06
NPP->PSP	***	0.72	0.00	0.50	***	0.65	0.56

to model 2 that imposed invariance for factor loadings with a chi-square of 1067.94 and 599 degrees of freedom. The chi-square difference ($\Delta\chi2$) was 24.17 (1067.94–1043.77) with 21 degrees of freedom and a *p*-value of 0.29, which was not statistically significant. Thus, the two models exhibited full metric invariance. That is, the same five factors and factor loadings for specific items measuring each factor were invariant for low and high R&D intensity firms.

Metric invariance is established through measurement invariance tests, which is sufficient to test for moderation in the relationship between constructs. Following the same procedure to specify the two-group CFA model testing for differences according to R&D intensity, a two-group structural model was set up. The unconstrained model (TF model) estimates an identical structural model in both groups simultaneously, and the second group model is estimated by constraining the eight construct paths to be equal in both groups. The fit indices and path estimates are presented in Tables 5.16 and 5.17. Both models indicate an acceptable model fit. The chi-square

Table 5.18 Testing for R&D intensity as a moderator in the structural model

Model tested	$\chi 2$	df	$\chi 2$/df	RMSEA	CFI	$\Delta\chi 2$	Δdf	*p*
Constrained model (all paths invariance)	1136.52	634	1.79	0.06	0.84			
PSS->NPP (path invariance relaxed)	1137.58	635	1.79	0.06	0.85	1.06	1	0.30
PSS->CE (path invariance relaxed)	1136.52	635	1.79	0.06	0.85	0.00	1	0.99
PSC->NPP (path invariance relaxed)	1137.53	635	1.79	0.06	0.84	0.01	1	0.93
PSS->PSC (path invariance relaxed)	1139.32	635	1.79	0.06	0.84	2.8	1	0.09
PSC->CE (path invariance relaxed)	1136.84	635	1.79	0.06	0.84	0.32	1	0.57
CE->PSP (path invariance relaxed)	1136.81	635	1.79	0.06	0.84	0.30	1	0.59
NPP->PSP (path invariance relaxed)	1137.66	635	1.79	0.06	0.84	1.16	1	0.28
CE->NPP (path invariance relaxed)	1137.17	635	1.79	0.06	0.84	0.66	1	0.42

difference was 2.78 with 8 degrees of freedom, which is statistically insignificant with a *p*-value of 0.95. This means that R&D intensity did not moderate the relationship in the structural model. Consequently, H11 was rejected, i.e., the path model relationships were invariant across firms with low and high the level of R&D intensity. We also applied the approach of Doll et al. (1998) to test the multigroup invariance. A two-group model with equality constraints imposed for each path coefficient across the groups was executed and chi-square values recorded. Next, the equality constraints for the path coefficients were relaxed one at a time. The chi-square difference was used to check for statistical significance. A threshold of 2.71 ($p < 0.1$), 3.84 ($p < 0.5$), and 6.63 ($p < 0.01$) was used to reject a specific path invariance hypothesis. The results (Table 5.18) show none of the path coefficients were statistically significant across the groups with low and high R&D intensity. The results are in line with the ones obtained with the first approach reported above.

5.4.1 The Mediating Effect of NPP on CE and PSP

The mediating effect of NPP on CE and PSP deserves thorough evaluation as the insignificant relationship between concurrent engineering and product safety performance seems contradicting the literature.

"A mediating effect is created when a third variable or constructs intervenes between two other related constructs" (Hair et al. 2010, p. 751). If the relationship between two constructs remains significant and unchanged once a third construct is introduced in the model as an additional predictor, no mediating effect exists.

Table 5.19 Testing for mediation in the structural model

Model element	Model without NPP	Model with NPP
Model fit		
$\chi 2$ (chi-square)	312.34	570.33
df (degree of freedom)	166	291
$\chi 2$/df	1.88	1.96
Probability	0.00	0.00
RMSEA	0.06	0.06
CFI	0.94	0.92
Standardized parameter estimates		
PSS->PSC	0.71*	0.71*
PSS->CE	−0.08	−0.10
PSC->CE	0.91*	0.91*
PSS->NPP		0.32*
PSC->NPP		0.46*
CE->NPP		0.21**
CE->PSP	0.57*	0.06
NPP->PSP		0.61*

*significant at 0.01 level, **significant at 0.1 level

If the effect is reduced but remains significant after a third construct is added as a predictor, partial mediation is supported. If the effect is reduced to a point where it is not statistically significant after a third construct is included as an additional predictor, full mediation is supported. In order to evaluate the mediating effect of NPP between CE and PSP, one must first verify whether there are significant correlations between the constructs. This was done by checking the CFA correlation in Table 5.5. All the three constructs were significantly correlated. The next step involves estimating the model without NPP present (Table 5.19). The model fit indices showed a good fit with normed chi-square = 1.88, CFI = 0.94, and RMSEA = 0.06. The path between CE and PSP also showed a significant relationship with CR of 5.79 ($p < 0.001$ level), with a direct effect of 0.57. Then, the model was estimated again by adding NPP to the model as a mediator between CE and PSP. The model fit indices changed slightly but still showed good fit between the model and the data (normed chi-square = 1.96, CFI = 0.92, RMSEA = 0.06). The path between CE and PSP was not significant anymore after introducing the mediating construct NPP, the standardized regression weight was dropped from 0.57 to 0.06 (total effect 0.19, indirect effect 0.13). Consequently, the full mediating effect of NPP on the relationship between CE and PSP was supported, meaning that CE influenced PSP through the mediator NPP. This explains why the direct relationship between CE and PSP was not significant in the structural model.

5.5 Root Causes for Product Safety Issues

To investigate the root causes for product safety issues, respondents were requested to select or specify the major root causes that led to product safety issues in their firms. A multiple-choice question offering ten common root causes for product safety issues was used to collect the responses (see Fig. 5.1). The results show that the top root causes for product safety issues were considered to be:

1. Foreseeable misuse not considered by engineers (g)
2. Supplier's material out of specifications (h)
3. Inadequate product safety test and review, such as hazard analysis (e)
4. Design engineers not familiar with the product safety standards (c)
5. Inadequate manufacturing process capability (b)
6. Cost considerations (f)

Most of the product safety issues appear to be related to inadequate hazard analysis and foreseeable misuse. Manufacturing issues such as material out of specifications or inadequate process capability were also considered significant causes for product safety issues.

The data also shows that 67.3% of product safety issues were thought to be caused by design defects and 32.7% were due to manufacturing defect. This is more or less in line with the findings from SEM analysis and the previous literature suggesting that about 70% of product recalls in the US market were due to design defect (White and Pomponi 2003; Bapuji and Beamish 2008; Beamish and Bapuji 2008).

Note:

(a) Lack of design experience on the product
(b) Inadequate manufacturing process capability
(c) Design engineers not familiar with the product safety standards

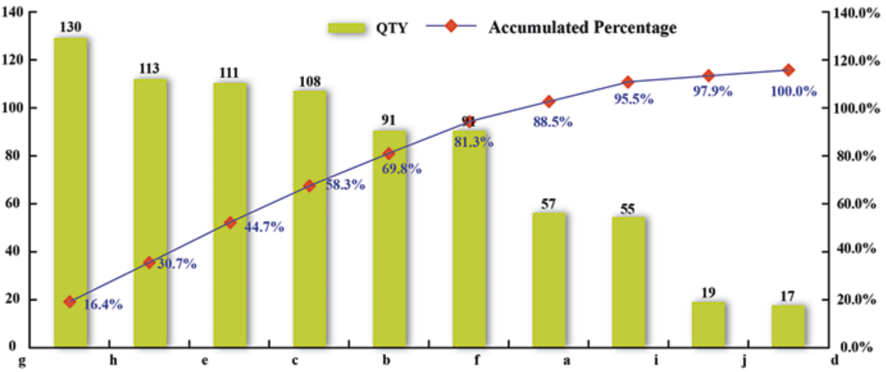

Fig. 5.1 Pareto chart for root causes for product safety issues

(d) Product not reliable
(e) Inadequate product safety test and review (such as hazard analysis)
(f) Consideration of cost
(g) Foreseeable misuse not considered by engineers
(h) Materials/components from suppliers not compliant with specifications
(i) Manufacturing process out of control
(j) Product safety standards/requirements not clear

5.6 Summary of Quantitative Analysis

The quantitative analysis reveals the relationships among product safety strategy, product safety culture, concurrent engineering, NPD process, and product safety performance as presented in the product innovation and product safety model. Eight of the 12 main hypotheses are supported. Product safety strategy, product safety culture, and NPD process are predictors of product safety performance, but concurrent engineering is not significantly related to product safety. There are eight sub-hypotheses covering relationships of manager's perceptions of ideal and actual constructs in the conceptual model and contextual factors (firm size, origin of firm, firm's target market, and firm's R&D intensity). Of the eight sub-hypotheses, six are supported and two are rejected. Detailed discussion of the relationships among the five constructs and triangulation analysis between the quantitative findings and the outcomes of the qualitative analysis are presented in Chap. 7.

Chapter 6
Qualitative Results

6.1 Introduction

This chapter presents the results of in-depth interviews with 40 senior managers from 33 firms, the observations in some firms interviewed, and a thorough review of secondary information. The results are summarized in four key themes: product safety strategy, product safety culture, concurrent engineering, and new product development processes. Key practices enhancing product safety are highlighted in bold face. Major issues observed during the interviews are summarized in the last part of this chapter.

6.2 Product Safety Strategy

Product safety strategy plays a key role in product safety. An (expected) observation from the interviews is that the top management paid a lot of attention to product safety issues in most of the firms. They set product safety policy, strategy, and goals and devote resources to achieve these objectives. The most prevalent practices showing top management support to product safety were quite similar to the management practices of top management support to quality as identified by Saraph et al. (1989).

First of all, the top management drives product safety. They held regular meetings to review product safety issues; set product safety policies, direction, and goals; and provided necessary resources to manage product safety. Some of them were involved personally in design reviews and made key decisions in terms of product safety, as some interviewees elaborated:

> *The executive committee gets together every week to discuss a myriad of issues, product issues, business issues, safety issues. They got a very connected role as far as product safety is concerned in our company. They are always aware of projects that are being worked on,*

A.Y. Zhu et al., *Responsible Product Innovation*, Innovation, Technology, and Knowledge Management, https://doi.org/10.1007/978-3-319-68451-2_6

> *regulatory issues that are going on… for the most part, [they are] defaulting to the side of safety when decisions are being made relative to risk factors.* (I5)

Second, the top management authorized quality departments to stop or suspend product development projects and even projects already in production if there were potential product safety concerns. The top management and department heads took responsibilities for product safety. Below are some explanations from the interviewees:

> *They (top management) default to product safety when making decision. They delegate the authority to the quality team.* (I3)

> *They (top management) consider product safety as No. 1 and authorize quality to make decision. They drive product safety.* (I12)

Although all firms claimed top management concerns about product safety, the best performers (group A, check Chap 4.3.1) paid much more attention to product safety than other firms (group B). In general, group B firms were more likely to take on risk than group A best performers when there was a trade-off between product safety and cost. For example, if issues were found with any of the products, best performers would immediately stop the product and rectify the issue, even if it was a minor one. They did not want to take any risk when it comes to product safety. However, most of group B firms were likely to accept more risk than the best performers if the issue was not obvious and if there would be significant cost incurred to rectify the issue (e.g., rework the products or delay shipment).

Another observation is that the best performers had much more stringent internal requirements for product safety than general regulatory standards. However, most group B firms normally just barely met regulatory requirements.

Most of the best performing firms used product safety as a core competency and because they knew how “safety” contributed to product sales. They gave product safety highest priority versus cost and schedule, as some interviewees from group A elaborated:

> *Everybody in the company thinks safety is No. 1: the ownership, the management, employees. They also know safety sells so they don’t mind to spend or invest in safety because they know whatever they spend for safety, it will come back to them a few times.* (I4)

We also presented interviewed firms with the following scenario and asked them what they would do: Assume that during new product development, the quality engineer (or product safety engineer) thinks there still is a hazard problem and the product can be made safer if the issue was addressed. However, the product meets all regulatory requirements, and addressing this safety issue would increase product cost or delay the product launch. What would your company most likely do?

Most respondents from the best performers said they would consider addressing the issue if the cost increase was not too great. However, for most group B firms, especially for OPP (open price point) and MPP (medium price point) products, they would not consider addressing the issue due to the incurred cost increase. This supports the earlier insight that group A best performers give higher priority to safety than group B firms.

Summing up, product safety starts with the top management. The results show that the leading firms have a strong commitment to product safety by the top management. They give product safety a top priority and promote a safety-first culture in the firm. They devote necessary resources to manage product safety proactively. They have senior management staff in charge of product safety independent of engineering and production. A strong quality team in charge of product safety is prevalent in these firms. Although the leading firms claimed they had more stringent internal requirements than the regulatory standards, it is still evident that in most firms, top management commitment to product safety was largely affected by external contextual factors such as legal and regulatory changes and government interventions.

6.3 Product Safety Culture

The importance of building a product safety-oriented culture is evident from the interviews. All 40 interviewees thought product safety culture impacted product safety performance, as I4 explained during the interview:

> *When you think safety, safety, safety… they all think how to improve safety, how can we make products safer. In a cost-conscious company, all engineers think about how can I cut cost…I'm not saying it [safety culture] conflicting, but it's the culture, let's [first] make it safer, then think about how to cut cost.* (I4)

All group A interviewees mentioned that product safety was absolutely the first concern in their firms. It appears that a "safety-first culture" permeated all levels of employees in group A firms. Some firms even wrote "product safety first" in their quality policies:

> *Product safety is number one in our vein and blood.* (I11 from group A)

> *Everybody in our firm thinks safety is number one: the ownership, the management, employees…* (I4 from group A)

> *…the understanding of importance for product safety is the same in the whole company. In any processes from R&D, engineering, to production, if the quality team brings up any issues, other departments will take actions to rectify it. The quality team has the highest authority in terms of product safety.* (I22 from group A)

Comparing group A and group B firms, the former had stronger product safety culture than the latter. In group B firms, although product safety was considered important, the level of urgency seemed lower than that of group A firms. Only a few group B interviewees mentioned that they had "safety-first" culture. Furthermore, the importance of product safety was inconsistent in different departments:

> *… product safety first culture has not been established consistently in all departments.* (I24 of group B)

Product safety culture was not only affected by top management but also by the external context such as regulations, recalls, competition, media, etc.:

> *…while years ago, you always got resistance from design engineering who design a product that you feel it could be safer, but today, they argue with me to make the product safer. Their awareness has been brought up. The guys I worked with go to Washington to meet with [the] CPSC so they don't think that we are making it up. The entire team, the project manager, product managers, marketing folks: they now listen more to quality and engineering.* (I8 from group B)

Twenty percent of firms interviewed had a **product safety committee**. The product safety committee was normally led by the quality department head, with members from R&D, engineering, and—in some cases—the legal department. They had direct access to senior management and decided product safety policy, strategy, and product safety initiatives and whether to recall the products from the market if there were safety issues. The quality department head (normally at vice president or director level) was in charge of product safety management and reported to the CEO of the organization. They were normally the ones to make final decisions on product safety issues. This is in line with White and Pomponi's (2003) research results, where they found 90% of the world-class performance firms have a dedicated, senior position focused on product safety, regulatory, and environmental issues. Kitzes (1991) already pointed out this very important principle in product safety management.

