Tampere University

Eda Ülkü Şahin

# IMPROVEMENTS FOR PRODUCT SAFETY REQUIREMENTS COMPLIANCE MANAGEMENT PRACTICES

## Case Study: Automotive Battery Industry

Master of Science Thesis
Faculty of Management and Business
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# ABSTRACT

**Eda Ülkü Şahin**: Improvements for Product Safety Requirements Compliance Management Practices–Case Study: Automotive Battery Industry
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Recently, advancements in technology improve product safety considerations globally. High-tech equipment and tools become more accessible for organizations to manage manufacturing effectively and safely. In this way, they focus on producing safer products that are qualified for public consumption. With the introduction of clean energy technologies on roads, product safety discussions about electric vehicles increased simultaneously. Especially for globally operating battery manufacturers, demonstrating their compliance with international regulations, standardizations, and customer requirements poses difficulties. Unreliable and inadequate compliance management processes may obstruct operations and decrease competition capability in the global market.

Throughout this thesis, safety-related requirements compliance inside an EV battery manufacturer company is investigated in accordance with a combined compliance management model. This model comprises the following steps: identifying and discovering the requirements, interpreting the requirements, identifying possible changes required in products or operations, identifying and evaluating compliance risks, compliance decisions specifying a method of compliance, communication, implementation, and evaluation and monitoring. In this thesis, safety-related requirements cover regulations, legislations, standards, and customer-specific requirements. A qualitative research approach with a descriptive case study is adopted in the thesis in order to provide in-depth outcomes related to the research topic.

The findings from investigation of literature and semi-structured interviews are utilized in the process of discovering the company's current status and encountered problems in management of compliance with product safety requirements. With the help of the findings and examination of the best practices regarding compliance management processes, improvement opportunities for the EV battery manufacturer company are recommended.

The findings of the thesis show although the current applications of the case company in management of compliance with product safety requirements are not in poor quality, there still exist some parts to improve their insufficiencies and missing sides. Need for more skilled people for interpreting and comparing the requirements with the company's operations, confronting language differences in discovering global requirements, not having an efficient communication process, and unclear responsibilities are some of the findings of the research as improvement needs.

This thesis proposes possible enhancement activities for the company by exploring literature, and previously conducted research related to best practices for management of compliance with product safety requirements. Different solutions are listed as following: management system adoption, efficient documentation, regular compliance checks, global design file, benchmarking, external support, requirements follow-up by product safety people, platform to reach all customers, international networking, product safety and compliance plan, attending to standards drafting processes, comparison between different market standards, global product committee, defining common minimum requirements, and continuous training for people involved in product safety.

Overall, this study contributes to the company and academics in the context of managing compliance of product safety requirements for globally operating manufacturers by investigating previous studies, regulations, standards and an EV battery manufacturer company.

Keywords: Product Safety, Compliance Management, EV Battery Technology, Automotive Industry, Requirements Management

*To my one and only Yasin, my Patronus against the world…*

# PREFACE

Two years ago, I was wondering how it feels to write a preface to my master's thesis. Now it is the moment, and I couldn't imagine my current feelings back on those times. It has been a long journey for us to relocate another country with completely different culture, language and obviously weather in order to pursue my master's degree in Finland. When I look back where we started (and what we finalized for this start), I couldn't be more grateful for everything I lived through.

This journey couldn't have gone without the support of precious people. First, I would like to thank Valmet Automotive for this valuable and compelling opportunity to collaborate with them throughout my thesis. Especially, I want to thank Soili Kulkki for sparing time for me despite her occupied calendar, Kimmo Lehtonen for giving me the chance to start this journey, and Tim Zander for his valuable feedback. Also, many thanks to all the interviewees from Finland, Germany, and Poland for their help.

Being a graduate of Tampere University is a privilege. I am very thankful to gain different perspectives about the education system, student life, many opportunities for international students, and of course interesting and challenging courses. Thus, I would like to express my greatest gratitude to my supervisor Professor Jouni Kivistö-Rahnasto and to SAFER teachers for guiding me in the master's degree process and thesis research with valuable feedback. I couldn't even find where to start without their support.

Many thanks also go to my dear family, Aydın, Şükran, Emel, and Mustafa who always supported me throughout my life despite the distance. Special thanks to my beloved little niece Melis who cheered me up every time and brought joyful moments without even knowing what I was doing. Also, I want to thank all my friends and relatives wherever they are for believing in me and winding me up.

Finally, my biggest appreciation is for my lovely hubby Yasin. He was always there for me, fully supported me, encouraged me, and picked me up whenever I stumbled. He is my source of motivation, and I couldn't complete this journey without having him by my side. It was him who made each step bearable and enjoyable.

Now, I am so happy, relieved, and excited to step ahead with wonderful memories, unforgettable experiences, and deep knowledge about my area of expertise. Not to mention, also with my '*teekkari cap'* next to me.

Turku, 25 April 2023

Eda Ülkü Şahin

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# LIST OF SYMBOLS AND ABBREVIATIONS

| | |
|---|---|
| ANSI | American National Standards Institute |
| AM | Acquaintance Meeting |
| AQSIQ | General Administration of Quality, Supervision, Inspection, and Quarantine |
| BEIS | Department for Business, Energy & Industrial Strategy |
| BEV | Battery Electric Vehicle |
| BMS | Battery Management Systems |
| CATARC | China Automotive Technology and Research Center |
| CATL | Contemporary Amperex Technology Co. Limited |
| CCPS | Center for Chemical Process Safety |
| CE | Conformité Européene |
| CEN | European Committee for Standardization |
| CENELEC | European Committee for Electrotechnical Standardization |
| CF | Cross Functional |
| CNESA | China Energy Storage Alliance |
| CP | Contact Person |
| CPSC | Consumer Product Safety Commission |
| DIN | Deutsches Institut für Normung (German Institute for Standardization) |
| EC | European Commission |
| EEA | European Economic Area |
| EFTA | European Free Trade Association |
| ESS | Energy Storage Systems |
| ETSI | European Telecommunications Standards Institute |
| EV | Electric Vehicle |
| EVS | Electric Vehicle Systems Business Line |
| EU | European Union |
| FMEA | Failure Modes and Effects Analysis |
| GB/T | GuoBiao/TuiJian (Chinese National Standards/Recommended) |
| GWh | Gigawatt-hours |
| HR | Human Resources |
| HSE | Health, Safety, and Environment |
| IATF | International Automotive Task Force |
| IBM | International Business Machines Corporation |
| IC | Interview Consultant |
| ICE | Internal Combustion Engine |
| ICT | Information and Communications Technology |
| IEA | International Energy Agency |
| IEC | International Electrotechnical Commission |
| ILO | International Labor Organization |
| IP | Interview Participant |
| ISO | International Organization for Standardization |
| JASIC | Japan Automobile Standards Internationalization Center |
| JASIC | Japan Automobile Standards Institute |
| JISC | Japanese Industrial Standards Committee |
| KATS | Korean Agency for Technology and Standards |
| LIB | Lithium-Ion Battery |
| METI | Ministry of Economy, Trade, and Industry |
| MIIT | Ministry of Industry and Information Technology |
| NAD | New Approach Directives |
| NC | Number of Consultants |
| NEC | National Electric Code |
| NERC | North American Electric Reliability Corporation |

| | |
|---|---|
| NFPA | National Fire Protection Association |
| NHTSA | National Highway Traffic Safety Administration |
| NI | Number of Interviews |
| OECD | Organization for Economic Co-operation and Development |
| OEM | Original Equipment Manufacturer |
| OPSS | Office for Product Safety & Standards |
| PHEV | Plug-in Hybrid Electric Vehicle |
| PSCR | Product Safety and Conformity Representative |
| PSE | Product Safety Electrical Appliance & Material |
| QHSE | Quality & Health, Safety, and Environment |
| REACH | Registration, Evaluation, Authorization and Restriction of Chemicals |
| RESS | Rechargeable Energy Storage Systems |
| RKS | Roof and Kinematics Systems Business Line |
| SAC | Standardization Administration of the People's Republic of China |
| SAE | Society of Automotive Engineers |
| SFS | Finnish Standards Association (Suomen Standardisoimisliitto ry) |
| SPICE | Software Process Improvement and Capability Determination |
| TÜV | Technischer Überwachungsverein (Technical Inspection Association) |
| UL | Underwriters Laboratories (Safety Organization) |
| UN | United Nations |
| UNECE | United Nations Economic Commission of Europe |
| VA | Valmet Automotive |
| VCM | Vehicle Contract Manufacturing Business Line |
| VDA | Verband der Automobilindustrie (Association of the Automotive Industry) |