In all firms interviewed, a quality team was in charge of managing product safety. Among other responsibilities for quality management, they were responsible for defining quality requirements (QR), hazard analysis, safety requirements, foreseeable misuse/abuse analysis, product safety testing, product safety review, etc. In almost all group A firms, they had strong quality teams that were given power to hold projects or stop production if there were concerns about product safety. Most of group A firms had representatives to participate in establishing national product safety standards. However, 88% of the firms interviewed had no product safety engineer:

> *Right from the start [of a project], quality engineers evaluate the product concept. If there is an inherent issue with the product concept, they report it to the team, and the team will report it to their leadership. I can give you an example. A product some years ago was proposed by our marketing department: a belt for the rear seat of a car that attached a child to the seat belt so they can sleep in the back of the car. When the group reviewed it, they said "no, this is not a good idea, it doesn't look safe, there is probably regulatory issue with it and there may be legal issue with it." The team provided a negative recommendation to the executives, and the project was dropped.* (I5)

> *[The] quality department has strong voice in evaluating the results to say yes or no, as engineering is very focused on time-to-market… we have an engineer who is a specialist on standards… He will also be involved in design review/product safety reviews. When the products are tested in our internal lab, the results are reviewed by quality and engineering, and if the performance is not good enough, it's a no-go.* (I11)

Training for employees on product safety requirements is crucial to improve product safety. Training on product safety for technical staff is an area that most firms do not do well. Although all firms provided some sort of training on product safety standards and regulatory requirements to technical staff (e.g., design engineers), only a few firms had a formal safety training program. Only few firms provided formal training on risk management tools such as hazard analysis, fault tree analysis, FMEA, etc. This is in line with the research findings from Main and Frantz (1994) that most engineers do not receive formal training in safety methodologies common to the safety community.

Almost all group A firms interviewed participated in establishing mandatory or voluntary product safety standards in the industry. They had regular meeting to review the standards or any upcoming revisions of the standards. In contrast, only a few firms from group B were involved in establishing national product safety standards. For example, in the USA, ASTM (American Society for Testing and Materials) meetings take place twice a year. By participating in these meetings, company representatives from our sample firms were able to relay updates and provide training to relevant employees within their companies (some even included their suppliers). The firms were also able to take proactive measures on their products and process before the revised standards became effective. Some firms sent employees to attend third-party training or brought in outside people to conduct in-house training once per year.

Based on the observations from the in-depth interview, the importance of product safety culture to product safety is obvious. Firms with strong product safety culture tend to have better product safety performance. Consequently, we think product safety culture can also be used as “leading indicators” to measure product safety proactively.

6.4 Concurrent Engineering

77.5% of the firms interviewed used cross-functional teams for NPD projects. Most interviewees thought it was important to consider process capability during design, especially for the critical-to-safety process. Ninety percent of firms involved manufacturing people NPD project start. Somewhat fewer respondents used cross-functional team in NPD the reported in the samples reported by Griffin (1997) (84%) and Cooper et al. (2004b) (79.3%). The NPD teams had regular reviews (e.g., weekly or monthly) and shared failure information in those reviews. In each team, quality engineers championed hazard analysis, misuse/abuse analysis, and product safety review practices. But only 9% of the surveyed firms had full-time product safety engineers in engineering groups to work on product certification or compliance. In most firms, team composition stayed constant from start to end of a project. However, their level of participation engagement is different for each function at different stages. The entire team is accountable for the success or failure of a project. There is no evident difference between group A and B in terms of their use of cross-functional teams: the use of cross-functional team is not a differentiator between the best performers and the rest. This appears in conflict with literature that repeatedly stressed that safety professionals should be involved in the design as early as possible and recommended design-for-safety and concurrent engineering as a mechanism to ensure product safety (Dowlatshahi 2001; Rausand and Utne 2008; Wang and Ruxton 1997).

Ninety-one percent of the interviewees thought cross-functional teams help enhance product safety because it allowed access to people with different perspectives, permitted issues to be addressed earlier, and had product safety reviews to be more thorough with different specialists participating in the review:

> *Yes: You got different perspectives. When you talk about product safety, you think about how the product is used and [how it] incorporates customer requirements. So, when you talk about FMEA, you want to have cross functional people, you not have just one perspective how the product is used.* (I9)

Nine percent of the interviewees thought that cross-functional teams would not affect product safety as different functions were normally to focus only on their own area. As I4 and I13 explained:

> *Although it [the cross-functional team] smooths the launch, I don't think it will have impact on the safety of the products because different groups focus on different things. For example, manufacturing people are mainly interested in timing, how to produce it, how to assemble it; purchasing people are mainly interested in communicating with suppliers, starting ordering the material… I really don't think it will have impact on the safety of the product as much as on the commercial side… to launch it smoother...* (I4)

> *… cross-functional teams will shorten product development cycle time. Product safety is still under the responsibility of quality department. So, I don't think cross-functional teams will impact product safety.* (I13)

As far as **customer involvement in NPD** is concerned, 94% of the firms involve customers in their NPD process in one way or another and to different degrees. Only 6% of the firms claimed they did not involve customer in their NPD process. I4 explained why customers are not involved in their case:

> *…because our customers are retailers... They have no idea, they don't care. You give them the product. If the buyers like it, they buy it. They don't care about anything else.* (I4)

Whether customer involvement enhances product safety depends heavily on what kind of customer is engaged in the NPD process. Seventy-six percent of the interviewees thought that customer involvement did enhance product safety. In these cases, customers were mostly well-known brand owners with in-depth know-how about their product categories. These customers normally also have substantial experience in the industry and strong technical competency. Their input and participation in NPD should definitely enhance product safety. For those 24% of interviewees who thought that customer involvement would not enhance product safety, their customers were identified as retailers, which normally have no knowledge and no focus on product safety. As I5 and I11 explained:

> *For retailers, I'm not sure. I don't recall too many incidents that sales and marketing came back to say that the customer [retailer] didn't think it looked safe... They're more looking at style, price, and competitors, and what margin they can get. Again, I think they are like consumers, they assume it's going to be safe. You know we are expert, the assumption is it's going to be safe.* (I11)

> *… [customer involvement has] no help at all for safety because they [retailers] absolutely no focus on safety, they focus on fit and functions.* (I11)

Supplier involvement in NPD is prevalent in most of the firms interviewed. Eighty-one percent of the firms involved major suppliers in their NPD process to some degree. Of these, 93% of them thought involving suppliers in NPD would enhance product safety. As I8 explained:

> *…I think our suppliers are experts in the manufacturing of these products. So, we depend on our suppliers to give us feedback on making the product better, safer, and design the product for manufacturability. But we're not experts in manufacturing ourselves.* (I8)

I4 also elaborated why involving suppliers won't improve product safety:

> *… I don't think so. It won't improve safety, but it will eliminate problems that may result in safety deterioration, because safety is the core competency of our company. We know a lot better than the suppliers. The main role of the suppliers is to ensure everything we want to do is being done.* (I4)

In summary, CE has been widely used in most firms. There is no obvious difference between best performers and the rest in terms of use of cross-functional teams, i.e., the use of cross-functional teams is not a differentiator between the best performers and the rest. At first glance, this appears surprising as researchers and safety experts have recommended concurrent engineering as a mechanism to ensure product safety. But as some of the interviewees mentioned, even if different groups participate in NPD already at an early stage, in reality, different functions still mainly focus on issues in their own areas, which does not have much impact on product safety. Also, given our focus industry, juvenile products are not very complex, and most of the hazards related to these products have been mostly captured in regulatory standards, and at the end of product development, the product has to be tested according to these regulatory standards. Therefore, earlier involvement of quality engineers might not have as significant an impact on product safety of the final products. But it might delay product launch if issues are detected at a late stage.

6.5 New Product Development Processes

A well-documented formal process for NPD is now the norm (Barczak et al. 2009). In the interviews, we also found that all firms used a formal and flexible NPD process with quality control plans at each stage for new projects. The process guides all activities from concept to launch, with defined stages such as concept review, development, prototype, EP (engineering pilot), FEP (final engineering pilot), PP (production pilot), and RTP (release to production). Depending on how complicated the project is, some stages might be combined, and some stages may be labeled differently in different companies. But overall, no significant difference between group A and B firms in terms of the NPD process was found. The difference is the execution quality of the process, which is outlined below.

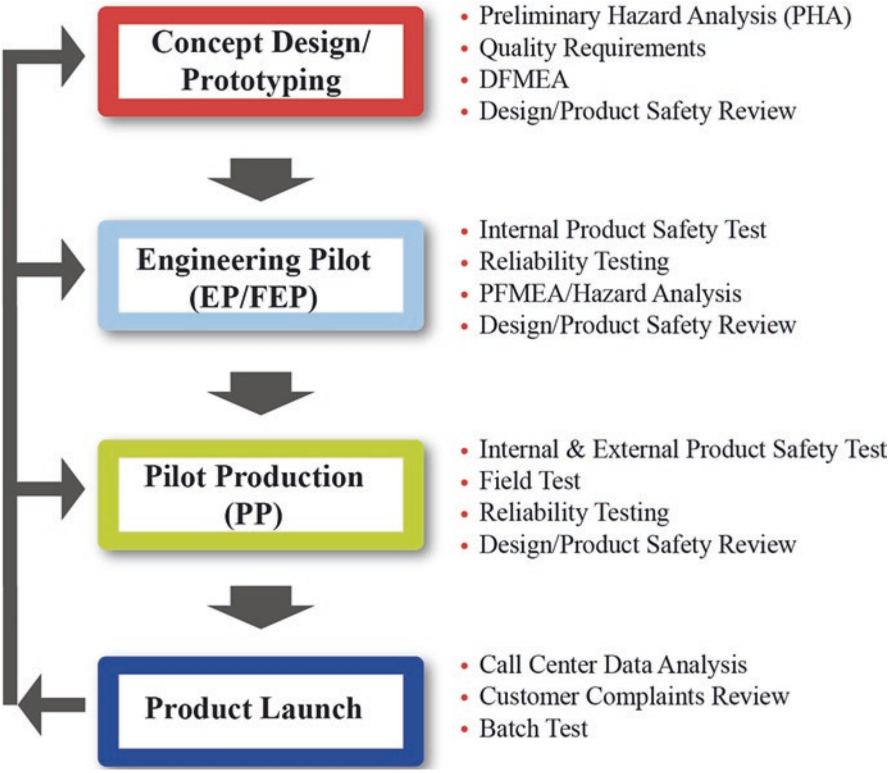

Fig. 6.1 Product safety management process in NPD

A Well-Documented Formal NPD Process All firms interviewed implemented such a process incorporating some sort of product safety review and acceptance criteria at each stage. The process itself did not vary much among the companies interviewed; the difference was in the product safety requirements, the hazard analysis, and the quality of the execution of the process. Figure 6.1 presents a typical NPD process along with activities relevant for product safety management as implemented in some of the leading firms.

Product Safety Requirements All group A firms had well-defined robust product safety requirements, e.g., QR (quality requirements) or QP (qualification plan). These requirements normally included regulatory requirements in the market and a firm's own internal requirements. The internal requirements were based on previous failure experiences in manufacturing process or market for similar products, product recall information for the same category, customer feedback, foreseeable misuse analysis, abuse analysis, the engineers own experience, etc. It also included other requirements such as reliability, durability, and functions. QR robustness largely determines how safe a product can be as it captures all safety requirements for the product. All group A firms mentioned that their requirements are much more stringent than regulatory requirements. Therefore, changes on regulatory requirements had no much influence on their product safety performance. As I4 from group A explained:

> *… Safety requirements include regulatory requirements, voluntary requirements (such as ASTM) and internal requirements. Internal requirements come from products we got back from field, e.g., you see this person didn't use it correctly, [so] how can we make it better to avoid this problem. That is where we gain a lot. That's why I think [our firm] is a very good company in terms of safety because of the returns from the field. They weren't returned because they were bad. In fact, they protected the children. Because once a car seat has been involved in car crash, it shouldn't be used again. So instead of them throwing it away, we take it back and give them a new one free of charge. Because we think the value we gain from these seats is very valuable in developing future generations of car seats… We have a committee from quality and engineering to look at them every week, inspect them, investigate them…. (I4)*

> *We do preliminary design evaluation, which is when the product is considered and you have something to look at from the sketch standpoint of the model. We'll initially give our design concerns associated with product safety from appearance, by looking at the products. From there you create quality requirements because you know what category it is in, you know what voluntary standards are required. You also take in historical recall [data] of similar products. You make sure the original recalls are not presented in the new product. The quality requirements develop from stage to stage. You're always constantly doing evaluation of the product till you get to FMEA. It's important to know that FMEA is not done on every product. That's something we like to do in the future, but it's not done yet. They are done on high-risk items, medical devices, safety items… The ultimate result is [that] you have a Quality Requirements that's robust. You want to catch these concerns early in the sketch phase…* (I9)

On the other hand, most of group B firms only use regulatory standards as their requirements. Some firms in group B also have their own internal requirements which are more stringent than regulatory requirements, but most of the firms—especially small ones—barely meet the regulatory standards. Small firms tend to have fewer resources and capability to perform professional hazard analysis. Firm product safety requirements seem to have a strong relationship with product safety performance: the stricter the requirements, the better product safety performance.

VOC (Voice of Customer) for Product Safety Numerous studies cited that VOC is key to the success of NPD (Griffin and Hauser 1993; Cooper et al. 2004b). However, product safety seems to be taken for granted or implied. Normally nothing on product safety will be mentioned in the VOC or customer needs for new projects, unless product safety is a feature for the project. It appears retailers and consumers are not paying enough attention to product safety. As some of the interviewees explained:

> *Marketing is the one to define customer requirements. Only when safety is an added feature to enhance value, it will be mentioned there... (I5)*

> *Safety is implied and assumed… Most consumers will talk about comfort, ease of use, features, and—believe-it-or-not!—cup holders. Nobody [actually] uses cup holders but it's a feature that consumers keep asking for, and they still don't use it. You must have a cup*

> *holder in the booster seats, otherwise buyers will not buy it. But I'm yet to see a booster seat in a car with some drink in the cup holder. (I4)*

> *…There are no voice-of-customers for safety requirements because they [the customers] don't know. That's the issue. They don't know anything about safety regulations, testing for strollers and car seats. Our customers, consumers, the shops, and retailers, they don't have any knowledge of that. They blindly trust the brand. (I11)*

Product Safety Review Thorough product safety reviews and records retention at each NPD stage are common practices in leading firms. Kitzes (1991) already recommended independent product safety review processes. Ninety-five percent of the firms combined product safety reviews with design reviews. Only 5% of the firms in our sample separated product safety reviews from design reviews, partially to allow more focus on product safety and partially to prevent any product safety oversight during the design review. In 90% of the firms, product safety reviews were led by quality engineers; in the other 10%, they were led by product safety specialists from a certification department. One of the risks to combine the design review and the product safety review was that critical elements of product safety might be overlooked given the many other, sometimes more pressing, concerns in design review. Product safety reviews should cover aspects such as (1) compliance with relevant product safety standards and internal QR or checklist, (2) internal or external test results on safety and reliability, (3) hazard analysis and FMEA, (4) warnings required, (5) safety devices, (6) interaction with consumers (children or parents), (7) handling (how the product will be handled by consumers), and (8) failure information of similar products in the manufacturing process and market. One of the interviewed experts (I9) elaborated on their design review and product safety review:

> *We do separate process for design review and product safety review although I wrote the process to combine them to take the advantage of people in the same meeting being involved in the same thing. Normally we have design review, and then if we need FMEA, we have FMEA separate from design review. Design review typically occurs first… We look at durability, functionality, strength, consumer abuse, misuse. For example, for step tool versus a stroller, I can be very confident that the ASTM standard captured a lot of my concerns because it's been developed over time. But for the step tool, there are no ASTM standard requirements, so I'm going to come up with all these requirements as an engineer. These are really depended on the experience and knowledge of personnel in the team… We definitely look at the misuse and abuse of the products…* (I9)

Product safety testing is another crucial stage and common practice observed in the firms interviewed. Governments and courts expect manufacturers to fully test their products before marketing them. Most of the firms interviewed had some kind of in-house product safety testing capability to check whether the product was safe and whether it met QR. All firms required that their product pass third-party tests according to relevant mandatory or voluntary product safety standards before releasing the product to production, even though there might be no such requirement from governments. One company emphasized the importance of testing:

> *Testing is the most significant practice. In fact, some of the advertising slogans we use in conference are: in order to make it safe for your child, we test it, test it, test it, test it…* (I4)

Most sample firms conducted at least elementary hazard analysis or reasonably foreseeable misuse and abuse analysis of their products. Hazard analysis or foreseeable misuse was not carried out in some group B firms (especially small ones). They purely relied on third-party lab testing results, mostly because they did not have the resources or capability to conduct a proper hazard analysis themselves. Hazard analysis was considered a difficult task by most interviewees as it might not be possible to foresee all potential misuse and abuse. Most of the engineers in charge of conducting hazard analysis were not actually trained to do professional hazard analysis and mainly relied on the engineering experience. The majority of the interviewees remarked that most safety issues that products encountered in the market were due to the firm's inability to foresee how the consumers would use or abuse the products in specific ways or in specific environments. In the present regulatory context in the USA (as per 2016), all it takes for the product to be recalled from the market is one case. As I8 explained:

> *Misuse evaluation is part of quality responsibility based on experience. Misuse is a big one. I told the development team: I bring up a potential issue, they will say nobody will do that. It takes one person to do that, we're in trouble. So, if we develop a product, let's design the product taking into consideration that one person may do that. But that's all it takes now for one person to do something wrong...* (I8)

> *Often you cannot anticipate a consumer's lack of common sense when they use your products. I think CPSC can do a better job when there are safety issues; they should understand that it may not be [the fault of] the products and it may be the consumer. And they should do a better job communicating to consumers when it comes to product safety.* (I5)

Field Test or Consumer Trial Test Thirty percent of the firms conducted field test for new products, which they consistently considered a very valuable practice to capture issues impossible to foresee during the development and to save money overall. Most interviewees cited time (i.e., lack of time) as the major barrier to perform a perfect field test. Often, field test had to be carried out concurrently with production. Some firms (mostly from the A group) used focus group to observe how the consumers handled and used the products without providing any instructions. This practice was not done in most group B firms. Below are some comments from the interviewees:

> *…We do focus groups, go to local hospitals and local schools, show the products to the parents and get their feedback. The best test is with the children sitting in it, and observe the children how they sit in it. You watch and see how the people are using the products. You can learn a lot. It's helpful for product safety and quality because I'm sitting here and designing a product assuming this will be used… because nobody reads manual. Yes, you have it in the manual how to use it, but nobody will read it. You have to be self-interactive. And to test how self-interactive it is, take it to the field, don't give them the manual and see how they are going to use it because the majority of users will not read the manual.* (I4)

> *It depends on timeline. Sometimes, I do field testing while in production. We're late because there is no time, but I decide we still need to do field testing. They will bring consumers in at first shot, something like to get some mother's opinion. It sounds like this is not field test. We give it to consumers, let them use it and give them surveys for feedback. To me that is*

> *one of this tings that is very valuable. We have the ability for real simulation. All the data and reports they generated [goes into] a column we call new product report. So, we actually generate special reports for brand-new products we're going to introduce to the market. We got a lot focus from what the consumers say about the product. The field test is a huge save… unfortunately retailers take products twice a year. You have to be well ahead of the schedule for what I say is a perfect timeline for field testing, whether 4 weeks, 8 weeks, or 12 weeks, you got to be ahead of the timeline.* (I10)

Design for Safety The best way to ensure product safety is to design safety into the product, which requires design engineers to be familiar with product safety standards and safety tools such as hazard analysis, FTA, and FMEA. Unfortunately, as Main and McMurphy (1998) reported, most design engineers received very little formal training on these tools. This limits their capability to improve product safety. Most of our sample firms were not using a systematic safety-based approach to address product safety issues. This seems in conflict with the safety literature. However, the main reason is likely because juvenile products are not as complicated as automobile or other complex equipment. Most of hazards related to these products have been identified and regulated in national safety standards.

Post-launch Review Although post-launch review has been identified as a best practice to ensure lessons learned, only around 20% of firms conduct formal post-launch reviews (Cooper et al. 2004c; von Zedtwitz 2003). In the firms interviewed, the majority of firms conducted post-launch reviews only when there were pending issues or new issues reported during production. However, some firms performed batch tests for new products to evaluate product safety and quality. If they found issues, they would call the team to review the products. In some firms, the team still owned the project for another 30 days after its release to production. None of the firms had a formal procedure for post-launch review. Quality teams were the only ones who lived through the whole life cycle of the product and enabled lessons learned through analyzing issues in the manufacturing process and the market.

Risk Management Tools Used in NPD In our sample firms, the use of safety management tools was fairly weak in NPD. The interviewees stated that using FMEA would absolutely help improve product safety. However, only 27.5 % of firms used FMEA, and 27.5 % of firms used it partially or used it for high-risk items such as CRS (child restraint systems) and medical devices. Forty-five percent of firms did not use it at all. Barczak et al. (2009) reported 48% of best performing firms used FMEA. Group A firms (63%) used FMEA slightly more frequently than group B firms (47.6%). It was very rare to find firms using other tools, such as FTA (fault tree analysis). Only 37% of firms conducted formal hazard analysis. Most interviewees commented that using these tools would be very time consuming, and the products were not that complicated as reasons for not using them. This is thus one area that most firms need to enhance in order to improve product safety performance. Another major reason for not using the tools was lack of formal training of the engineers on these tools. Especially small manufacturers have limited knowledge on these tools and therefore seldom use them. They heavily relied on third-party testing to verify whether products were safe or not. As I2 explained:

> *Of course, in theory the tools will enhance product safety performance, no doubt about it. But in reality, as mentioned TIME is what we do not have...* (I2)

> *FMEA is very time consuming and detailed. We don't have the resources to do it. So right now, we don't do formal FMEA for large furniture team. The health and safety team, they are required to do FMEA. Medical devices, there are probably the only team to do FMEA. Some other teams do FMEA here and there, but it's not a consistent part of our process.* (I8)

6.6 Summary

The analysis of our interviews and observations yields a number of conclusions. Thirty-four prevalent aspects critical to product safety practices in the NPD process (see Table 6.1) were uncovered. These practices are commonly applied by most of the best performers. Although we were unable to establish causal relationship between the practices and product safety performance based on the interview findings, most of the practices are differentiators between the best performers and the rest.

6.6.1 Best Performers Versus the Rest

Table 6.2 summarizes the key differences of product safety management between the best performers and the rest in terms of product safety strategy, product safety culture, concurrent engineering, and the new product development process. It is apparent that product safety strategy, product safety culture, and NPD process were key differentiators between the best performers and the rest. Another major finding is that the best performers implemented most practices more systematically and simultaneously; they did not rely on applying one practice more extensively or better. This is in line with the finding by Griffin (1997 p. 431) that "the best don't succeed by using one practice more extensively or better, but by using a number of them more effectively and simultaneously."

For product safety strategy, in contrast with the rest, the best performers showed stronger senior management commitment to product safety, dedicated more resources to product safety, considered product safety as priority concern, and made product safety one of their core competencies. In terms of product safety culture, the best performers fostered a product safety-first culture across all teams. In comparison, the rest had weaker product safety culture and commitment than the best performers, or product safety-first culture had only been established in certain departments such as quality, not across the board. There was no obvious difference regarding the use of cross-functional teams between the best performers and the rest.

In the NPD process, although most firms had a documented NPD process in place, there were significant differences in the execution and the activities incorporated in the process. First, the best performers had much more stringent QR requirements

Table 6.1 Critical-to-safety practices used in leading firms

A. Top management supports product safety
1. Top management holds regular meeting to review product safety issues
2. Top management gives higher priority to safety versus cost and schedule
3. Top management defines strategy, policy, and goals for product safety
4. Top management involves personally in making decisions on safety issues
5. Top management promotes product safety in all occasions
6. Top management kills the project if there are potential safety concerns
B. Role of quality department
7. The quality department head reports to the top leader in the organization
8. The firm has professional safety engineers in charge of safety analysis
9. The quality team has high visibility and autonomy
10 The quality team has the authority to hold projects/products if there are product safety concerns
11. The firm participates in establishing product safety standards for the industry
C. Product safety culture
12. The firm considers product safety is the no.1 priority
13. A senior person is in charge of product safety who is independent of production and distribution and can access to the top leader in the organization
14. There are incentives (such as CEO quality award) to promote product safety
15. There is a product safety committee to oversee all product safety management programs
D. NPD team organization
16. The firm uses cross-functional team for NPD project with members from R&D, engineering, quality, manufacturing, sales, marketing, purchasing, etc.
17. The firm practices concurrent engineering (quality/safety and manufacturing engineering participating in the earlier stage of NPD process)
18. The NPD team is accountable for the success or failure of the projects
19. The firm has adequate NPD resources
20. The firm provides formal training on product safety for all relevant employees
21. Design engineers and quality engineers are required to study product safety standards
22. The firms provide training for design engineers and quality engineers on safety management tools such as PHA, FTA, FMEA, etc.
E. NPD process
23. The firm has a formal NPD process incorporating product safety requirements, product safety review, and acceptance criteria at each stage
24. The firm has well-defined robust product safety requirements, which provide enough safety margin and include regulatory requirements and the firm's own internal requirements
25. The firm has thorough product safety review (PHA/FMEA) at each NPD stage
26. The firm has in-house product safety testing, and all products are third-party tested before release for production
27. The firm conducts thorough reasonably foreseeable misuse and abuse analysis
28. The firm conducts field test
29. Design engineers consider product safety in the design process
30. The firm promotes design for manufacturability
31. The firm involves customer in NPD

(continued)

Table 6.1 (continued)

32. The firm involves major suppliers in NPD
33. The firm has post-launch batch testing/review procedure
34. The firm uses risk management tools such as PHA, FMEA, FTA

Table 6.2 Summary of key differences between groups A and B

	Group A (best performers)	Group B (the rest)
PS strategy	Strong management commitment to PS	Committed to PS but not as strong as that of group A
	PS is priority concern in tradeoff between PS, cost, and schedule	PS may or may not be priority concern
	PS as a core competency	Inadequate resources dedicated to PS
	More resources dedicated to PS	
PS culture	Product safety-first culture across the board	Inconsistent understanding on importance of safety in different departments
Concurrent engineering	Use CFT	Use CFT
NPD process	QR is more stringent than regulatory requirements	Most firms just meet regulatory requirements
	Hazard analysis/product safety review is more robust and complete	Not strong on hazard analysis
	More thorough and complete evaluation and testing	Product testing only according to regulatory requirements
	Strong quality or product safety team who have the power to kill the project	Quality or product safety team not very strong
	Participating in establishing regulatory standards	Most firms not involved in establishing regulatory standards
	Better PS training	Not enough PS training

than regulatory standards, and in most of the cases, others only meet the regulatory requirements. Second, the best performers tended to have more robust and comprehensive hazard analysis, product safety reviews and evaluations, and testing; and others rely more on third-party test results. Third, the best performers had also stronger quality teams with high status and autonomy to make final decisions on product safety issues. Last but not least, best performers tended to provide better training on product safety management tools.

6.6.2 Product Safety Community Versus Industry

One evident observation from the interviews is the big gap between the safety community and the industry on how to manage product safety. In the safety community, product safety is recommended to be managed in a systematic approach with appropriate safety tools such as PHA, FMEA, FTA, etc., at different stages, with focus on hazard control. However, in reality, product safety was rarely managed in that way and was mainly managed based on experience. The majority of safety management tools promoted by the safety community were not widely used in the juvenile product industry. Most interviewees cited time constraints, the product being matured and simple as reasons for not using a systematic approach and neglecting safety management tools such as FMEA, FTA, etc. They considered an experience-based approach is more practical and sufficiently effective. But they do believe it is necessary to follow the systematic approach for brand-new products and complex products. This is in line with the findings of Main and McMurphy (1998) who studied different safety approaches used in the design and safety communities. In the design communities, safety was addressed through techniques such as safety factors, safety checklist, personal experience, and standards or codes. In the safety community, the focus was on hazard control and elimination.