# 1. INTRODUCTION

## 1.1 Background

In recent years, the introduction of lithium-ion batteries (LIBs) into the market increased activities to enhance cost and energy efficiency and battery performance. The improvements in battery technology paved the way for electrification in the automotive industry. Electric vehicles (EVs)'s potential of reducing oil dependency and negative environment impact caused by car emissions leads nearly all automobile manufacturers to start EV production with a rapid grow (Carey et al., 2010). In 2018, EV sales hit two million for the first time and overall EVs' sales climbed to 75% in the first quarter of 2022 compared to 2021 when sales were twice of the 2020 rates (International Energy Agency, 2022). By 2030, BEVs are estimated to make 81% of total EV sales based on analyses (Woodward et al., 2020). After 2030, the escalation will be even more due to the governmental sales ban of ICE vehicles (European Commission, 2022). This also creates rapid grow in battery manufacturers' production rate. A Finnish company, Valmet Automotive, delivered 400.000 battery pack units in 2021 while exceeding one million units in total in less than three years (Valmet Automotive, 2022a). Also, EV battery production rate will require 20 Giga factories (1 Gigafactory produces 35 GWh volume/year) annually for the next decade considering a rise to 6600 GWh in 2030 (International Energy Agency, 2021).

Rapidly emerging EV battery industry engenders challenges such as higher storage capacity, less charging times, long-lasting cell life, cost-efficiency, and battery safety on which this research will mainly concentrate (Karden et al., 2005). Especially, effectively managing global product safety requirements requires systematic approaches. EV battery producers must ensure their products comply with industry regulations and standards to justify safe utilization in the market. A safe product means not causing any harm to people with the intention of reducing the possibility of losses. To achieve this purpose, battery manufacturers must carefully monitor existent, continuing, and amended regulations throughout the entire lifecycle of the product. There exist guidelines framing product safety requirements for automotive industry and batteries (International Organization for Standardization, 2011; International Automotive Task Force, 2016). However, companies may encounter obstacles during collecting and handling country-specific instructions and predicting different costumer requirements when operating globally.

Currently, China dominates the lithium-ion battery market for EVs with around 60% of supply chain and Europe being the second-largest market (Baars et al., 2021). The upcoming new EU Battery Regulation will affect global trade (European Union, 2020a). Any manufacturers from United States, China, or South Korea will adhere to the new Regulation in order to be operated in the European region. Similarly, when the other countries update their policies, European players will need to comply with them as well. Since standards on battery safety and its supply chain activities are internationally unbalanced, manufacturers must adopt methodologies to hold proficiency amongst competitors.

Furthermore, operating globally will bring new customers from different industrial areas. To illustrate, battery manufacturers may have the ability to produce products for electric vehicles, also for aviation, space projects, missiles, marine vehicles, or elevator systems (Lemond, 2005). Entering a new market will require new quality demands, different operational and transportation scenarios, and changes in product design which mandate gaining knowledge about the customer expectations related to product safety. No company intends to lose customers due to unsafe products. Damage to reputation may also negatively affect long-term relationships and may even lead to bankruptcy.

The importance of compliance with safety legislation for a producer is acknowledged in the industry. Research and development are particularly critical for battery technology. Hence, increased production quality and efficiency, effective communication between divisions especially related to the requirement management are required. Managing and demonstrating compliance with the several product safety requirements such as EU Directives, international standards, local legislations, and customer specific requirements decreases occurrence of unwanted events caused by lack of product safety.

In this context, some studies have been performed from automotive manufactures' perspective. However, the analyses from the first-tier manufacturer' viewpoint are insufficient, which is important for the organizations that intend to become a Tier-1 manufacturer. Furthermore, although there exist compliance management tools, they lack the ability to investigate global approach in the perspective of suppliers (Vasara, 2019).

The untouched area of the research is to propose improvements for global product safety requirements compliance applications inside Valmet Automotive based on the best practices established from the scientific literature and on the experiences of contributors from the case company. Throughout the thesis, the researcher will analyze the existent solutions within the case company to resolve and coordinate product safety requirements' compliance in the global market.

## 1.2 Objectives and Research Questions

The purpose of this study is to understand how a globally operating EV battery manufacturing company manages product safety requirements compliance and how their current status can be improved for future activities.

More specifically, there are three objectives in this study.

A. Identifying what kind of practices embraced within the case company related to managing product safety requirements compliance

B. Investigating what kind of problems, the case company encounters in management of compliance with safety relevant requirements

and by evaluation of the outcomes of above objectives and scientific framework

C. Recommending possible ways to improve the company's operations for compliance management

Following four research questions are addressed to satisfy the research objectives:

1. What is the current state of the case company regarding product safety requirements management practices in the global framework? (Objective A)
2. What kind of problems does the company encounter in managing compliance with product safety requirements? (Objective B)
3. What are the most applicable procedures regarding product safety requirements compliance management? (Objective C)
4. How to improve compliance management practices of safety related requirements inside the case company? (Objective C)

Answering research questions will provide common knowledge about how the case company manages global product safety requirements compliance and about challenges they face during this process. Furthermore, analysis of the findings and literature survey will contribute to uncovering development opportunities for the company.

## 1.3 Research Process and Timeline

Performing this research study lasted approximately eight months between September 2022 and April 2023. The research activities and timeline are illustrated in Figure 1. Following the figure, each activity and milestones are explained thoroughly.

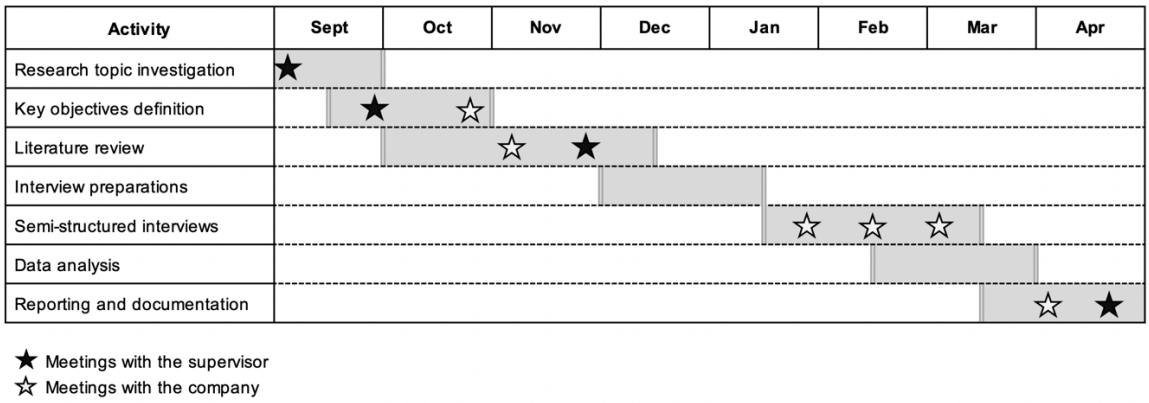


***Figure 1.*** *Thesis timeline.*

As can be seen from the timeline, the research is started by investigating a research topic in September 2022. The researcher also communicated with the supervisor about possible research topics during May 2022 and August 2022. However, these dates are not presented in the timeline due to the actual starting of the thesis project with the case company is September 2022.

There were two research seminars at Tampere University at the end of September and November 2022. In the first seminar, possible research topics and planned data collection were discussed. Based on the feedback from the supervisor, further modifications and plans are revised. Later, by searching the literature and collaborating with the company, the researcher defined the key objectives of the research. Then, in the second seminar, an advanced version of the research was offered. In meantime, the researcher discussed the scope of the study and how to cooperate with the organization and align with their needs during the meetings with related people in the case company.

Conducting literature review was the longest and the most compelling part of the study. Even though mainly three months of duration for literature survey exists in the timeline, the researcher review the literature whenever needed throughout the entire research process. Then, December 2022 passed mostly by preparing interview questions and procedures for how to conduct them. In addition, the interviewees were contacted, and their participations were scheduled.

Between January and March 2023, the researcher conducted semi-structured interviews and simultaneously prepared the collected data for further analysis. After obtaining the required qualitative data, the researcher started to analyze them. During this process, responses are examined based on the research objectives and questions to provide reasonable results. Finally, all the findings of the research were reported throughout the last two months of the timeline. To assess the outcome, the research was sent to the case company expert and the university supervisor.