The safety community mainly focuses on technical aspects to address product safety issues anyway. However, in the juvenile product industry, considering the products are not as complicated as automobile and aircraft and the regulatory standards have captured most of the hazards, it appears that having a safety-first strategy and culture are more important than anything else. These are the real drivers for product safety. Speaking of the importance of senior management commitment and product safety culture, I9 elaborated at the end of his interview:

> *… with respect to the culture of the company, putting safety at the utmost priority first: I think this [our] company does that... I know management from other companies doesn't, some of the smaller ones. But having that support from the management, to have the right people in place to come up with recommendations… That's key because then you know you have senior management support. So, everything you're doing is worth it, it's worth the effort. I think that's the single most important thing in any system... But without that, there is no safety system that will ever work if you don't have the management support to make safety a priority.* (I9)

6.7 Issues Observed in the Interview

The interviews revealed several issues faced by the sample firms. If these issues (see below) cannot be addressed, the goal to improve product safety remains elusive:

1. Product safety is not managed in a systematic approach. In most firms, product safety was managed by experience instead of systematic approaches such as formal hazard analysis and product safety reviews with appropriate tools.
2. Resources are not adequate, especially not for product engineers and quality engineers in charge of conducing hazard analysis and safety reviews. Most of the firms were facing this significant obstacle to improve product safety.
3. There is insufficient formal training for design engineers and quality engineers on safety methodologies such as FMEA, FTA, etc.

4. Most firms do not even have a product safety engineer position, with quality engineers assuming some of the responsibilities of safety engineering (for which they are often not professionally trained). A full-time professional safety engineer as a champion for product safety review and hazard analysis would be far more effective.
5. How safe is safe enough? Reasonably foreseeable misuse and abuse analysis is a considerable risk in the quality and skill level of safety engineers. Most engineers are struggling with this analysis, especially engineers who are not well-trained on safety tools.
6. To satisfy the requirement of "everyday low price," safety is easily compromised in the trade-off, especially for products that have no regulatory standards. Product safety is often overlooked by consumers and retailers, as there is no VOC on safety. Designers have to consider costs before anything else. If retailers and consumers had an "everyday safer" requirement (or mentality), chances are that products would become "everyday safer".
7. Most firms must also make a trade-off decision between speed and safety. Most interviewees remarked that they did not have enough time for a thorough FMEA, hazard analysis, field testing, etc. because they had to meet tight project schedules.

Chapter 7
Discussion

7.1 Introduction

This chapter discusses the qualitative and quantitative findings on product safety strategy, product safety culture, concurrent engineering, NPD processes, and product safety performance. The key findings are presented and discussed first, followed by triangulation analysis between qualitative and quantitative findings.

7.2 Summary of Results

The results of the hypothesis tests are summarized in Table 7.1 and discussed in accordance with product safety strategy, product safety culture, concurrent engineering practices, and NPD process practices as presented in the product innovation and product safety model. Among the 12 main hypotheses, four were rejected, one was partially supported, and seven were supported. Figure 7.1 presents the product innovation and product safety model after removing insignificant relationships. There are eight sub-hypotheses covering relationships between manager's perceptions of ideal and actual constructs in the conceptual model and contextual factors (firm size, origin of firm, firm's target market, and firm's R&D intensity). Of the eight sub-hypotheses, six were supported and two were rejected. Triangulation analysis is conducted between the quantitative findings and the outcomes of the qualitative analysis based on in-depth interviews. Detailed evaluations and discussions are presented below.

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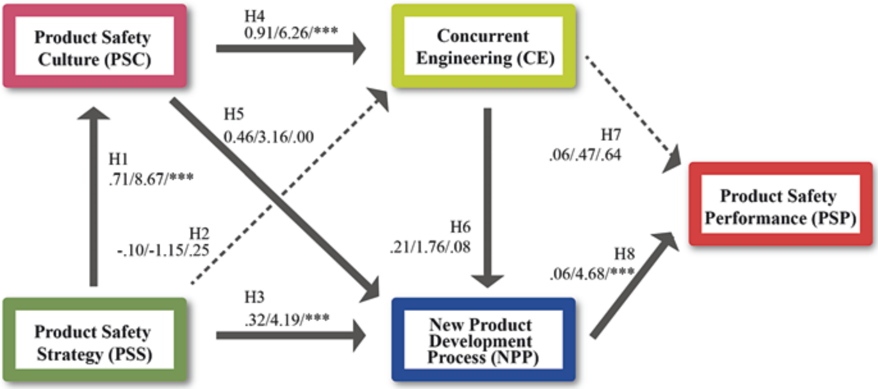
Table 7.1 Summary of the hypothesis tests

Hypothesis	Supported	Partially supported	Not supported
H1: Product safety strategy has a positive effect on the group-level product safety culture in new product development	X		
H2: Product safety strategy has a positive effect on the use of concurrent engineering			X
H3: Product safety strategy has a positive effect on the use of new product development process	X		
H4: Group-level product safety culture in new product development has a positive effect on the use of concurrent engineering	X		
H5: Group-level product safety culture in new product development has a positive effect on the use of new product development process	X		
H6: The use of concurrent engineering has a positive effect on the use of new product development process			X
H7: The use of concurrent engineering has a positive effect on product safety performance			X
H8: The use of new product development process has a positive effect on product safety performance	X		
H9: Manager's perceptions of actual model constructs (PSS, PSC, CE, NPP, and PSP) are influenced by contextual factors (firm size, firm origin, target market, R&D intensity)		X	
H9a: Manager's perceptions of actual model constructs (PSS, PSC, CE, NPP, and PSP) are not affected by firm size	X		
H9b: Manager's perceptions of actual model constructs (PSS, PSC, CE, NPP, and PSP) are not affected by firm origin	X		
H9c: Manager's perceptions of actual model constructs (PSS, PSC, CE, NPP, and PSP) are not affected by firm's target market			X
H9d: Manager's perceptions of actual model constructs (PSS, PSC, CE, NPP, and PSP) are not affected by firm's R&D intensity			X
H10: Manager's perceptions of ideal model constructs (PSS, PSC, CE, and NPP) are not affected by organizational contextual variables (firm size, firm origin, target marketing, and R&D intensity)	X		
H10a: Manager's perceptions of ideal model constructs (PSS, PSC, CE, and NPP) are not affected by firm size	X		
H10b: Manager's perceptions of ideal model constructs (PSS, PSC, CE, and NPP) are not affected by origin of firm	X		

(continued)

Table 7.1 (continued)

Hypothesis	Supported	Partially supported	Not supported
H10c: Manager's perceptions of ideal model constructs (PSS, PSC, CE, and NPP) are not affected by target market	X		
H10d: Manager's perceptions of ideal model constructs (PSS, PSC, CE, and NPP) are not affected by R&D intensity	X		
H11: Firm's R&D intensity will moderate the relationships posited in Fig. 3.4, thereby suggesting that the relationships of those firms that have high R&D intensity will be different from those that have low R&D intensity			X



Note: a) The line size represents the strength of the relationship; a dotted line indicates that the relationship is not significant. b) Model fit indices: CMIN/DF = 1.96, CFI = .92, IFI = .92, TLI = .90, RMSEA = 0.06. R square values: Product Safety Culture (0.51), Concurrent Engineering (0.71), New Product Process (0.81), Product Safety Performance (0.43)

Fig. 7.1 Product innovation and product safety model

7.3 Product Safety Strategy

The results of SEM analysis indicate that product safety strategy has a great impact on product safety culture and the NPD process. This ultimately affects product safety performance. Since 71% of the total variance for product safety culture and 32% of the total variance for the NPD process can be explained by product safety strategy, the strong and positive effect of product safety strategy on product safety

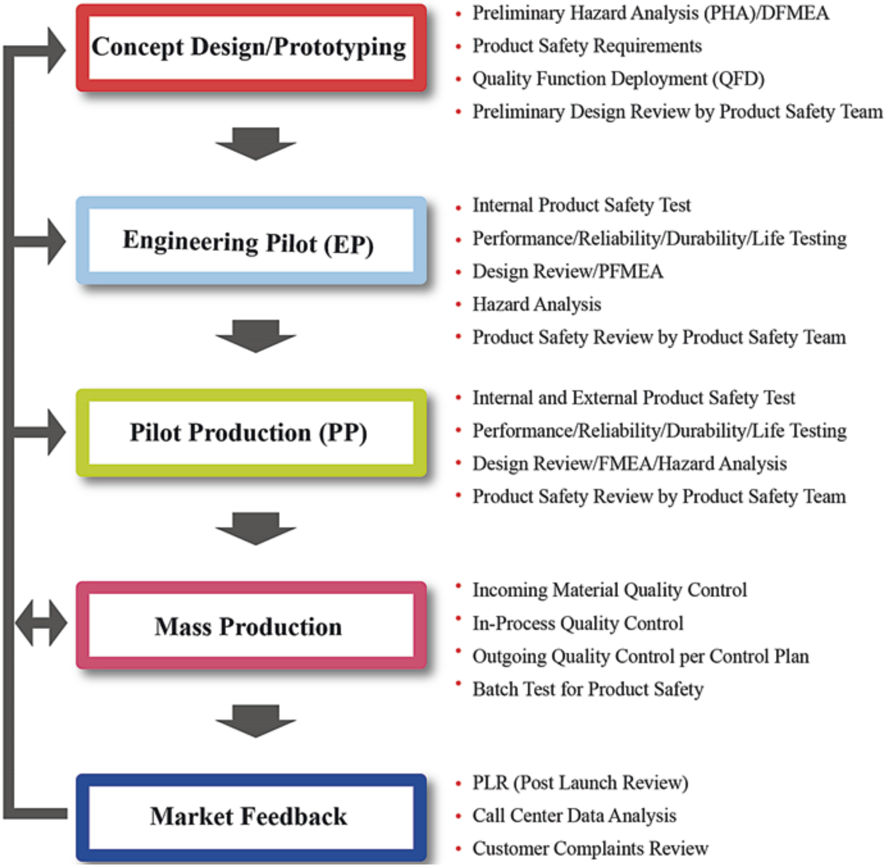


Fig. 7.2 Product safety activities during key NPD stages at Goodbaby (see also Fig. 6.1)

culture and the NPD process is apparent. With an indirect coefficient of 0.5, the strong indirect effect between product safety strategy and product safety performance cannot be overlooked. However, the different coefficients indicate that product safety strategy has a much stronger effect on product safety culture than on the NPD process. This means that product safety strategy affects product safety through the culture dimension more than the technical dimension (NPD process practices).

The qualitative findings also support the notion that product safety strategy plays a key role in product safety management. The results of in-depth interview analysis show that the best performers have strong commitment by the top management toward product safety. They position product safety as their primary priority and promote a “safety-first” culture in the firm. They devote necessary resources to manage product safety proactively. They have a senior management staff member in charge of product safety who is independent of engineering and production. A strong quality team in charge of product safety is prevalent in these firms. These practices are major differentiators between the best performers and the rest.

Although the best performers claimed they have more stringent internal requirements than the regulatory standards, it is also clear that most of top management commitment to product safety is affected by external contextual factors such as legal and regulatory changes and by government interventions.

The results of this study confirm safety management literature reporting that top management commitment to safety is linked to positive safety culture and better safety performance (Cheyne et al. 1998; Dedobbeleer and Beland 1991, 1998; Flin et al. 2000; Shannon et al. 1997; Zohar 1980, 2000). It also affects the management practices a firm adopts (Benson et al. 1991). The result is furthermore consistent with White and Pomponi's (2003) finding that firms with a safety-oriented strategy achieve better product safety performance.

The result not only confirms the claim in literature that company product safety policy and top management support to product safety play an important role in product safety (Kolb and Ross 1980; Roland and Moriarty 1983; Eads and Reuter 1983; Bass 1986; Kitzes 1991) but also provides empirical evidence to support these prescriptions. In addition, it serves as empirical evidence to validate the relationship between strategy, culture, and process management posited in theoretical models such as Schein's conceptualization of culture, the MBNQA model, the EFQM model, and the innovation diamond.

Contrary to what was predicted, SEM analysis revealed that there is no significant relationship between product safety strategy and concurrent engineering. Not only is the relationship insignificant, the effect is even negative. The standardized direct effect is −0.10. However, the total effect that product safety strategy has on concurrent engineering is quite high at 0.50, due to a very strong and significant indirect effect (0.65) that product safety strategy has on concurrent engineering through the mediation of product safety culture.

We propose three reasons for the insignificant relationship between product safety strategy and concurrent engineering. First of all, concurrent engineering has been mainly linked with cycle time reduction instead of product safety (Gerwin and Barrowman 2002), and cycle time and product safety are often competing goals. Therefore, companies with a strong focus on product safety strategy may not necessarily adopt concurrent engineering practices. Instead, they may focus on the quality of execution in the NPD process with tough product safety reviews, robust hazard analysis, and comprehensive product safety testing. Secondly, as most juvenile products are not very complex and major product-related hazards have already been captured in the regulatory product safety standards, the practitioners may think it is unnecessary to use CE or have product safety engineers involved at the earlier stages in the NPD. Finally, as most of the firms claimed that they do not have adequate product safety/quality engineers, this absence of expertise may prevent firms from adopting concurrent engineering practices.

The above findings are not confined to the juvenile product industry. The General Motors (GM) faulty ignition switch recall in 2014 provides a good example on how the top management and organizational culture (prioritized cost over safety) affects employees' behaviors on cost and product safety, ultimately leading to quite disastrous consequences for GM (see details below for the case study on GM's ignition switch recall). The company's cost-driven strategy misguided its employees to prize cost over quality and safety. Consequently, product safety was compromised in the cost-benefit analysis. If GM had had a safety-first strategy and culture in place, the outcome of this case would have been totally different, and GM could have fixed the faulty ignition switch with a fraction of the recall cost, or the faulty ignition switch would have never been released to production as it did not meet its specifications at the beginning. Cost-benefit analyses like these bring back memories of the failed Ford Pintos into the 1970s. The estimation to fix the Pintos' faulty gas tanks was $11 per car. Ford apparently determined not to fix it as it would have cost more to fix every gas tank than handling a limited number of lawsuits. The cars were eventually recalled. In one lawsuit, a jury awarded over $3 million in compensatory damages and $125 million punitive damage.

Summing up, the findings of both quantitative and qualitative analysis prove that product safety starts at the top management. Top managers drive product safety through establishing safety-oriented product safety strategy, dedicating necessary resources to product safety management, establishing product safety policies and objectives, committing to build a positive safety-oriented culture, and instilling incentives to promote product safety. This in turn affects the employees' attitude and attention to product safety and encourages them to apply the best NPD practices to address safety issue. If the top management pays more attention to product safety, employees will also be more concerned about product safety. Still, the impact of external contextual factors such as government intervention on top management commitment to product safety is apparent as revealed in the in-depth interview. This is one of the main driving forces for product safety. This is in line with the "system-structural view" of organizational theory. As Astley and Van de Ven (1983), p. 248 explained, "according to system-structural view, the manager's basic role is a reactive one. It is a technician's role of fine-tuning the organization according to the exigencies that confront it. Change takes the form of 'adaptation'; it occurs as the product of exogenous shifts in the environment. The manager must perceive, process, and respond to a changing environment and adapt by rearranging internal organizational structure to ensure survival or effectiveness."