# 2. THEORETICAL FRAMEWORK

## 2.1 Product Safety

As stated by (Rausand & Utne, 2009) the conception of product safety relates to implementation of engineering and management approaches, procedures, and methods to minimize hazard occurrence while maintaining effective operations and staying within budget and time limitations across the entire product life cycle. A safe product is as free as possible from the likelihood of death, injury, illness, or accident to people, property, equipment, or the environment as a consequence of utilization the product. According to (Zhu et al., 2016) product safety requirements and safety engineers should be integrated early on in product design to ensure manufacturing a safe product.

According to (Baram, 2007), new product development and industrial operations should be under the control of social factors such as marketplaces, governmental regulations, independent self-regulation, and tort liability doctrines. Development of a product by considering these social factors leads to an active reaction to risks and harm caused by unsafe products. Therefore, organizations must adhere to current and foreseen regulations concerning manufacturing safe products (Vasara, 2019).

In their study, Haefel and Westkämper (2014) emphasize the importance of regulations on product and process development. From the product safety viewpoint, manufacturers must accomplish three key responsibilities in favor of complying with legal requirements. The first one is the existence of technological achievements to build safer products. Reliability engineering activities and product testing are examples of technical responsibilities of an organization for product safety. The latter is the capability of establishing a safety culture inside the company. To illustrate, clear distribution of responsibilities and effective communication among related people should be developed. Finally, an organization must verify that their products conform with legal requirements. This verification demonstrates that the products are manufactured safely before they emerge into the marketplace (Marucheck et al., 2011).

Organizations should express compliance with legislation by identifying and interpreting the legal requirements in a way that relates to their products and services. Thereafter, they perform product development and testing practices by combining those requirements into their operations (International Organization for Standardization, 2014). The most efficient way to involve safety-related requirements from the beginning of a product design is utilization of information technology (Dowlatshahi, 2001). Implementation of

various safety tools such as PHA, FMEA, and FTA in the design phase yields increased safety and decreased product liability issues.

## 2.2 Importance of Product Safety

Improved competitiveness, lower warranty costs, reduction in product liability claims and recalls are the primary drivers for product manufacturers to offer customers safer products (Vasara, 2019; Polinsky & Shavell, 2010). According to (Chen & Hua, 2017), there is a profound relationship between product liability and market competition which are two important factors for increased product safety. In the trade market, competition between organizations to provide safer and high-quality products allows them to protect and enhance their market share (Dana & Fong, 2011).

Decrease in product liability claims is another important factor in product safety. Product liability is mainly manufacturers' financial and legal responsibility towards unsafe products (Epple & Raviv, 1978) As a result of producing harmful products and disregarding safety, manufacturers suffer extensive legal actions with enormous costs which may even lead to bankruptcy. To avoid experiencing these negative outcomes, manufacturers should invest in product safety (Dowlatshahi, 2001).

Moreover, product liability issues cause image losses from the customer perspective. Even though customers are unaware of the firm's effort for product safety, they can witness the harmful results of unsafe products (Chen & Hua, 2017). Changes in customer beliefs in their product are directly related to reputation concerns. Especially big-sized companies are affected by product safety reputation losses more than small companies due to their several product lines and deep-rooted business network (Polinsky & Shavell, 2010). Therefore, it becomes inevitable for companies to invest more in product safety in their operations.

Regulations regarding product safety are apt to be more forceful in the broader industries such as automotives, pharmaceutics, and airplanes compared to narrow ranged industries (Polinsky & Shavell, 2010). One argument for this situation is that higher sales rates influence higher populations hence, authorities act more responsibly considering safety regulations. The other argument is that widely purchased products receive more problem reporting and even recalls in case of any hazardous situations caused by the product. This circumstance opens the pave for obtaining more regulatory information.

In the automotive industry, total vehicle recalls rate tends to increase in the latest years as reported by National Highway Traffic Safety Administration (DOT DataHub, 2023). While it is possible to assume that the raised number of recalls is the outcome of unsafe

products, the real reason is the development of more stringent lawful expectations as well as existence of several demands from different customers globally (Haefele & Westkämper, 2014). Correspondingly, to avoid product recalls, manufacturers are obligated to satisfy various strict requirements simultaneously facing more sensitive and faster responsive governmental agencies around the world.

Additionally, automotive engineering operations have become more complex and their accelerated development cycles require improvements in learning and monitoring systems to prevent errors (Valmet Automotive, 2022). For example, introduction of electrified vehicles to the automotive industry requires producers focus on battery safety, safe storage of energy, understanding of chemical and electrochemical reactions, and preventing explosion of the battery during design, production, commissioning, aftersales and decommissioning procedures (Marcos et al., 2021). However, besides these difficulties from the perspective of manufacturers, customers still expect to purchase safe and reliable products. Several surveys examining customer behavior when selecting vehicles show that safety is always one of the top criteria (EY, 2021; Armstrong, 2022). Therefore, manufacturers should pay special attention to product safety in order to succeed in global market demand.

## 2.3 Product Safety in Global Operations

The safety of products that are circulating around the trade market is crucial for all customers at the same time as guaranteeing legislation, regulation and enforcement. Even though product safety is acknowledged globally and integrated into legislation, the essence and framework of them differ geographically. Therefore, a company is obliged to comply with both regulatory requirements and other specifications that the target market requires in order to operate worldwide (Stark, 2011).

### 2.3.1 Challenges in Global Operations

A globally operating company can face several challenges throughout its operations. Not to mention language and cultural differences; various legal landscapes, diverse customer expectations, different communication and technological sufficiency as well as differing environmental concerns are some examples of these challenges.

From the legal perspective, companies must demonstrate that their products are safe to transform, purchase, use and circulate within the market area in order to operate in the target market. For instance, it can be achieved by complying with European regulations and standards if the company operates in the European region. However, beyond the

EU, a European company may encounter obstacles while collecting and handling the regional information and specifications (Vasara & Kivistö-Rahnasto, 2015). Hence, companies must have the capability of understanding different product safety requirements, liability concerns, and compliance declarations.

Interpreting different customer specific requirements is another key factor that companies need to consider. When a company enters the international market, it must identify potential customers while building a reliable reputation to sell their products. Moreover, customer feedback must be received and analyzed regularly to foresee possible problems that may emerge in the future (Bergman & Klefsjö, 2010). Also, having dedicated personnel while receiving regular feedback from the customers predicts possible larger issues that may occur. Nonetheless, customer needs are wide and vary across countries and between different industrial areas. Therefore, companies are responsible for satisfying customer demands and their specific safety requirements with several enhancements on the product, services, procedures, or declarations to trade around the world (Sarathy, 2006).

A further challenge for organization is communicating the knowledge between regions. When operating around the world, companies have high numbers of employees, offices, facilities, and sales representatives. Accordingly, knowledge acquisition within the company becomes problematic when not handled effectively. In addition, if the company lacks the same technology competency level across all its locations, it creates uncertainties, difficulties in following operations, disturbances in operational pace and efficiency, and even incorrect steps.

### 2.3.2 Product Safety Requirements for EV Battery Production

Product safety represents a key for a successful market within the global automotive industry. It becomes more vital with the introduction of battery-electric vehicles as any failure of batteries may cause catastrophic results (Deng et al., 2020). To manufacture safe EV batteries, companies must demonstrate compliance with relevant product safety requirements.

Safety related requirements can be described as governmental regulations, international standards, codes of practices, guidelines, customer specific demands, internal safety exercises (Vasara & Kivistö-Rahnasto, 2015). Depending on the product's nature, those requirements can be specified as qualitative and quantitative (Murthy et al., 2008). To illustrate, while the amount of energy density for battery cells is written with numbers and scientific units, it can be required from the batteries to impact the environment at the lowest.

The pressure from governmental authorities about significance of environmental concerns, increasing the quality of the air, and avoiding oil dependency forces market increase of electrical vehicles solution (Rothe, 2015). In conjunction with governmental support on research and development of EVs, they reveal the compulsory input by describing the regulatory framework. Therefore, manufacturers consider governmental regulations as a fundamental part to build safe products (Baram, 2007).

Those regulations are strongly lawful and any failure while showing compliance with them may result in breaking the law. Accordingly, Baram (2007) argues that companies can be claimed legally liable for any harm created by their products and processes, which provides a strong incentive for them to prioritize safety in their design and operations. Therefore, they must show compliance with current and future regulations in order to sell their products.

Standards perform a crucial role in defining the specifications of a product and can be created by various entities such as private or public organizations, trade associations, or regulatory bodies. Some standards in the industry are optional and compliance with them is monitored by impartial boards. There are no penalties for not following these standards (Marucheck et al., 2011). Nevertheless, in particular industries, standards have the same level of importance as laws. Standards can either be prescriptive, specifying specific guidelines, or non-prescriptive, which require justification for meeting the principles of the standard (Hawkins et al., 2013).

As products have become more intricate, the number of standards that must be taken into account has increased. However, the advantages of standards are still a matter of debate. Standards improve the quality of products and indicate good management practices, but some companies may only implement these measures to satisfy the standards (Baram, 2007; Marucheck et al., 2011). Additionally, some research claims that standards serve as trade barriers. For small businesses, the costs associated with implementing and obtaining accreditation for a standard can act as obstacles rather than facilitators (Dinham, 2003). Harmonizing regulations and standards across countries is a significant challenge internationally. It can help ensure consistent safety management practices throughout the supply chain and reduce bureaucratic obstacles for companies that want to sell their products in different countries (Boutrif, 2003). However, before this can happen, regulations and standards must be harmonized inside a country internally (Yang, 2008; Marucheck et al., 2011).

## International Market

### International Labor Organization

The International Labor Organization (ILO) is a specially originated agency of the United Nations (UN) that was established in 1919 as being one of the oldest organizations. The ILO is a part of the UN agency and a combination of representatives from governments, organizations, and workers to enhance social and labor rights, and to improve working conditions around the world (International Labour Organization, 2022a).

The primary reasons for the establishment of the ILO were aiming to enhance the conditions of people's working conditions, the need for changing production processes, and struggling for social rights in the global context. Hence, the ILO's main duty is to develop international social policy. To achieve this, the organization marks recommendations for the organizations and minimum requirements for occupational safety and labor rights. Additionally, this organization cooperates in research to technical besides the main activities for safety-related legislation and standardization internationally (International Labour Organization, 2022b). Based on the scope of ILO, the products should be manufactured in a safe and healthy environment as well as manufactured products should be safe to use.

### International Electrotechnical Commission Standards

The IEC is a leading organization in the development of global standards for electrical, electronic, and related technological systems. The IEC develops and publishes their standards in order for them to be accessible in the global environment.

The standards published by the IEC also covers safety concerns of the products. Electrical safety, performance, and test methods as well as product compatibility and environmental safety are the points addressed by the IEC. One example for this context is IEC 62133 standard which includes safety testing for rechargeable lithium-ion batteries. Satisfying this standard shows the compliance in international trade (International Electrotechnical Commission, 2017a, 2017b). Moreover, IEC 62619 standard which titles as safety requirements for secondary lithium cells and batteries, for use in industrial application contains safety considerations of battery packs of lithium cells (International Electrotechnical Commission, 2022). It also specifies testing methods for safe operations. Additionally, the international standard, IEC 61508 namely functional safety of electrical/electronic/programmable electronic safety-related systems, provides safety requirements for battery management systems of lithium-ion batteries (International Electrotechnical Commission, 2010).

### International Automotive Task Force – IATF

International Automotive Task Force (IATF) is a global organization for developing and managing the IATF 16949 quality management system standard for the automotive industry. This standard presents requirements for automotive manufacturing and related equipment. The IATF 16949 standard is compatible with the standard of ISO 9001, Quality Management Systems by combining specific requirements for the design, development, and production processes. Furthermore, this standard provide information related to installation and functioning of automotive-related products. The IATF 16949 standard is an international standard and is compulsory for suppliers and manufacturers in the automotive industry. The objective of the standard is to assure that producers satisfy the highest quality and safety requirements in the automotive industry. It also requires improving customer satisfaction by means of persistent and continuous improvement (International Automotive Task Force, 2016).

In global operations, this standard is widely adopted by the automotive industry. In order for them to continue their business, they must demonstrate compliance with this standard. It also acts as proof of how committed the company is in terms of producing qualified, and safe products with respect to customer needs.

### Association of the Automotive Industry – VDA

VDA is the German acronym for "Verband der Automobilindustrie" which is the Association of the Automotive Industry based in Germany founded in 1901. The association is combined with automobile manufacturers and component suppliers. The VDA publishes many technical standards and guidelines for the automotive industry which needs special attention from the international organizations as well, not only in Germany (VDA, 2022).

The developed and published standards of the VDA comprise all industrial areas of the automotive industry. For instance, product safety, quality management, component-level requirements, process descriptions, automotive engineering activities, logistics operations, and supplier responsibility are in the scope of the VDA standards. Below a list is inserted in order to present some examples of the most recognized VDA standards.

- VDA 6.2: This standard, namely Quality Management System Audit for Services, covers transport and logistics requirements for the automotive industry. It provides guidelines for conducting audits to evaluate product quality, customer orientations, and continuous improvement in companies' processes.
- VDA 6.3: This standard, namely Process Audit, explains process-based audits to evaluate and improve control actions in automotive manufacturer companies in their newly developed products and production processes.

- VDA 6.5: This standard, namely Product Audit, presents guidelines for assessing how efficient the quality of the products is prior to delivering them to the customers.

To summarize, the VDA standards are broadly adopted by automotive and its component manufacturers as a benchmark for quality and process improvement. These standards are also mostly utilized supplementary to other quality management standards, such as ISO 9001 and IATF 16949.

**European Union Market**

The production of electric vehicle (EV) batteries is subject to strict product safety requirements in the European Union (EU). The EU's fundamental product safety and health requirements are outlined in directives and in standardization which supplements the legislation. These requirements are designed to ensure the safety of EVs and their users, as well as to minimize the risk of accidents or malfunctions that could damage the environment. Managing these requirements is done through a combination of international and national standards and regulations.

**European Standardization Organizations**

European standardization organizations, such as the European Committee for Standardization (CEN), European Committee for Electrotechnical Standardization (CENELEC), and the European Telecommunications Standards Institute (ETSI), are liable for organizing their standards. Also, they provide technical qualifications to match the fundamental requirements. These European Standards Organizations develop and publish harmonized standards for manufacturers to prove their compliance with EU legislation (European Commission, 2023). However, it should be mentioned that strictly following these harmonized standards is not mandatory for manufacturing companies. Rather, satisfying these standards shows their products meet the essential minimum requirements (CEN-CENELEC, 2023).

The International Organization for Standardization (ISO) and International Electrotechnical Commission (IEC) are being international standards approved these harmonized standards in the context of similar functioning in the EU (Murthy et al., 2008). Additionally, international standards such as ISO 45001 for occupational health and safety, ISO 9001 for quality, and ISO 14001 for environmental concerns are in the scope of European region and adopted extensively by organizations and manufacturers. To mark a side note, ISO 45001 from 2018, previously known as OHSAS 18001, is the latest version of the related standard (International Organization for Standardization, 2018).

### Free Movement of Goods

Furthermore, the free movement of products is a key principle in the European domestic market and is ensured through the removal of traditional duties and quantitative constraints, as well as the ban on other measures with similar effects. This principle is further strengthened by common recognition, withdrawal of physical and technological obstacles, and advertising the standardization among EU members (Ratcliff et al., 2022). In addition to the European Union, there exists the European Free Trade Association (EFTA) which consists of four European states that are not in the EU, Iceland, Liechtenstein, Norway, and Switzerland. This association aims to maintain the requirement of free movement of goods in those countries as well. Except for Switzerland, the EU and EFTA are part of the European Economic Area (EEA). Countries in the EEA are traded in the same way as EU member countries, and they are obligated to the same EU market rules.

### New Approach Directives

New Approach Directives (NADs) are a set of regulatory requirements aiming to ensure utmost product safety in the European market trade. They provide safety-related requirements for the manufacturers in order to protect the organization itself, customers, and the environment. The scope of the Directives includes the manufacturers of motor vehicles, medical devices, construction products, toys, and machinery (Council of the EU, 2022).

### Directives of the European Parliament and of the Council

Directives are legal objectives established by the European Union (EU Monitor, n.d.). They require to be fulfilled by all EU members without dictating the form and method of implementation. They aim to set general policies inside the European region to achieve mutual results without obtaining single, inflexible rules.

In the context of batteries, the Directive 2006/66/EC can be guided which provides legal acts on batteries and accumulators and waste batteries and accumulators (Directive 2006/66/EC, 2006). This Directive covers all types of batteries excluding the ones used in military and used in space projects. Therefore, automotive battery manufacturers for starter, lighting or ignition power should also consider this Directive for their products' safe disposal and recycling in order to protect the environment from hazardous elements.

This Directive also explicitly refers to Directive 2000/53/EC for automotive and industrial batteries used in vehicles. The Directive 2000/53/EC provides clear targets for end-of-life vehicles and their components including EV batteries (Directive 2000/53/EC, 2000). Moreover, this Directive forbids the utilization of hazardous substances such as cadmium

and mercury during manufacturing of new vehicles supposing there are no decent alternatives. For EV battery manufacturers using Nickel-Cadmium elements must pay special attention to this Directive.