7.4 Product Safety Culture

While organizational-level safety culture focuses on shared perceptions on product safety policies, procedures, and practices, group-level safety culture emphasizes the execution of product safety policies, procedures, and practices (Zohar 2008). Therefore, a positive product safety culture in NPD will enhance the quality of the execution of product safety policies, procedures, and practices. The results of SEM analysis demonstrate a very strong support for the relationship between product safety culture and concurrent engineering and NPD process. The group-level product safety culture in new product development accounted for 91% of the total variance for concurrent engineering and 65% of the total variance for NPD processes. Product safety culture had a much stronger effect on concurrent engineering than on NPD processes. With such a strong relationship with concurrent engineering and NPD processes (which in turn affect product safety performance), the importance of product safety culture on product safety performance is evident. The strong indirect relationship between product safety culture and product safety performance was observed in the SEM analysis with an indirect effect of 0.45. In the juvenile product industry, product safety culture appears to be more important for achieving better product safety performance than the quality of the technical solution, as the products are less complex and most product-related hazards are known.

The quantitative findings were also strongly supported by the in-depth interview analysis, as all 40 interviewees agreed that product safety culture impacted product safety performance. It is also evident that the best performers listed product safety as their primary concern and had a far stronger safety-oriented culture than other firms, as many of our quoted interviews in the previous chapter attest.

In the safety management literature, safety climate has been linked to safe work behavior (Hofmann and Stetzer 1996; Varon and Mattila 2000) and fewer employee injuries (Barling et al. 2002; Hofmann and Stetzer 1996; Mearns et al. 2003; Zohar 1980). The findings of our research indicate similar results, that is, a positive safety-oriented culture will lead to better product safety performance. This is in line with the research findings by Svenson (1984), White and Pomponi (2003), Van Vuuren (2000), and Rollenhagen (2010).

In high-reliability industries, there has been a shift from “lagging indicators” (such as fatalities, lost time accident rate, and incident rate) toward so-called leading indicators (such as measurement of safety climate) to measure safety performance (Flin et al. 2000). This shift in focus is primarily due to the observation that organizational, managerial, and human factors rather than purely technical failures were identified as major root causes of the accidents in these industries (Weick et al. 1999), and organizations with strong safety climates tend to have fewer employee injuries. This is explained by the presence of well-developed and effective workplace safety programs and the fact that these programs reinforced management commitment to safety for their employees (Hahn and Murphy 2008). The same principle can be applied to the juvenile product industry, as the key issues that led to product recalls are well-known issues. Building a product safety-oriented culture is the single most important thing to improve product safety performance, and product safety culture can be used as a leading indicator for product safety performance.

With regard to the importance of safety-oriented culture, the recent recall cases of GM, Toyota, Volkswagen, and Samsung all presented hard lessons for companies to learn. In order to launch Galaxy Note 7 ahead of its rival Apple, Samsung expedited the NPD process and prioritized time to market over product quality and safety, which led to its high-profile smartphone being recalled for fire risks only 2 weeks after its launch. Samsung eventually recalled all Galaxy Note 7 units and terminated the product after 2 months. It not only cost Samsung billions of dollars in lost revenues but also damaged its brand and reputation. Similar crisis can happen in any company when product safety is not given high priority. Toyota recalled 12.8

million cars between 2008 and 2010 for unintentional acceleration problems, which again cost the company billions of dollars. In a statement by Akio Toyoda, the president and CEO of Toyota, the root cause for the issue was explained as follows (Guardian 2010):

> *Toyota has, for the past few years, been expanding its business rapidly. Quite frankly, I fear the pace at which we have grown may have been too quick. I would like to point out here that Toyota's priority has traditionally been the following: First: Safety, Second: Quality, and Third: Volume. These priorities became confused, and we were not able to stop, think, and make improvements as much as we were able to before, and our basic stance to listen to customers' voices to make better products has weakened somewhat. We pursued growth over the speed at which we were able to develop our people and our organization, and we should sincerely be mindful of that. I regret that this has resulted in the safety issues described in the recalls we face today, and I am deeply sorry for any accidents that Toyota drivers have experienced. Especially, I would like to extend my condolences to the members of the Saylor family, for the accident in San Diego. I would like to send my prayers again, and I will do everything in my power to ensure that such a tragedy never happens again.*

A similar case in our sample led to an even worse outcome for another Japanese company. Company A is one of the most well-known companies in the juvenile product industry in Japan that had built a reputation on product quality and safety. Quality and safety had been the principal mission of its founder throughout its history, supported by its senior executives and shop floor workers, and became the most well-known brand in the industry representing excellent quality and safety. The company enjoyed great success for more than half a century, achieving the biggest market share in the childcare articles in Japan. However, due to the fierce price competition, the company initiated several cost reduction programs in the early 2000s, including relocation of manufacturing to China. Consequently, its safety-first culture began to slowly deteriorate over the years, and it led to massive product recalls in the market. As the interviewee explained:

> *… five years ago, the top management focused on cost reduction. Therefore, product quality and safety had been deteriorating. It led to a massive recall in the market…, and the company was acquired by another MNC because it couldn't afford for the recall expenses. But after the recall, product safety has become the number one concern in the company instead of cost, and the product safety culture has been changed totally.* (I1)

Case Study: GM Ignition Switch Recall (The Tipping Point for Safety Culture Change)

In 2014, General Motors (GM) recalled nearly 30 million cars worldwide because of faulty ignition switches, which could shut off the engine while driving and thereby prevent the airbag from inflating. This defect was linked to at least 124 deaths. GM acknowledged the ignition switches were known to have been faulty for at least a decade but had not recalled cars prior to 2014. As part of a Deferred Prosecution Agreement, GM agreed to forfeit $900 million to the USA. NHTSA imposed a $35 million fine on GM for delaying the recall of defective cars, which is the highest penalty the NHTSA is able to levy. By February 2015, the total cost involved for the recall had reached $4.1 billion with more unsettled lawsuits pending. GM was blamed to put profit before human lives. Valukas (2014) asserted that

GM's failure to fix the defective switches sooner was not due to a cover-up on the company's part, but rather due to "their failure to understand, quite simply, how the car was built."

According to documents issued by the House Energy and Commerce Committee, GM may have known of the problem as early as 2001 but believed that a design change fixed the problem. But the faulty ignition switch did not meet GM's specifications. The issue was revisited again in 2004 after a customer complained that the vehicle could be keyed off "by knees" while driving. Considering lead time, cost, and effectiveness, GM decided not to fix it. Instead, GM advised customers to remove heavy items such as their key rings (Fletcher and Mufson 2014). GM internal emails revealed the cost to fix the ignition switch and discovered that the change would have cost an extra 90 cents per unit and additional tooling costs of $400,000, but those tooling costs typically are amortized over several years. In 2006, GM began to use modified ignition switches in 2007 models.

As Himsel (2014) pointed out, GM became a practitioner of cost culture as a result of recent economic recessions and intense cost-cutting measures in the 2000s. It was restructuring, shrinking, and cutting costs out of survival of the company, followed by years of an "organizational culture that prized cost over quality, hesitating to pass along bad news and possibly condoned a cover-up." The quiet, cost-driven culture potentially caused employees who knew about the problem not to speak up. This pattern of silence could have contributed to the company's eventual bankruptcy and federal bailout in 2009 (Fletcher 2014). It also led to the massive and expensive recall for the ignition switch in 2014, which became the tipping point for GM to change from a cost-oriented culture to safety-first culture. After the recall, the new CEO Mary Barra hired a new safety chef and started the "Speak up for Safety" program. This new safety program encourages employees to share ideas to improve product safety and is meant to establish a product safety and quality-first culture in GM (General Motors 2014).

7.5 Concurrent Engineering

The use of concurrent engineering seems to have a weak direct effect on new product development process: only 21% of variance for the new product development process could be explained by the use of concurrent engineering. The findings indicate that the execution of NPD process practices was weakly influenced by the use of cross-functional teams, involvement of downstream employees such as manufacturing, and quality employees in the design at earlier stages and concurrent workflows. CE promotes coordination and communication among multiple functions so that both downstream and upstream issues can be resolved early in product design. Downstream project participants such as manufacturing and quality voice their concerns before the design is finalized. Cross-functional teams provide a platform for different participants to express views and concerns and serve as a mechanism for mutual learning. Simultaneous planning of product, process, and manufacturing allows issues of manufacturability, quality, and safety to be raised and evaluated and its solutions to be incorporated into the final product design. All these practices enhance the execution of the NPD process.

Our SEM results showed that concurrent engineering had no significant direct effect on product safety performance. However, there was a moderating indirect effect between concurrent engineering and product safety performance that should not be overlooked. At first glance, this finding seems unexpected and nonintuitive. Researchers and safety experts have repeatedly stressed that safety professionals should be involved in the design as early as possible and recommend design-for-safety and concurrent engineering as a mechanism to ensure product safety (Dowlatshahi 2001; Rausand and Utne 2008; Wang and Ruxton 1997). Empirical studies also reported that the use of CE teams had a positive effect on product quality performance (Koufterous and Marcoulides 2006; Koufterous et al. 2002; McDonough 2000; Rusinko 1997, 1999; Sethi 2000; Takikonda and Montoya-Weiss 2001). Unfortunately, product safety was not explicitly addressed as a dependent variable in these studies. The findings of the quantitative evaluation were consistent with the results of our in-depth interview analysis. CE has been widely used in most firms interviewed. However, there was no obvious difference between best performers and the rest in terms of use of CE practices.

There may be several reasons for this insignificant relationship between CE and product safety performance. Firstly, most of the literature on concurrent engineering uses cycle time as the sole performance indicator and fails to evaluate the impact on other competing objectives; with the conclusion that CE is linked to shortened time to market unanimously agreed upon in the literature (Gerwin and Barrowman 2002). As time to market and product safety are often competing goals, this might help explain why CE has no effect on product safety.

Secondly, as mentioned earlier, juvenile products are not very complicated, and most of the hazards related to the products have already been captured in regulatory standards. Any hazards or safety issues can still be detected during product safety tests and hazard analysis at a later stage, even if product safety and quality engineers are not involved in the early NPD stages. Therefore, the use of CE is not necessarily linked with better product safety performance.

Thirdly, as CE has been widely used in most firms, it is no longer a differentiator between the best performers and the rest.

Finally, as some of the interviewees mentioned during the in-depth interviews, even if different groups participate in NPD at the early stages, different functions still mostly focus on their own areas in practice. This function-specific focus does not help with addressing product safety issues arising at the product system level. This finding is reminiscent of the results by Clark and Fujimoto (1991) and Koufteros et al. (2001). In their study of the automobile industry, Clark and Fujimoto found that CE used in incremental projects decreased product quality. Koufteros et al. (2001) did not find any significant direct relationship between CE and quality in their research.

7.6 New Product Development Processes

The positive relationship predicted between the use of new product development processes and product safety performance was strongly supported by the SEM analysis. Sixty-one percent of variance for product safety performance could be explained by the use of new product development processes. This finding is in line with reports that about 70% of product safety recalls are rooted in product design (White and Pomponi 2003; Bapuji and Beamish 2008; Beamish and Bapuji 2008). Our root cause analysis for product safety issues based on company data in our sample (Chap. 5) also showed that 67.3% of the product safety issues were caused by design defects. Clearly, product development carries a larger share of the responsibility for the product safety issues than manufacturing.

The finding of our research is more or less in line with the conclusion that a well-defined, high-quality NPD process is a key success factor for NPD (Cooper et al. 2004c; Montoya-Weiss and Calantone 1994) and that there is a positive causal relationship between NPD process practices and product quality (Calantone and Benedetto 1988; Calantone et al. 1996; Millson and Wilemon 2008; Song and Parry 1997), even though product safety was not explicitly mentioned in these studies. In our study, we included safety management methodologies such as product safety review, hazard analysis, FMEA, design for safety, etc. as independent variables in the measurement of the NPD process and evaluated the relationship with product safety performance explicitly. The findings of our study provided strong empirical evidence that NPD process practices have great impact on product safety performance. It is supplemental to previous NPD practice studies in which product safety methodologies and product safety performance were overlooked.

The results of our qualitative analysis also provided strong support for the quantitative findings. All firms interviewed had implemented a process that incorporated some kind of product safety review and acceptance criteria at each stage. Although most firms had a documented NPD process in place, there were huge differences between the best performers and the rest in the execution and other activities in the innovation process. First, there were significant differences in quality requirements. The best performers had much more stringent standards than required by regulatory standards, and in most of cases, the less-well-performing firms only met the regulatory requirements. Second, the best performers tended to have more robust and complete hazard analysis, product testing, product safety review, and evaluations; and others relied more on third-party test results. Third, the best performers also had strong quality teams with high status and autonomy to make final decisions on product safety issues. Last but not least, the best performers tended to have more resources to manage product safety and provided better training on product safety management tools. Therefore, the best performers implemented R&D practices more systematically and simultaneously, and they did not rely on applying only one practice more extensively or better. This is in line with the findings of Griffin (1997).

Based on our SEM analysis, the NPD process is the only variable in the conceptual model that has a direct impact on product safety performance in product development. This confirms the EFQM model that process management is the only immediate factor leading to operational performance. Overall, looking at the total effects between product safety strategy, product safety culture, concurrent engineering, the NPD process, and product safety performance, the NPD process has far more direct impact on product safety than other factors. Concurrent engineering has less impact on product safety than other variables. Although there is no direct effect between product safety strategy, product safety culture, and product safety performance, their strong indirect effects cannot be overlooked. On the other hand, product safety strategy, product safety culture, and concurrent engineering affect product safety through the NPD process. Even if the firm has great product safety strategy and positive product safety culture, it may not necessarily achieve better product safety performance if the NPD process is not well managed. The importance of the NPD process on product safety is clear. Companies which intend to improve their product safety performance should build an effective and efficient idea-to-launch process. This process should be well crafted and robust, emphasizing the quality of execution and integrated with safety management methodologies. The Goodbaby case below shows how product safety methodologies are integrated into the NPD process to achieve excellent product safety performance.

Case Study: Implementing Product Safety in New Product Development
Goodbaby Child Product Co., Ltd. ("Goodbaby") is the largest stroller manufacturer in the world. Its products are 100% safe—as measured by zero product recalls over our research period of 14 years (refer to Chap. 8 for a more detailed case study). It runs its product development as a stage-gate process and manages product safety accordingly (see Fig. 7.2). The product safety team gets involved early, during concept review or latest prototype evaluation, to conduct preliminary hazard analysis. During the review, relevant product safety standards (if available), product safety checklists, possible foreseeable misuse/abuse, issues identified in the market and the manufacturing process for similar products, and past experience are considered. Product safety requirements are established accordingly with extra safety margins. Prototypes are tested and evaluated in a purpose-built lab: If any potential hazards come up, designers must "design out" these hazards. If a hazard is unavoidable, the designers must safeguard it. If it is impossible to safeguard and the risk is unacceptable, then the product is terminated, or a warning is required if the risk is low and acceptable. The product safety team joins all discussions of quality function deployment (QFD) and DFMEA (design failure mode effect analysis). Well-defined acceptance criteria are maintained at each stage, and the product is not permitted to move in the next stage unless everybody (including the product safety team) signs off.

When product design is completed and the project enters into the engineering phase, thorough hazard analysis and product safety/reliability testing are done with off-tool parts. At this stage, quality engineers verify whether previously identified hazards have been fully resolved and whether there are any new hazards after load testing, reliability testing, and life testing. Besides conducting independent product safety reviews, quality engineers also participate in PFMEA (process failure mode effect analysis) and the design review. A quality control plan is generated based on the FMEA file, and a critical-to-safety process must be identified and included. Normally, fine-tuning of product design and mold changes are expected during this stage. Once the design is frozen and tooling is approved, the project enters the pilot run stage to verify process capability.

Pilot production is important to ensure that the process is capable and stable. Further product safety, reliability, and durability tests are carried out for pilot run products with appropriate sample sizes. Normally, products are sent to third-party lab for external tests or certification at this stage. In the meantime, field tests are carried out in the target market. Quality engineers conduct a final product safety review based on various test results and update the FMEA file and the quality control plan. All these results and findings are reviewed in the final design review. Special attention is paid to the earlier identified critical-to-safety process. After the product is released for mass production, critical-to-safety processes and characteristics are monitored closely by the quality team (incoming quality control, in-process quality control, and outgoing quality control), batch tests for complete products are carried out to verify consistency, and a post-launch review is carried out. Feedback on product safety issues in manufacturing process and the market are communicated to the product safety team for immediate action.

For incremental product innovations or relatively simple new products, the abovementioned process can be simplified significantly. Depending on the nature of changes or the complexity of the product, the engineering pilot (EP) and pilot production (PP) gates are combined. In any case, the product safety team must conduct preliminary hazard analysis and define safety requirements at the concept or prototyping stage. Thorough product safety, reliability, and durability tests are carried out, and complete product safety reviews are performed with pilot run products.

7.7 Contextual Factors

In our study, the relationship between manager perceptions of ideal and actual model constructs and contextual factors (firm size, origin of firm, firm's target market, firm's R&D intensity) was tested through multivariate analysis of variance (MANOVA) with the actual and ideal model constructs as dependent variables and context as factors. The MANOVA results indicate that the actual model constructs PSS, PSC, CE, NPP, and PSP were not influenced by firm size and origin of firm. Firm target markets had a weak effect on the actual model constructs PSS, PSC, CE, NPP, and PSP; and R&D intensity had significant effect on CE, NPP, and PSP. On the other hand, the MANOVA results also showed that the manager perceptions of ideal model constructs (IPSS, IPSC, IEC, and INPP) were not influenced by firm size, origin of firm, firm target markets, and firm R&D intensity. This finding is in line with the conclusion of Benson et al. (1991) that manager perceptions of ideal and actual quality management practices are influenced by firm size.

7.8 Moderating Effect of R&D Intensity on the Product Innovation and Product Safety Model

While six out of eight hypotheses in the structural equation model were supported, it is not clear whether the relationships hold across different environments. For example, would the model relationships vary across firms of low and high R&D intensity? To answer this question, hypothesis 11 predicts that R&D intensity will moderate the relationships posited in Fig. 4.2, thereby suggesting that the relationships of those firms that have high R&D intensity will be different from those that have low R&D intensity. To ascertain whether the structural model relationships are invariant, it is essential to establish measurement model invariance through multi-group analysis. The outcome of multi-group analysis shows that R&D intensity did not moderate the relationship in the structural model. Therefore, the relationships in the product innovation and product safety model hold across all firms with high and low R&D intensity.

Chapter 8
Implications and Recommendations

8.1 Managerial Implications

Managerially, the results of this study provide input to various stakeholders of product safety, especially regulators/policy makers, manufacturers, retailers, and consumers. The immediate benefits are a better understanding of how to develop products that are safe—with obvious benefits for manufacturing firms and their customers. It also provides empirical guidance for governments to regulate industries properly and effectively.

8.2 Implications for Regulators

Governments play a critical role in product safety. Self-regulation does not always work in the business environment. Regulators and policy makers often have an obligation given by their public mandate to establish and enforce product safety standards. Although it is the manufacturer's responsibility to create and market safe products, this goal is difficult to achieve purely through self-regulation. Firms face fierce competition in the market and are tempted to fulfill only the minimum requirement on safety, in order to compete on other product characteristics such as features and price. This is not a China-specific problem: the massive product recalls in the USA and Europe proved that product safety is difficult to achieve in the absence of government intervention there, too. Hence, the US government has increased the CPSC budget, and the CPSC has started to convert voluntary product safety standards into mandatory standards. The heightened attention on regulation has led to a dramatic decrease of unsafe product recalls in the USA.

A.Y. Zhu et al., *Responsible Product Innovation*, Innovation, Technology, and Knowledge Management, https://doi.org/10.1007/978-3-319-68451-2_8

The Chinese government has also done more to ensure product safety in toys and children's products. The Chinese government also released a new product recall policy for toys in 2009. Safety standards for many juvenile products are still missing or not mandatory in many countries, especially in the developing world, so it is important for the regulators and policy makers to pay extra attention to these products. For example, the Chinese General Administration for Quality Supervision, Inspection and Quarantine (AQSIQ) and the China Inspection and Quarantine (CIQ) inspect Chinese factories in terms of quality systems, process capability, and necessary equipment to manage product safety and test the products before issuing export licenses to factories. For all products exported, CIQ conducts sample checks between 5% and 100% lot inspections based on the performance classification of the manufacturers. The Chinese government has made significant efforts to strengthen product safety in the toy industry: 701 manufacturers lost their export licenses in 2007 (EC 2008). And as everywhere, while the policies signal good intention and long-term vision, it is the execution of these policies and the expertise of the people in charge that make the difference.

Policy makers and regulators from different countries need to consider working together to create harmonized product safety standards (as the European Commission has done for Europe) and to keep them state of the art. At present, different countries maintain their own unique and different standards. This not only creates complexity to manage product safety for manufacturers who market products in different countries but also incurs huge costs to the manufacturers: money that otherwise could have been used more usefully for even better product design. Worse, many local product safety standards are not state of the art, and new hazards and injury information are not updated into these standards on a timely basis. This leads to product recalls despite these products being compliant with the regulatory standards. As many manufacturers use regulatory standards as their sole requirements for product safety, policy makers need to update local standards regularly to ensure that even products compliant with those standards are reasonably safe.

Also, in most countries, surveillance of local market by responsible regulators is not adequate. More resources should be provided to ensure reasonable surveillance is carried out to monitor compliance of products.

Government agencies also tend to focus on the bigger firms when addressing product safety issues as they have bigger market shares. However, it is often the smaller companies (which we learned focus more on cost competition) that need more attention from the government as they have fewer resources, less capacity, and shortages in expertise to manage product safety issues by themselves.

Finally, governments should establish systems to collect product injury data and maintain an integrated database with recalls of unsafe products and relevant injury information. This database should be updated in a timely fashion, and it should be open and easily accessible to the public. The USA has done an exemplary job in this regard. Other countries, however, including China as the main manufacturing base for many industries and a fast-growing market, need to build similar databases so that policy makers and manufacturers can use it as a basis for decision-making.

8.3 Implications for Retailers and Consumers

“Every day safer” vs. “everyday low price”: retailers have a huge influence on manufacturers by means of their bargaining power. Unfortunately, product safety is often overlooked by consumers and retailers. Product designers are constantly required to consider final costs (manufacturing costs, purchasing costs, etc.) to satisfy the expectations of “everyday low price,” and thus safety is easily compromised in the trade-off. This is dangerous for products that have no (external) regulatory standards. If retailers and consumers had an “everyday safer” requirement or mentality, we believe that products would ultimately become “everyday safer” too. Therefore, retailers should pay more attention to product safety through formal requirements on products and product safety management systems as employed by manufacturers.

Product misuse and product abuse are among the main reasons for product-related injuries. Consumers should bear in mind the potential hazards related to using products in unintended ways, and follow user instructions to avoid injury, especially for secondhand products or old products that have been used for a long time. Caregivers should be aware of the safety hazards products may pose to children and ensure they are always under the supervision. Should a product be involved in an incident causing injuries, manufacturers appreciate feedback on the conditions that led to the incident and any potentially unsafe situation so that they can take action immediately to address the safety concerns.

8.4 Implications for Manufacturers

8.4.1 The Three Cornerstones of Product Safety

As our study has emphasized throughout this book, there are three critical pillars (or cornerstones) to product safety (see Fig. 8.1):

1. A safety-oriented strategy
2. A safety-first culture
3. A robust NPD process

Therefore, manufacturers intending to improve product safety need to focus on these three aspects of responsible product innovation.

A Safety-Oriented Strategy

The top management needs to provide strong support to product safety, commit necessary resources to implement best practices for safety management, and position product safety as its first priority. It is the job of the top management to craft

Fig. 8.1 The three cornerstones of product safety

and communicate this strategy. More importantly, the top management should "walk the talk" and get personally involved in product safety decisions. To build a safety-oriented strategy in the company, the top management should:

- Position product safety as their primary priority and promote a "safety-first" culture in the firm
- Include product safety concerns and issues in the top management's meeting agenda
- Dedicate necessary resources and manage product safety proactively
- Establish product safety policies and objectives
- Instill incentives to promote product safety
- Appoint senior management staff (e.g., at vice president level) in charge of product safety who is independent of engineering and production
- Build a strong quality team in charge of product safety

A Safety-First Culture

Building a product safety-first culture across the company is the first and most important thing to do to improve product safety performance. A company's product safety culture can be used as a leading indicator for product safety performance. A company should have programs and incentives to ensure that all employees (irrespective of their hierarchical or functional level) understand the importance of product safety and position product safety as the company's first priority. All technical employees (R&D, engineering, quality, production, etc.) should be well trained on relevant product safety standards and safety management tools. The quality team should be empowered to make decisions on product safety independently (e.g., through independent product safety review teams). More importantly, R&D and engineering teams should be trained to know how to design product safety into the products instead of waiting for quality teams to find and control design issues.

A Robust NPD Process

A well-designed NPD process is not only important for delivering predictable innovation but also as a cornerstone for ensuring and enabling product safety. Based on an effective, efficient, and robust idea-to-launch process, product development teams integrate professional safety management methods such as hazard analysis, FMEA, and product safety reviews at appropriate and defined stages. Cooper's (1990) stage-gate model or similar phased product development processes need to be extended with product safety criteria throughout. A safety-oriented NPD process should include the following characteristics:

- High process maturity: A formal, well-defined, and implemented NPD process incorporating product safety requirements, hazard analysis, FMEA, product safety testing, product safety review, and acceptance criteria at each stage.
- Stringent safety requirements: Manufacturers must maintain well-defined product safety requirements that exceed regulatory requirements with safety margins based on internal hazard analysis, foreseeable misuse and abuse analysis, failure history for similar products, etc. R&D engineers must honor these requirements when designing products. Market and consumer research and technical service usually have rich data sets that can be put to good use. It is not sufficient to fulfill only minimum regulatory requirements.
- Front-end hazard identification: Anticipating all foreseeable misuse and abuse, R&D engineers must incorporate PHA, hazard elimination, and control already when designing products.
- Complete in-house product safety and reliability tests: Companies should not rely only on third party tests, which normally only follow minimum regulatory requirements.
- Empowered quality teams: Assign high hierarchical status and autonomy to the quality team(s) to make final decisions on product safety issues.
- Free up time and resources: Dedicate resources and attention to manage product safety; train all NPD engineers on product safety management tools.

Table 8.1 illustrates product safety management activities along Cooper's stage-gate process. In stages 1 and 2, product safety engineers and quality engineers work side by side with the project team defining product safety requirements, ensuring that potential product hazards are identified, assessed, and eliminated as earlier as possible. Products with existing national or international product safety standards have most hazards captured in this stage. Product safety engineers collect safety-related information from product recalls in the market, changes of regulatory,

Table 8.1 How product safety is integrated into a stage-gate process

Stage	Product safety activity	Purpose
Stage 1: idea, discovery, scoping	PHA/DFMEA	To identify potential hazards and regulatory requirements relevant to the product and define product safety requirements
	Regulatory requirements	
	Product safety requirements	
Stage 2: business case	Update PHA, DFMEA, and product safety requirements	To ensure all potential hazards and regulatory requirements are considered and captured in product safety requirements
Stage 3: development	Hazard analysis	To evaluate hazards relevant to the product and ensure these hazards are designed out or reduced to an acceptable level at the development stage
	DFMEA	
	PFMEA	
	Control plan	
	Design review	
Stage 4: testing	Product safety test/certification	To evaluate whether the product meets all predefined product safety requirements and regulatory requirements and whether the product is considered safe
	Reliability/durability/life test	
	Consumer use test (field test)	
Stage 5: launch	Final product safety review final design review	To evaluate whether the product can meet product safety requirements consistently and whether it's considered safe with the changing requirements on safety in the market
	Batch test/review	
	Post-launch review	
	Feedback from consumers on product safety-related concerns on the product	

customer complaints, consumer injuries, and consumer reviews on relevant products on the Internet and incorporate them with the results of PHA and DFMEA to define the company's own and more advanced product safety requirements. This is especially important for complicated products as changes in later stages will be very costly or even impossible. Product safety engineers also participate in preliminary design reviews and concept reviews. If any of the identified hazards are dangerous or unavoidable, the project should be put on hold or killed unless alternative solutions are found to reduce the hazard to acceptable levels.

In stage 3, the core development phase, design engineers hone out any remaining hazards already identified in stage 2 or surfacing in stage 3. Once physical products are available as prototypes, product safety engineers conduct formal hazard analysis, identifying potential hazards in normal use, abuse, and misuse under various conditions and environments. Injuries can be due to mechanical, thermal, chemical, and radiated exposure. Therefore, special attention is being paid to all moving parts, parts generating heat, and hazardous materials. Product safety engineers also participate in FMEA and design reviews in this stage. The product safety requirements, FMEA, and the control plan are live documents which are reviewed and updated frequently.

In stage 4, various tests (such as lab test or field test) are carried out according to the control plan (or test plan) to verify whether the product meets the requirements of functionality, performance, safety (and regulatory requirements), reliability, and durability. For products that need to be certified before launch, products are sent to certification bodies for testing and evaluation. The product safety review team reviews the test results (both internal and external) in accordance with product safety requirements and the control plan defined earlier and again participates in intermediary or final design reviews. The product can only go to next stage once all requirements are satisfied or hazards are reduced to an acceptable level.