Additionally, the European Commission is working on a new Regulation which will be a replacement for Directive 2006/66/EC as of 2004 (European Commission, 2022, December). The aim of the new Regulation is to provide new and more stringent rules for the manufacturing, recycling, safer, and more circular production of batteries. To illustrate, for lithium batteries the required recycling rate will be stricter to 50% by 2027 and 80% by 2031 in the target of the new EU Regulation. Therefore, EV battery manufacturers will face tougher and more comprehensive regulatory requirements in the foreseeable future.

#### European Commission Regulation, REACH

European Union developed a regulation related to registration, evaluation, authorization, and restriction of chemicals (REACH) in 2006, which has the number of EC 1907/2006 (Council of the EU, 2006). This regulation also provides information about rechargeable batteries and cells since they consist of critical chemical ingredients. Hence, it is important for the EV battery manufacturers to comply with REACH as well.

Previous scientific studies show that the manufacturing process holds an important role in ensuring the safety of EV batteries. For instance, it is indicated that proper control of the manufacturing process, including the use of highly qualified materials and the implementation of robust quality control procedures, can help to reduce the risk of safety incidents during the production of EV batteries (Tang et al., 2023; W. Liu et al., 2022; Christensen et al., 2021).

In conclusion, the EU handles product safety requirements for EV batteries through a combination of international and national standards and regulations. The EU also requires manufacturers to go through a certification process to guarantee that EV batteries satisfy the required safety standards.

### United States Market

In contrast to the uniform market in the EU, the situation in the US is different. In the US, the legislative branch of the federal government, which is Congress, sets laws domestically. Besides, governmental agencies, governmental courts, and state and regional governments also issue regulations, agreements, and laws (USAGov, 2022). In the United States, there is no equivalent to the CE conformity mark that is used in the EU, but products must still display warnings to indicate compliance with safety regulations (Bergen-Henegouw, 2021). Products not only have to meet technical regulations, but also adhere

to private sector standards in the US. There are several standard development organizations in the country. Some of them are governed by the American National Standards Institute (ANSI, 2023; International Organization for Standardization, 2021a). Even though complying with these private sector standards is not mandatory, not following them may cause juridical consequences.

### Consumer Product Safety Commission

In the United States, U.S. Consumer Product Safety Commission (CPSC) participates in developing regulations for batteries in consumers' products including e-mobility vehicle batteries (CPSC, 2023). This commission is a self-governing agency as a part of the federal government. Moreover, it aims to safeguard the people from severe harm or loss of lives caused by the consumer products. It establishes product safety standards and enforces manufacturers to comply with them. Moreover, the CPSC closely collaborates with other federal agencies, such as the National Highway Traffic Safety Administration (NHTSA), to ensure the safety of consumer products.

### National Highway Traffic Safety Administration

The NHTSA is a federal agency that regulates the safety of automobiles and its equipment as being a part of Department of Transportation (NHTSA, 2023). The NHTSA establishes enforcing standards and regulations for the vehicles in order to ensure safe vehicles in the roads. Moreover, it holds the power of recalling vehicles that is seen unsafe during use as well as that don't satisfy the safety-related requirements.

### National Fire Protection Association

Additionally, the National Fire Protection Association (NFPA) establishes the standard (NFPA 855) for the installation, maintenance, and use of energy storage systems. Companies which are manufacturing and selling EV batteries and supplying their components are responsible for demonstrating compliance with this standard as well (National Fire Protection Association, 2023a).

### National Electric Code

National Electric Code (NEC), or NFPA 70, in the United States aims to provide guidance for safer electrical design, installation, and inspection to ensure a protection for people and environment from electrically hazardous situations (National Fire Protection Association, 2023b). The United States and local jurisdictions adopt this code as a model for their inspection activities. Additionally, the NEC consists of assessments criteria for lithium-ion batteries' hazardous conditions. Furthermore, it is updated based on technological advancements in the batteries design. According to the NEC batteries should meet

specific performance and functional requirements, such as overcurrent device protection and ground fault protection.

**Chinese Market**

China is the world's biggest manufacturer of EV batteries, with a large number of battery manufacturers such as CATL operating in the country. China, being a leading manufacturer of electric vehicle (EV) batteries, has implemented a comprehensive regulatory framework for the safety of these products through a combination of national standards and government regulations, and international collaboration.

**General Administration of Quality Supervision, Inspection, and Quarantine**

The Chinese government has established various agencies and departments, such as the General Administration of Quality Supervision, Inspection, and Quarantine (AQSIQ) and the Standardization Administration of the People's Republic of China (SAC), to oversee the safety and quality of EV batteries under GuoBiao Standards (GB) (GBS, 2023). These agencies are responsible for enforcing standards, conducting safety assessments and testing, and issuing certifications for secondary batteries, which are the main component of EVs, related to electrical performance, lifetime, safety, and cells, modules, packs, and systems.

**Ministry of Industry and Information Technology**

Moreover, the Ministry of Industry and Information Technology (MIIT) is the primary institution responsible for managing the safety of EVs and their batteries (MIIT, 2023) by formulating the Normative Conditions for the Lithium-Ion Battery Industry. The MIIT establishes technical standards for EV batteries, including requirements for performance, safety, and environmental protection.

**China Automotive Technology and Research Center**

China Automotive Technology and Research Center (CATARC) is an institute founded in 1985. The CATARC establishes requirements for managing China's need in operations of automotive industry (CATARC, 2023). They provide governmental, scientific and industrial services related to automotive manufacturing. To illustrate, they develop standardization and technical regulation for production management, project evaluation, automotive testing, engineering and policy making. Additionally, they make efforts to contribute research regarding automotive safety technologies, energy saving advancements, and environmental protection technologies as well as lithium-ion batteries, and hybrid powertrains. Hence, in China, EV battery manufacturers must prove compliance with the CATARC to demonstrate their products are safe to be sold inside the country.

### China Energy Storage Alliance

In addition to these regulatory issues, China Energy Storage Alliance (CNESA) as being an industry organization, collaborates with governmental organizations to help improve safety, security, and sustainability in global context in the scope of energy storage industry. CNESA is China's first nonprofit organization committed to develop energy storage technologies (Yu et al., 2017). Additionally, it promotes advancements in energy storage applications throughout the country.

China is also quite active in participating in international standardization drafting. For instance, they cooperate with the International Organization for Standardization (ISO) in the process of battery safety regulations in line with the global market. Additionally, China has agreements with other countries such as the European Union for promoting cooperation and mutual recognition of product safety certifications.

### Japanese Market

Japanese companies such as Panasonic and Sony have a long history of producing batteries for consumer electronics and have now extended their expertise to EV batteries (Panasonic, 2023; Sony, 2023). In Japan, the government regulates the safety of EV batteries through technical regulations and industry standards. The Ministry of Economy, Trade, and Industry (METI) is responsible for establishing technical regulations for EV batteries and other products, while industry standards are developed by organizations such as the Japanese Industrial Standards Committee (JISC) and the Japan Automobile Standards Internationalization Center (JASIC) (METI, 2023; JISC, 2017; JASIC, 2023). Compliance with both technical regulations and industry standards is mandatory in order to sell EV batteries in Japan. Additionally, the Japanese government offers a certification program, known as the PSE (Product Safety Electrical Appliance & Material) mark, which is similar to the CE-marking in Europe and indicates that a product has been certified as safe for use (JQA, 2023). The PSE mark is mandatory for several categories of electrical products, including EV batteries.

### South Korea Market

South Korean companies such as Samsung SDI and LG Energy Solution are two of the largest manufacturers of EV batteries in global market (Samsung SDI, 2016; LG Energy Solution, 2023). South Korea is recognized as having a robust regulatory framework for product safety of the manufactured goods. In the country, these regulations are implemented and enforced by governmental agencies, such as the Ministry of Trade, Industry and Energy, the Ministry of Environment, and the Ministry of Land, Infrastructure, and Transport (MOTIE, 2016; ME, 2023; MOLIT, 2023).

Moreover, the Korean Agency for Technology and Standards (KATS) is the standardization organization inside the company (KATS, 2023; TÜV SÜD, 2019). This agency is also a member of ISO and IEC to improve collaboration with other countries internationally. They mainly handle testing and analyzing of the products in the scope of enforcing product safety, providing technological support, and improving products quality. By this way, they focus on increasing their recognizability internally in evaluation and certification of product manufacturing.

To summarize, each country and region has its own regulatory requirements for product safety in addition to internationally accepted legislation. In order to do business in those countries, the manufacturers must testify their products' compliance with the country specific requirements as well as mandatory global requirements. In some cases, there might be mutual protocols between countries to adjust their regulations in order to sell products. However, this is not a must, rather it depends on the situations and negotiations between those countries.

As a final contribution, the researcher adapted below Table 1 from Finnish Standards Association (2020) to demonstrate different standardizations around the world is established.

***Table 1.*** *Standardization organizations around the world in different levels.*

| | **Electrotechnical Industry** | **Other Industries** | **Telecommunications Industry** |
|---|---|---|---|
| Global Level  | IEC<br>International Electrotechnical Commission | ISO<br>International Organization for Standardization | ITU<br>International Telecommunication Union |
| European Level  | CENELEC<br>European Committee for Electrotechnical Standardization | CEN<br>European Committee for Standardization | ETSI<br>European Telecommunications Standards Institute |
| National Level  | SESKO<br>Electrotechnical Industry | SFS<br>Finnish Standards Association with its standards writing bodies | Traficom<br>Finnish Transport and Communications Agency (*law-based regulations and guidance*) |

**Customer Specific Requirements**

Customer specific requirements for EV batteries vary extensively depending on the industry and application as shown in Table 2. These requirements may include safety and performance specifications, battery life and capacity, temperature range, operating environment, and compatibility with other equipment (Deng et al., 2020). Furthermore, customer specific requirements may involve regulatory requirements, intended use of the vehicle, cost, the preferences of the end-user, and availability. Due to the importance of understanding what the customers' specific needs are, EV battery manufacturing companies should work closely with their customers and ensure that their batteries satisfy those needs. This satisfaction can be verified by testing and validation, and continuous monitoring and maintenance activities (Albertsen et al., 2021).

***Table 2.*** *Examples of customer requirements for EV batteries.*

| | |
|---|---|
| Energy density | The amount of energy stored in the battery per unit of volume or weight. Higher energy density means longer driving range for the vehicle. For example, >750 Wh/L or >350 Wh/kg for cells |
| Power density | The amount of power the battery can deliver per unit of volume or weight. For high-performance vehicles, higher power density is required. |
| Cycle life | The number of charging and discharging cycles the battery can endure before its capacity starts to decrease. For example, 15 years |
| Cost | The cost of battery evaluated based on per unit of volume. For example, <€100/kWh for cells |
| Charging time | The time that it takes to fully charge the battery. Faster charging times are demanded for convenience. |
| Operating temperature range | The range of temperatures the battery is operating without any failure of losing performance. |
| Safety | The battery must be designed to ensure safety at the time of normal utilization and in the case of a crash or other circumstances. For example, no fire/flame/rupture/explosion |
| Recycling | The battery must be recyclable, and the manufacturer must prepare an action plan for the disposal of worn batteries. |

These requirements vary depending on the individual customer and their case-by-case needs. The customers of the batteries also vary globally starting from electric vehicle manufacturers, and energy storage systems (ESS) producers for residential and industrial use. Specifically, since the demand for clean and sustainable energy sources is increasing rapidly, the demand for EV batteries also increases (Yang et al., 2022). These batteries can also be used in public transportation other than personal automobiles. Hence, governments, technology companies, and start-ups can also be seen as EV battery customers. The manufacturing of EV batteries is supported by the governmental authorities due to its pioneering to clean energy, which is also proof of the increased popularity of EV battery production. Some examples of customers of EV batteries are listed as following:

Automotive manufacturers: Companies like Tesla Inc, Nissan Motor Co. Ltd., BMW AG, etc. who produce electric vehicles require high-performance, reliable and safe batteries for their vehicles. Moreover, General Motors (Chevrolet, Cadillac, and GMC brands), Volkswagen AG, Ford Motor Company, Honda Motor Co. Ltd., Toyota Motor Corporation, Hyundai Motor Company, Kia Motors, and Porsche AG can be given as examples of automotive manufacturers that utilize EV batteries (EnergySage, 2022).

Energy storage systems (ESS) providers: Energy storage systems are used for residential, commercial, and industrial purposes, and demand for these systems is increasing. ESS providers purchase batteries to store excess energy generated from renewable sources.

Electric utilities: Utilities use batteries in their grid systems to stabilize the supply and demand of electricity.

Governments: Governments around the world are heavily investing in EV manufacturing and infrastructure to support them. They utilize EV batteries in their roads, aviation and naval operations as well as for the development of charging infrastructure.

In summary, EV battery manufacturers can also have customers in other industrial areas. EV batteries are not limited to the automotive industry and can be used in industries such as marine, aerospace, renewable energy, and other industries that require high-performance, durable, and safe batteries (Ghiji et al., 2020). For example, to deliver power to the grid in times of extreme need, EV batteries can be used in ESS to accumulate excess energy from sustainable sources, such as wind and solar energy within the renewable energy industry. In the marine industry, EV batteries can be used in electric boats, ships, and submarines. In the aerospace industry, they can be used in electric aircraft. It is also possible for an EV battery manufacturer company to have customers in the lifting industry

(Konecranes, 2023). The lifting industry includes various applications such as cranes, hoists, and elevators, and these applications may require batteries for power supply. Hence, an EV battery manufacturer may provide batteries that meet the power and capacity requirements of the lifting industry, allowing their products to be used in a variety of applications beyond the automotive industry.

### 2.3.3 Product Safety Consideration of EV Battery Manufacturers

EV battery manufacturers have a significant responsibility to produce safe products that meet regulatory and safety requirements and that are clear from defects and hazards that could create harm to users and/or the environment. This responsibility extends across the entire product lifecycle, from the selection of unprocessed materials to the design and manufacturing processes to the deployment and utilization of the product (Rausand & Utne, 2009). In addition to meeting regulatory and safety requirements, manufacturers must also consider the potential hazards that may arise from normal use of the product, as well as from foreseeable misuse or abuse (Baram, 2007). They must also consider the potential impacts of their products on the environment, including the use of hazardous materials and the need for safe disposal or recycling at the retirement of the product (Leveson, 2020)

Solutions for managing safety must satisfy specific requirements, and designers perform an important role in ensuring safety. It is important to have detailed knowledge of the design of objects and prototypes to make safety-related decisions (Baram, 2007). Although product safety considerations should be an essential part of the design and development process and should be considered from the very beginning of the product development lifecycle, it is often questionable to acknowledge safety at the beginning of the design stages. Therefore, it is essential to establish a common design process which outlines milestones to decide if design engineers meet the constraints (Hale et al., 2007). Later, safety evaluation should be revised at each step of the product development process, and manufacturers must verify if the safety status is acceptable to progress to production. It should also be assessed by manufacturers whether the level of safety is sufficient or not (Ridley & Pearce, 2005).

However, it's also important to mention that other parties who are involved in the production process, distribution cycle, and utilization of the product are accountable for ensuring product safety. For example, suppliers of raw materials which are employed in the battery manufacturing process must ensure that their deliveries satisfy related safety standards. Likewise, the consumer of the product is also responsible to adhere to the instructions

for handling, disposing after use, and transporting that are provided by manufacturers. By this way, they can minimize the possibility of risks occurrence to them and their surroundings. Ultimately, ensuring product safety is a shared responsibility, and all parties involved in the product lifecycle must work together to identify and address potential safety risks (Ridley & Pearce, 2002).

Some recent examples of product safety aspects that an EV battery manufacturer should consider cell design and chemistry to ensure safe and reliable performance as well as robust testing and quality control processes to identify and prevent defects. Moreover, they should prevent overheating and thermal runaway by providing adequate thermal management systems such as liquid or air cooling. Electrical safety features such as fuses and isolation devices in addition to protection against short circuits, and over-discharging should also be in the consideration scope of the manufacturer (Deng et al., 2020). Besides these, physical protection against vibration also requires special attention for a safe battery. Moreover, manufacturers should ensure safe handling and transportation of the product by providing proper labeling and documentation. Finally, end-of-life considerations, including safe disposal and recycling methods for the battery should responsibly be dealt with in consideration of product life cycle perspective.

Handling product safety concerns requires manufacturers to have a comprehensive understanding and systematic way of working in their operations. For instance, they should conduct extensive research and development in designing of safe and reliable cells by investing in testing and validation activities throughout the projects (Schupp et al., 2006). Additionally, using advanced battery management systems (BMS) which is monitoring the battery's charging state and temperature condition can be beneficial to prevent the battery from overcharging and over-discharging. Battery pack design is also critical to ensure physical protection. For instance, using protective enclosures and selection of shock-absorbing materials may lead to the production of safer batteries (Xiong et al., 2018).