In stage 5, when the product is transitioned to production, the quality team ensures that critical-to-safety processes and characteristics are controlled properly in accordance with the control plan. Normally batch tests and pilot runs are carried out at this stage. Post-launch reviews are conducted to review any remaining issues or hazards or new issues identified during manufacturing. Feedback from field tests (if still ongoing) and feedback from markets are continuously collected and reviewed by product safety engineers who decide on any follow-up action. Product safety requirements, FMEA, and control plans are updated based on these findings and critically important for improving future hazard analysis and product safety reviews.

8.4.2 Roadmaps for Manufacturers to Improve Product Safety

Manufacturers can be grouped into four basic types of firms based on two analytical dimensions: safety-oriented product and safety strategy/culture and NPD process capability (Fig. 8.2). This yields four types of firms in terms of product safety management: “troubled,” “anxious,” “confused,” and “best performers.”

“Troubled” Manufacturers that rate low on both product safety strategy/culture and NPD process capability (i.e., they pay little attention to product safety and have little capability to manage product safety in the NPD process) are classified as “troubled” or a “problem child.” These are normally small companies (e.g., small manufacturers or traders) in the industry which mainly compete on low cost. They do not have much knowledge and focus on product safety. They purely rely on third-party lab testing to ensure regulatory compliance. Normally, product safety performance of these firms is poor. To escape this classification, manufacturers would need to establish a product safety-oriented strategy, allocate necessary resources, and improve their capability to manage product safety.

“Anxious” In firms that are categorized as “anxious,” the top management pays high attention to product safety and allocates resources to manage product safety, but they do not have good NPD process capability and know-how to manage product safety (yet). These companies are “anxious” to improve product safety, but they lack the skills and means to improve product safety performance of their own NPD. Firms in this category need to improve their technical competence, e.g., recruiting product safety engineers who have rich experience on the product

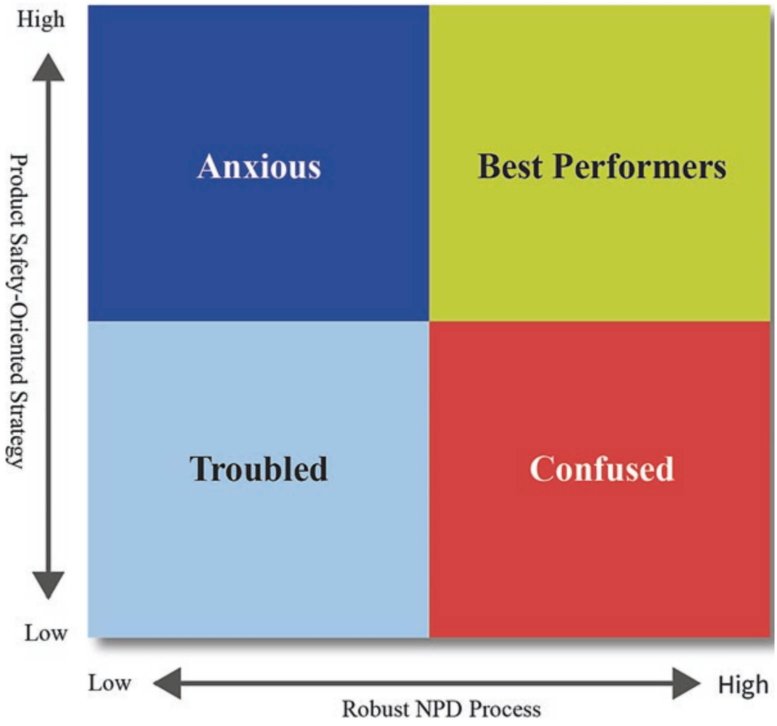


Fig. 8.2 Four types of companies on product safety management

category and good knowledge on regulatory standards, hazard analysis, and product safety management system.

"Confused" Manufacturers defined as "confused" normally have good experience and capability to manage product safety in NPD, but they do not have a clear product safety-oriented strategy or culture. Therefore, employees do not know where they are heading in terms of product safety, i.e., they are "confused." Although they have the skills and know-how to manage product safety well, they are not always giving priority to product safety. Hence, the product safety performance of these companies is inconsistent. The top management in this type of firms needs to cultivate a safety-first culture by defining a clear product safety-oriented policy and strategy to ensure product safety is always given a high priority. The case of Samsung's recall of Galaxy Note 7 below is a good example for this category.

"Best Performers" The fourth type of manufacturers is classified as the "best performers" or "world-class companies." These companies have a product safety-first strategy and culture and world-class NPD process integrated with robust hazard management systems. They have strong quality teams to manage product safety. Normally, this type of companies has very good product safety performance, which translates into a good market reputation. The case of Goodbaby strollers is great example in our sample.

Case Study 1: The Most Short-Lived Samsung Smartphone: Galaxy Note 7
The Galaxy Note 7 was one of Samsung's most high-profile smartphones. It is an evolution of Galaxy Note 5 and inherited hardware components and improvements from Galaxy S7 such as the restoration of expandable storage and IP68 water resistance. It also added new features such as a dual-sided curved display, support for HDR (high-dynamic range) color, and others. The Galaxy Note 7 received very positive reviews from critics on the quality of its construction, HDR support, and its streamlined user interface. TechRadar complimented that its "rich-looking, glass-and-metal-fused design" would "really wow people who are upgrading from those old [other smartphones]." Demand for the Galaxy Note 7 was high from its launch, breaking pre-order records in South Korea and causing international releases to be delayed.

Galaxy Note 7 was launched on August 19, 2016 (about 1 month ahead of Apple's iPhone 7), but after just 2 weeks, Samsung suspended sales of the phone and announced an informal recall after having received complaints that the phone generated excessive heat and caught fires. A formal US recall was announced on September 15 by CPSC based on 92 reports of the phone overheating in the USA, including 25 reports of burns and 55 reports of property damage. Samsung exchanged the affected phones with a version of the same phone that used batteries from a different supplier. However, after incidents reported that these replacement phones also caught fire, on October 10, Samsung recalled the Galaxy Note 7 worldwide and permanently ceased production of this device on October 11. This recall affected all of Samsung 2.5 million Galaxy Note 7 phones. It is reported that 112 Galaxy Note 7 phones had caught fire in the period of only 1 month after the initial product launch. This recall hit Samsung's business severely; Credit Suisse analysts estimate that Samsung lost at least US$ 17 billion in revenue as a result of this recall.

Samsung conducted an in-depth investigation of the causes of this problem and revealed that the first recall was due to a design flaw that caused electrodes on the top right of the battery susceptible to bending, weakening the separation between positive and negative tabs of the battery, and thus leading to short circuits. The issue with the replacement units was due to a manufacturing error introduced after Samsung's second supplier ramped up production to meet demand as the sole Note 7 battery supplier.

Technically, these two root causes are not insurmountable and can be fixed. But the damage had been done to the reputation of product and the trust the market placed into Samsung. These problems should never have occurred in the first place. If the product had been tested and evaluated comprehensively before launch, Samsung should have identified the issues easily. What went wrong with Samsung's NPD process and quality assurance system? Why did the Samsung quality control overlook such an obvious issue?

An analysis by Reuters (2016) provides answers to these questions: starting in 2015, Samsung had brought forward the launches of its Galaxy S and Galaxy Note series models by up to a month, in order to be able to release its products ahead of the scheduled launch times of its main rivals. This strategy had been very successful resulted in additional stress on the supply chain and on manufacturing. This induced rush raised concerns that Samsung cut corners in quality testing. According to Reuters (2016), a key observer and expert of this case, Professor Chang Sea-Jin said that:

> *Samsung might have over-exerted itself trying to pre-empt Apple, since everybody knows the iPhones launch in September… It's an unfortunate event; it feels like Samsung rushed a bit, and it's possible that this led to suppliers also being hurried.*

Counterpoint analyst Jeff Fieldhack shared the same view (Reuters 2016):

> *I believe they were trying to create a similar effect by beating Apple to market by (about) a month, too… Very often, lab times and testing periods are shrunk to expedite approval and time-to-market of key devices. It is possible all charging scenarios were not thoroughly tested.*

A Samsung executive who declined to be named told Reuters even before the recall announcement (Reuters 2016):

> *Our production engineers and managers are extremely experienced, and if you ask them to find a solution to adopt a design change, they'd promptly bring things under control. But even that capability is under growing strain, as we try out new materials and everything is on a very tight schedule.*

It seems clear that the root causes for the Galaxy Note 7 disaster is Samsung's prioritizing time-to-market over product safety. Quite obviously, with 70,000 engineers and a technology leader in the industry, Samsung had all the capabilities and resources to address such an issue upfront. However, what they do not have (or take) was time. When a safety-first strategy and culture is missing, it is impossible to reliably guide the organization in this direction. It does not matter whatever capabilities and resources the firm may have.

This was an extremely hard lesson for Samsung (and all organizations) to learn. After the recall, Samsung not only assured its commitment to quality and safety but also changed many internal innovation processes to ensure quality and safety always come first. They developed a comprehensive eight-point battery safety check, formed a battery advisor group, and improved battery safety standards (Samsung 2017). Here are excerpts from what Samsung posted on its website after the recall:

- Committed to Quality
  We learned from the Galaxy Note 7 issues and have made changes as a result. From reassessing every step of our smartphone manufacturing process to redesigning our quality assurance program, we are committed to implementing every learning to ensure the quality and safety going forward.
- Quality First

We’ve improved process throughout the company to make sure quality and safety always come first.

- Eight-Point Battery Safety Check
  We developed an extensive battery check protocol to ensure safety of the battery from component to complete device:
  - Durability Test: It starts with enhanced battery testing, including overcharging tests, nail puncture tests, and extreme temperature stress tests.
  - Visual Inspection: We visually inspect each battery under the guideline of standardized and objective criteria.
  - X-ray: We use X-ray to see the inside of the battery for any abnormalities.
  - Charge and Discharge Test: The batteries undergo a large-scale charging and discharging test.
  - TVOC Test (Total Volatile Organic Compound): We test to make sure there isn’t the slightest possibility of leakage of the volatile organic compound.
  - Disassembling Test: We disassemble the battery to assess its quality, including the battery tab welding and insulation tape conditions.
  - Accelerated Usage Test: We do the intensive test simulating accelerated consumer usage scenarios.
  - $\triangle$OCV Test (Delta Open Circuit Voltage): We check for any change in voltage throughout the manufacturing process from component level to assembled device.
- Multilayer Safety Measure
  We also improved the safety standards of our batteries, from hardware design to software protection.
- Battery Advisory Group
  We have invited a team of experts from academia and research centers so they can continue to provide us with their objective analysis to ensure the safety of the battery.

Case Study 2: 100% Safe Products: The Case of Goodbaby Strollers
Goodbaby Child Product Co., Ltd (Goodbaby) is not just one of the top performers in our firm sample, it has achieved 100% safe products—as measured by zero product recalls over our research period of 14 years (1999–2013). Zero product recalls may be easy to reach if you are a small niche player in a nonconsumption market, but as the largest stroller manufacturer in the world (with a combined 35% market share in the USA, Europe, and China), Goodbaby is operating in a fickle consumer market: safety-sensitive parents as customers and infants with low safety awareness make for a recall-potent consumer base. Not surprisingly, millions of strollers from even the most respected brands are being recalled every year for numerous safety reasons. However, Goodbaby managed to avoid even a single recall. How did they achieve it? What sets Goodbaby apart from many of its less fortunate competitors is how they manage product safety in the NPD process.

First of all, Goodbaby is not your average durable juvenile products company. With a staff of more than 300 R&D employees in 7 R&D centers worldwide, they apply some 500 patents per year and launch around 400 new products—more than one per day. They invested more than US$7 million to build one of the most advanced laboratories in the industry for product quality and safety testing, including car seat crash testing facility, and labs for chemical testing, biological testing, and mechanical testing. They also assembled a team of more than 50 experienced quality engineers to establish product safety standards not only at the company level but also at national and international levels. They participated in national standards settings in the USA, Europe, Japan, and China, with more than 80% of the national industry standards in China established by them. To most outsiders this industry appears low-tech, but engineering innovation has been at the core of Goodbaby from the start. Goodbaby's CEO and founder Z.-H. Song created the first baby stroller patents to start the company; he still retains an office within the main R&D building and personally reviews the progress of every single new product in the pipeline. Based on the principle of "caring for children," Goodbaby promotes "product safety first" across the company and has established product safety KPIs (key performance indicators) for all relevant departments. Its incentive system links employee variable bonuses to product safety performance and quality at all levels: about 40% of a shop floor operator's pay is linked to his or her performance on product quality and safety, and the performance and resulting pay are being updated and published daily on a board in front of each assembly line for every single operator.

Goodbaby's product safety committee includes the vice president of quality (as its chairman), the vice president of R&D, and senior members from engineering and the legal department. The committee determines product safety policies and procedures and makes final decision on product safety issues. A product safety team comprised of engineers from quality, R&D, and product engineering, and led by design quality engineers (DQEs) with in-depth knowledge on the product safety regulations, product safety standards, and product safety management methodologies, and reviews all projects for product safety concerns. The DQEs offices are also located in the R&D center. The DQEs actively participate in national or international product safety standard establishment or revision, and they monitor regulatory changes and product recalls in the markets and publish monthly reports to all relevant employees. All members of the product safety team are well trained for their safety jobs and have to sit for exams on relevant product safety standards and product safety management tools such as PHA and FMEA. Independent of the R&D teams whose work they evaluate, they carry out hazard analysis (PHA, DFMEA, PFMEA, etc.) and product safety review at each stage for each project. Based on hazard analysis (normal use, misuse, abuse analysis, and field test), relevant product safety standards, and observed experiences, they define internal product safety requirements for each product, which, in most cases, are much more stringent than national/international product safety standards. For example, the dynamic test requirement for a Goodbaby stroller is twice as strong as the European standard and four times stronger than the Chinese standard. The company has also developed a unique real walking test lab to simulate consumer use on various road conditions from around the world. Every newly developed stroller must pass a 375 km real walking test on this track. The product safety team has the power to stop or kill a project, if it finds unacceptable product safety risks.

By persistently pursuing total safety in all its processes and products, Goodbaby has managed to avoid any recalls for any of the strollers it has designed for the 14 years in our research period, and more and more of its customers are now shifting the early concept and development work away from their internal design teams to Goodbaby.