EV battery manufacturers must prove that their products comply with all relevant regulations and safety standards of their target markets. By following the regulations and standards, EV battery manufacturers demonstrate that their products meet minimum safety requirements and are less prone to entail a risk to users and/or the environment. Indicating compliance with these regulations is required by law and failure to comply may result in legal or financial consequences. However, it's important to remark that compliance only with regulations and standards may be insufficient to ensure product safety (Nordlander et al., 2010). Manufacturers should also take into account any possible hazardous

situations which are not presented by existent requirements. They can for example address these situations in their design and manufacturing processes by conducting risk assessments such as Failure Modes and Effects Analysis and/or Fault Tree Analysis. Additionally, they should be able to foresee whether the product will be utilized in forms other than its planned purpose and whether it will be utilized purposely or accidentally (Organisation for Economic Co-operation and Development, 2016). In those cases, it should be a proactive approach for assessing the risks and discovering mitigation actions.

Product risks consist of probable sources of harm, called product hazards, and the probabilities of those harms occurring. To ensure product safety, the producer must initially diagnose the whole possible hazards associated with the product throughout its entire lifecycle. In the optimum case, these hazards should be excluded, but if that is not achievable, the risks should be reduced by implementing various obstacles and safety exercises (International Organization for Standardization, 2012). Failure to assure product safety can lead to negative impacts, such as liability claims for damage or loss of life, not covered insurance of damage to properties, warranty claims, recall costs, and damage to the company's reputation or market share (Rausand & Utne, 2009).

EV battery manufacturers can apply various strategies involving hazard analysis, design for safety, testing and validation, and continuous monitoring and improvement to identify potential hazards and develop appropriate safety controls (Ridley & Pearce, 2002).

- Conducting a hazard analysis: This involves identifying potential hazards associated with the battery and its component in addition to the hazards that are not specifically explained by already existent regulations. These analyses can be based on historical data, expert knowledge, and simulation techniques.
- Performing risk assessment: After hazards are identified, a risk assessment can be organized to detect the likelihood and severity of possible harm to people, property, and the environment. These assessments are suitable to prioritize the implementation of safety controls.
- Designing for safety: Safety should be the principal concern in the battery design process. Therefore, design engineers should incorporate product safety features into the design activities as early as possible. For instance, they may pay special attention to thermal management systems, electrical safety systems, and mechanical protections.
- Testing and validation: Batteries should be tested and validated in accordance with the initially defined requirements. These activities demonstrate whether the

battery satisfies the safety requirements and whether there still exists any unidentified hazardous situations.

- Continuous monitoring: Manufacturers should monitor the performance and reliability of the battery throughout its entire life cycle and should intervene in appropriate actions to address possible safety concerns. To illustrate, they can revise safety controls regularly.

By adopting these strategies, EV battery manufacturers can proactively identify and mitigate potential safety hazards and ensure that their products are as safe as possible, even in cases where there is no explicit regulation for identifying specific hazards.

## 2.4 Compliance Management in Global Market

Compliance management is the course of action for ensuring that an organization's operations, processes, and practices are aligned with a set of predetermined requirements, ethical standards, and regulations that apply to its operations and practices. Effective compliance management should be considered an essential task of a company's management and business practices rather than a separate activity (Y. Liu et al., 2007; International Organization for Standardization, 2014). As defined within ISO 19600:2014, a comprehensive compliance management system demonstrates how committed a company is to be compliant in its operations within legal and ethical boundaries. Companies' failure to comply with those standards may result in noncompliance risks such as fines, legal liabilities, restrictions on institutional activities, and loss of licenses. Compliance risks increase when a company lacks the ability to satisfy essential requirements (Sparrow, 2000).

When a company adheres to the external requirements which are applicable to the product itself and its operations, it is recognized as being in compliance with those requirements (Vasara, 2019). For example, having products CE-marked demonstrates that those products can move freely in the European Region since it is a proof of conformity of product to the EU's safety, health, and environmental protection requirements. A manufacturer or authorized representative must issue a conformity declaration for the product to be marked with CE and sold in the EEA market. Without a CE marking, products cannot be offered for sale in the EEA market (TÜV SÜD, 2023; European Commission, 2021)

In the EU, EV battery product safety compliance is ensured by the manufacturer in addition to an external evaluation (European Commission, 2020a; European Commission,

2020b). One of the key regulations governing EV batteries in the EU is the Battery Regulation (EU) 2019/1020, which sets out safety, performance, and sustainability requirements for battery packs placed on the EU market (European Commission, 2020a). The regulation applies to all types of batteries and requires compliance with specific safety and environmental requirements.

Additionally, the IEC 62660 standard presents rules for the testing and evaluation of lithium-ion batteries used in EVs. The standard covers aspects such as performance, reliability, and environmental impact of rechargeable energy storage systems (RESS) (International Electrotechnical Commission, 2018). Manufacturers demonstrate compliance with this standard by undergoing testing and verification of the product regarding electrical, mechanical, thermal, environmental aspects, as well as safety-related requirements.

ISO 19600:2014 standard suggests guidelines for establishing, implementing, maintaining, and continually improving a compliance management system within an organization (International Organization for Standardization, 2014). Although it is not specific to product safety compliance, it covers general requirements such as role definition, organizational matters, compliance liabilities, risks, and policies for all kinds of organizations. Therefore, implementing ISO 19600:2014 standard depends on the manufacturers to ensure product safety compliance. However, this standard could be used as a general framework in conjunction with other compliance management system standards even though it is not designed for certification purposes (International Organization for Standardization, 2021b; International Organization for Standardization, 2015a; International Organization for Standardization, 2014)

ISO 15288:2015 standard also describes guidelines for the system life cycle processes used in the engineering and management of systems (International Organization for Standardization, 2015b). The main aim of the standard is not specifically addressing compliance management. However, it recommends compliance requirements which can be used as a supplement. Particularly, ISO 15288:2015 suggests that the compliance requirements should be identified and analyzed during the initial steps of the system life cycle, such as the system concept development and requirements analysis stages. This helps to ensure that the compliance requirements are properly integrated into the system design and development process. Furthermore, it proposes that compliance verification and validation activities such as testing, inspection, and audit, should be included throughout product life cycle.

ISO 26262 standard provides guidelines for functional safety in the development of electrical and electronic systems in road vehicles (International Organization for Standardization, 2011). The standard is specifically created for the automotive industry and is widely used by EV battery and other automotive component manufacturers. From its viewpoint, batteries are crucial components in EVs, and manufacturers must ensure their safety. Hence, ISO 26262 standard may be followed for ensuring the functional safety of the products as an essential part of quality and safety management systems. This standard provides instructions for the product development process, production, operations, and disposal of the product. It also requires manufacturers to identify and assess potential hazards and risks associated with their products. Moreover, it obliges to implement calculations to diminish these risks to an agreeable degree. Manufacturers must also implement a severe testing and verification process to guarantee that the battery systems satisfy the required functional safety needs. Within this standard, manufacturers may also find rules for the selection and use of appropriate tools, methods, and techniques for testing and verification. Eventually, compliance with this standard is assessed by a third-party certification body, which verifies that the manufacturer's processes and products meet the requirements of the standard (Tanner, 2000).

The specific process steps that an EV battery manufacturer should follow in the compliance management may vary depending on the standards and regulations and their internal quality and safety management systems (Keen, 2021). However, some general steps that they should adopt in the compliance process are: identifying and interpreting the applicable standards and regulations, performing a risk assessments such as hazard analysis and failure modes and effects analysis (FMEA), identifying changes required, design and development of the product, conducting testing and verification activities, implementing quality and safety management systems, deciding compliance, specifying method of compliance, communication, evaluation and maintaining compliance throughout the entire lifecycle of the product. Since the compliance process is iterative, manufacturers need to revisit previous stages even after they have evaluated and monitored the outcomes of compliance efforts.