Goodbaby's excellent performance on product quality and safety was also recognized by the visit of US CPSC chairman Inez Tenenbaum in 2011 who toured the company, its factories, and its design departments. She was so impressed by Goodbaby's safety culture, quality system, and practices that she invited Goodbaby to participate in the revision of the US stroller standards. As of the time of writing, Goodbaby has won all quality awards for which categories it was eligible to enter, including the China National Quality Award and the Asia Pacific Quality Award. After a factory tour, world-renowned quality guru Dr. James Harrington, past president of the American Society for Quality (ASQ) and the International Academy for Quality (IAQ), commented that this firm

> *…is one of the best ones that I have been to in a long time. You set a hard standard for others to follow.*

In an article in the US quality digest magazine (Harrington 2012), he remarked that the founder and CEO of Goodbaby Z.H. Song:

> *…made the quality of his product his personal responsibility, and he sets a role model that few CEOs in any part of the world can match. This kind and unassuming man is the heart of the quality movement at Goodbaby. Song … has made Goodbaby stand out as a benchmark for other organizations around the world.*

In review of Goodbaby's NPD practices, the following "must dos" improve product safety through NPD:

1. Create a product safety-oriented policy and procedures.
2. Allocate necessary personnel, financial, and intellectual resources to manage product safety.
3. Cultivate a "safety-first culture" companywide.
4. Make sure your process is robust and complete with independent product safety review/hazard analysis/FMEA at each stage.
5. Establish a product safety team and empower it to make decisions on product safety.
6. Train all technical employees on relevant product safety standards and safety management methodologies.
7. Participate in establishing national or international product safety standards to push regulatory requirements.
8. Establish a product safety management system covering the whole product life cycle.

9. Collect product safety information (e.g., recalls, injuries, complaints, change of regulations) from the field and the Internet, provide feedback to all relevant employees, and integrate this information in the knowledge management system and hazard analysis process.
10. Establish an incentive system to link product safety performance with the performance of relevant employees.

8.4.3 Summing Up: What Can Go Wrong and How to Emulate the Best

Establishing product safety policy and procedures and training employees on safety standards, safety methodologies, and practices are actually quite easy. Most companies fail in the execution of their own safety-oriented policies and strategies in the daily routines: Top management favors cost and schedule over product safety in decision-making; product safety management is not equipped with enough resources in staff, finances, and equipment; hazard analysis and product safety reviews are conducted superficially, incompletely, and not robust enough; and product safety performance is not linked attractively with the KPIs of the relevant employees. If the top management does not "walk the talk" and does not show genuine, daily commitment to product safety, the efforts to improve product safety are in vain.

Early warning signs of coming product safety issues are the following:

1. The company focuses on schedule and costs and overlooks product safety.
2. The quality team has no authority to make decisions on product quality and safety issues.
3. The company has no knowledge on the product and its engineers are incompetent to conduct hazard analysis.
4. The company focuses on minimum requirements on product safety without safety margin (e.g., just barely meeting regulatory standards).
5. The company does not conduct hazard analysis (e.g., foreseeable misuse, abuse analysis) and product safety tests or reviews.
6. There is no proper quality management (or product safety management) system in place.
7. Identified hazards during misuse, abuse analysis, lab test, or field test are not addressed.
8. Product safety issues have already been previously reported on similar products.

Although there are normally different product safety standards for different markets, firms should not use double standards for different markets, especially for known hazards. Firms should establish internal standards by considering various hazards identified in different national standards to ensure safe products.

Of course, it is impossible to completely eliminate all risk of accidents, but if you are serious about protecting and caring for your customers, then you must build product safety into new product development processes from the start, and you must implement a product safety-oriented strategy nurtured by a strong product safety-first culture to make this effort sustainable. A safety-first-oriented culture will also act as an internal control mechanism to detect and improve any NPD activities not resulting in high product safety. There are no excuses for companies not to put their best efforts behind product safety. Consider again Goodbaby: this company is based in China, a country not necessarily known for a stellar product safety record or a high degree of R&D intensity. But not only did Goodbaby achieve 100% product safety in a mass market, it also did so well in establishing and integrating product safety into its DNA that the US-based CPSC asked to visit and investigate—and the CPSC walked away with the recommendation to adopt Goodbaby's standards for American companies. Let's put safety into our product innovation: we owe it to our customers and the society.

Chapter 9
Conclusions and Limitations

9.1 Introduction

Based on the hypothesis testing and triangulation analysis of the quantitative and qualitative findings in previous chapters, this chapter summarizes the conclusions, the academic contributions, and limitations of the research and proposes future research directions.

9.2 Conclusions

This study investigated a crucial but poorly understood component of industrial activity: product safety in product innovation. SEM analysis explained the relationships between product safety strategy, product safety culture, concurrent engineering, NPD process, and product safety performance. This study was grounded on four theoretical models—Schein's conceptualization of culture, the MBNQA model, the EFQM model, and Cooper-Kleinschmidt's innovation diamond—which helped to enhance the understanding of the relationships among the five constructs. A conceptual model for product innovation and product safety was developed and tested with data collected from the juvenile product industry. Semi-structured in-depth interviews with 40 senior managers worldwide provided great insights on the relationships among the five constructs as well as on how product safety in NPD is managed in the juvenile product industry. Based on the SEM results and the qualitative findings, the following conclusions were drawn.

First, this study demonstrated a chain effect among the five constructs. The top management is the driver of product safety and dominates product safety strategy, which in turn influences a firm's group-level product safety culture in NPD and the NPD process practices that the firm adopts. The product safety culture influences concurrent engineering and NPD process, whereas NPD process determines product

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safety performance. Both product safety strategy and product safety culture have very strong indirect effects on product safety. Concurrent engineering shows a weak effect on the NPD process and has no direct effects on product safety performance. The relationships and best practices were explained in detail elsewhere, but here are the main highlights for the five constructs:

- *Product Safety Strategy:* If the top management puts its weight behind product safety by establishing a safety-first culture supported by corporate policy and the necessary resource allocation, the rest of the organization will follow, and the firm will manufacture safer products. Senior management and dedicated quality teams are empowered to design and implement safety-oriented NPD processes and practices. The top management deals with product safety proactively and responsibly.
- *Product Safety Culture:* A product safety-oriented culture also leads to improved product safety; it can even be used as leading indicator for product safety performance. The results of SEM analysis demonstrated a very strong support for the positive direct relationship between product safety culture and concurrent engineering and the NPD process—especially on concurrent engineering. At least in the juvenile product industry, product safety culture appears to be more important for product safety performance than mere technical solutions as the products are less complex and most product-related hazards are already known.
- *Concurrent Engineering:* In our study, CE had no direct relationship with product safety performance. This is in contradiction to existing claims by researchers and safety experts who stressed that safety professionals should be involved in the design at the earliest possible stage and recommended the use of design for safety and concurrent engineering as a mechanism to ensure product safety. Of course, CE is still an important contributor to improving overall NPD productivity and innovation, and early involvement of product safety/quality engineers in the NPD process might be helpful to address product safety, but at least in the studied industry, the use of CE has no direct relationship on product safety performance.
- *NPD Process:* As the determinant factor for product safety, the NPD process is the only variable in the conceptual model that has direct impact on product safety performance in product development. This supports the EFQM model in which process management is the only immediate factor leading to operational performance. We found that product safety performance is heavily determined by whether a firm has implemented an effective and efficient idea-to-launch process which is well crafted and robust, emphasizes the quality of execution, and integrates with professional safety management methodologies such as hazard analysis and product safety reviews.

Overall, looking at the total effects between product safety strategy, product safety culture, concurrent engineering, NPD process, and product safety performance, NPD process has more pronounced direct impact on product safety than other factors; concurrent engineering has less impact on product safety than all other variables. Although there is no direct effect between product safety strategy, product safety culture, and product safety performance, their strong indirect effects cannot be overlooked. It is also clear that product safety strategy, product safety culture, and concurrent engineering affect product safety through the NPD process. Even if the firm has great product safety strategy and positive product safety culture, it may not necessarily achieve better product safety performance if the NPD process is not well managed. Therefore, although different variables have different effects to product safety, a firm needs to have a holistic and systematic perspective by integrating all key factors in the model to achieve best results.

Second, this study showed that besides manufacturers, governments and consumers also play important roles in ensuring product safety. This conclusion mostly derives from the qualitative analysis. Although most of the best performers claimed they had more stringent requirements than the regulatory requirements, the goal to improve overall product safety performance in the market remains elusive in the absence of government intervention and consumer's (and retailer's) focus on product safety.

Third, the best performers do not rely on applying only one practice to achieve better product safety performance. Instead, they implement most of the practices simultaneously, systematically, and thoroughly. Firms should systematically adopt and adapt the 34 best practices identified in Chap. 6 (see, e.g., Table 6.1). Merely focusing on a few practices does not have systematic impact on product safety performance.

Fourth, manager perceptions on the five ideal constructs (product safety strategy, product safety culture, concurrent engineering, NPD process, and product safety performance) are not influenced by contextual factors such as firm origin, firm size, target market, and R&D intensity. However, manager perceptions on the five actual constructs are affected by target market and R&D intensity. Therefore, "Made in China" is not necessarily the blame for the current product safety issue in the market; it is individual companies ("bad apples") that create the problem; and it has less to do with national firm origin.

Finally, this study reveals a big gap in the approaches advocated by the safety community and actual industry practices on how to manage product safety. The safety community tends to focus on the nitty-gritty aspects, e.g., "bits and pieces," and overlooks the overall impact in the bigger environment, e.g., the "big picture." Consequently, some practitioners could assume that the claims of the safety community are irrelevant and use this assumption as an excuse for not adopting recommended practices and tools. Although the same fundamental principles for safety management might apply to all industries, adaptation and effectiveness for each industry may be different. To achieve better results, the decision on what should be adopted and adapted is context dependent.

9.3 Academic Contributions

This study has helped our understanding of the impact of NPD and other contextual factors on product safety and various relationships between key factors of the underlying model and introduced and tested a suitable research framework. It provided implications on theory building and theory testing with robust methodologies combing SEM, group analysis, in-depth interviews, and data triangulation. Specifically, this study contributes to the literature on NPD management, product safety management, and quality management in the following ways.

First of all, this study developed and introduced a solid research framework for product safety management in NPD which integrates organizational context and product innovation practices. A survey instrument and a product innovation-product safety model have been tested as a foundation for further study of product safety in NPD in different industries and different countries. New dimensions such as external context, product complexity, manufacturing, and supply chain management can be added to the current framework to further assess their effects on product safety.

Second, previous literature on NPD management has focused on NPD practices and their implications on overall financial success of product innovation. However, it did not address how product safety is best achieved as a result of optimized NPD policies and practices. This study supplements the previous NPD management studies by integrating the product safety dimension as a dependent variable and incorporating product safety management practices into the NPD process. Our product innovation and product safety model represents one of the first conceptualizations to empirically investigate the implications between product safety strategy, product safety culture, concurrent engineering, NPD process, and product safety performance in a rigorous fact-based fashion (using e.g., structural equation modeling). It provides a clear understanding on the relationships among the studied five constructs.

Third, previous product safety literature mainly focused on technical aspects (such as FMEA, FTA, HACCP, etc.) and principles of safety management. The majority of these studies were conceptual, prescriptive, and anecdotal. Solely focusing on the technical aspect may not be effective in improving product safety at all as the key factors that drive product safety as part of the “big picture” may be overlooked. Although safety culture has been extensively scrutinized in safety management literature on occupational health and safety and was recognized as a critical factor affecting safety performance, it had been rarely included in studies on product safety. By incorporating product safety in the broader context of organization and integrating strategy and culture with the safety management techniques and NPD practices, this study has gained a systematic and holistic view on product safety and provided empirical evidence to support some of the prescriptions in the safety literature.

Fourth, previous literature on product quality largely overlooked the significance of product safety as an independent dimension. Even the most widely used product quality definition (Garvin 1987) failed to address product safety explicitly, and most quality management literature overlooks product safety. This study provided new insights on this crucial but poorly understood dimension for product quality.

Fifth, this study also advanced scientific research and understanding of general innovation and product development management. The importance of product innovation in the industry is undisputed. However, if product safety is not adequately considered and integrated in the product innovation process, product failures and product recalls will be unavoidable. By looking at the factors that affect product safety in the innovation process, this study shed new light on a holistic view of product innovation.

Finally, this study has applied a wide range of methodologies available in academic research to develop and test theories. It is a good example for how to build and test theories combining robust methodologies such as structural equation modeling, confirmatory factor analysis, multi-group analysis, in-depth interview, observation study, and triangulation analysis. This study started with the identification of a gap in the intersection of NPD management, product safety management, and product quality management and built theories in the overlap of these three different disciplines. The methodologies applied for theory testing have shown a very thorough analysis from different angles with rich data collection. The causal relationships tested through SEM were verified with in-depth interviews and months of observation data. The robust methodologies and rich data collection have ensured the reliability and validity of the results in this study.

9.4 Limitations

Due to the nature of the study, several limitations should be considered in interpreting the results and conclusions of this study. First, as this is a cross-sectional survey-based study, caution needs to be taken in attributing cause-effect relationships across companies. A future longitudinal study should provide stronger confirmation of presumed cause-effect relationships.

Second, the survey was mainly conducted in two conferences organized by the CTA and limited by the network of the authors. Hence, the sample size is relatively small. Although the major firms in the juvenile product industry participated in the survey, it would be preferable to conduct the survey in a much larger scale and using a more representative method.

Third, the results of the qualitative investigation are heavily dependent on the skills of the researcher and can be influenced by the researcher's personal biases and idiosyncrasies. The researcher's presence during the in-depth interview can affect the interviewee's responses as well. Although care has been taken during the investigation to minimize the limitation of the qualitative research approach, we cannot statistically generalize the findings from the in-depth interviews due to the limitations of this methodology.

Finally, this study mainly focuses on the juvenile product industry. Although we included firms worldwide and different nationals in the survey, the in-depth interviews, and the case studies (including cases from industries other than the main focus) to enhance the generalizability of the findings, care need to be taken to use the results to explain the dynamics in other industries and other countries.

9.5 Future Research

First of all, the underlying model should be retested with new datasets, as always advisable especially for newly created measurement and structural models. While this study has provided a clear relationship among product safety strategy, product safety culture, concurrent engineering, NPD process, and product safety performance, further empirical work is needed to replicate and retest the product innovation and product safety model in other industries and other countries.

Second, good models allow future research to be built on them. Future research should also explore how other dimensions (such as complexity of products, organizational culture, and the manufacturing environment) moderate the product innovation and product safety. Although the effect of group-level product safety culture has been evaluated in this study, we did not evaluate company-level product safety culture effects on product safety.

Third, future studies should also further explore the effect of external contextual factors (e.g., government, consumers, regulations, competition) on product safety in NPD and how these factors moderate the product innovation and product safety.

Finally, as manufacturing issues account for about 33% of product safety issues in the market, future research should investigate the effects of manufacturing practices and supplier management practices on product safety through adding relevant constructs to this study model.

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