Monitoring legislation is a critical and ongoing task for businesses. Once a company becomes aware of new legislation, it must analyze it and determine if it affects their products or operations. If so, the company must evaluate what changes are required to ensure compliance (CCPS & CCPS Staff Center, 2011). This process of interpreting and complying with legislation is referred to as complying with "compliance obligations" in the ISO 19600:2014 standard. As part of this process, an organization should describe and assess compliance risks to develop a plan for preventing risks. After deciding how to

comply with the regulations, the company must designate a plan of action and communicate it to all relevant parties. In cases where requirements differ between regions, companies suffer to balance the needs of local business processes with common, international requirements (Vasara, 2019). Additionally, developing complex products requires extensive data collection and computational resources with analyzing capability (Dowlatshahi, 2001). The next stage of compliance management is implementation. Companies may choose to implement changes before regulations are enforced or in response to feedback from regulators. This phase can also be integrated with compliance evaluation and monitoring, which is the last step of the overall process. The standard, ISO 19600:2014, introduces guidance on monitoring and evaluating compliance management systems, including data collection methods and feedback sources (International Organization for Standardization, 2014). It is crucial to mention that compliance management is a continuous process, and companies could need to turn back to earlier steps to ensure ongoing compliance.

To demonstrate compliance with these regulations and standards, manufacturers of EV batteries must undergo a certification process. This process involves testing and evaluation of the batteries according to the relevant requirements, and the insuance of a conformity certificate or declaration of conformity by a notified body (Galland, 2013). The certificate or declaration serves as an evidence that the battery is in compliance with the relevant regulations and standards and can be used to obtain a CE-marking, which is required for the battery to be sold in the EU region.

Companies can respond to new or unfamiliar regulations in various ways, such as opportunistic behavior, full compliance, partial compliance, non-compliance, or attempting to influence regulatory issues (Castellanos-Ardila et al., 2021; Henson & Heasman, 1998). The decision to comply may depend on factors such as the potential impact of non-compliance. Non-compliance may carry both positive and negative impacts on a company, in both the short and long term (OECD, 2000). Choosing non-compliance as a strategic option means abandoning the full utilization of their resources. This may result in immense risk of encountering enforcement actions (Henson & Heasman, 1998).

To effectively design, manufacture and circulate products and services, manufacturers need to not only manage compliance but also be responsive to changing customer requirements (Griffiths et al., 2000). The demand for flexibility has increased due to shorter product lifecycles, decreased time to market, and the trend towards customer-focused production. It allows customers to configure products according to their individual preferences, while at the same time maintaining the efficiency and economies of scale associated with large-scale production (Ernst & Kamrad, 2000). Companies need to adapt

to changing and growing customer needs by being agile and robust (Narasimhan & Das, 2000). Achieving flexibility is identified by assessing potential advantages and working towards achieving them. These strategies have become increasingly important in industries such as end-user electronics and automotive manufacturing (Diffner, 2011).

To recap, EV battery manufacturers may use a combination of standards and regulations, their own internal quality and safety management systems, as well as changing customer needs to ensure product safety compliance and to testify that their products satisfy the related requirements.

The compliance process model shown in Figure 2 is derived from the requirements compliance management processes found by the scientific research in order to present different steps of the process (Henson & Heasman, 1998; International Organization for Standardization, 2014).

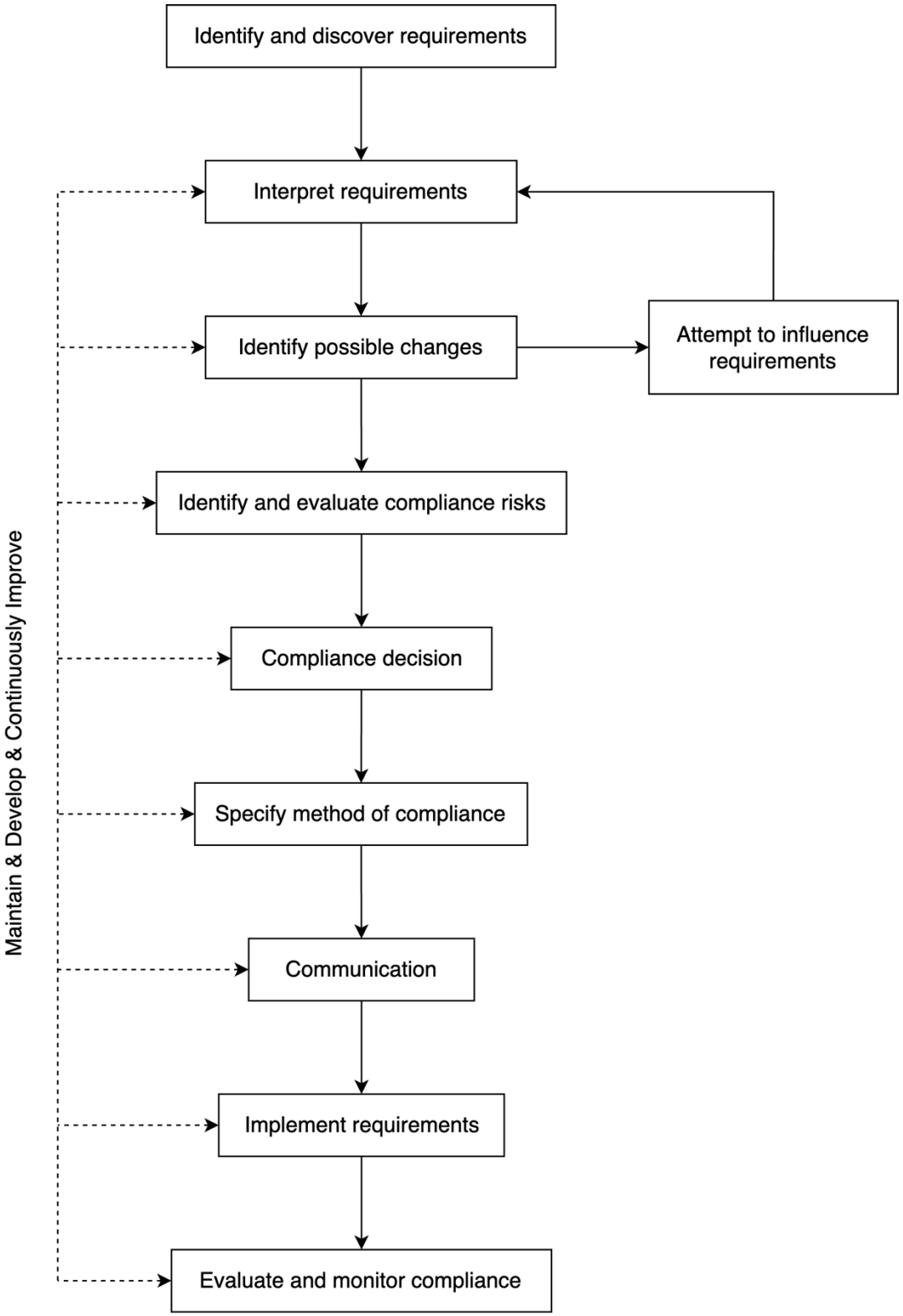


***Figure 2.*** *Derived model for management of compliance with product safety requirements*

*(Henson & Heasman, 1998; International Organization for Standardization, 2014).*

# 3. CASE COMPANY AND RESEARCH PHASES

## 3.1 Valmet Automotive

Valmet Automotive (VA) is a Finnish vehicle contract manufacturer company with the expertise areas of automotive engineering, convertible roof systems and electric vehicle battery production. Since the foundation, VA manufactures more than 1.7 million vehicles for well-known OEMs such as Mercedes-Benz, Saab, Porsche, Audi, BMW, and Fisker by building a reliable relationship with the customers and satisfying their needs (Valmet Automotive, 2019).

VA is established in 1968 in Uusikaupunki, Finland in partnership with Swedish Saab-Scania in a former name of Saab-Valmet. In 1995, the company renamed as Valmet Automotive after evolving into the sole ownership of a Finnish company, Valmet. In 2010, Pontos Group and Tesi (Finnish Industry Investment) became shareholders of VA by each acquiring 38% of the company's shares. Seven years later, Contemporary Amperex Technology Limited (CATL), a leading Chinese EV battery supplier company, acquired 23% of the company shares (Valmet Automotive, 2019; Valmet Automotive, 2022a)

VA consists of three business lines: Vehicle Contract Manufacturing Business Line (VCM) in Finland, Roof, and Kinematics Systems (RKS) Business Line in Germany and Poland, and Electric Vehicle Systems (EVS) in Finland and Germany. The number of employees is more than 4500 people in these three countries (Valmet Automotive, 2022b). While RKBL is providing engineering solutions to roofs and active spoiler systems for the automotive industry, VCM manufactures vehicles with the industry-wide know-how gained for decades.

The scope of the thesis is VA EV Systems.

### 3.1.1 Valmet Automotive EV Systems

VA adopts electrification idea since the first manufacturing contract for electric vehicles was signed for the Fisker Karma models in 2008 (Valmet Automotive, 2019). The company invests heavily into battery systems with the worldwide expansion of EV market and established a battery pack plant in Salo, Finland in 2019. In addition to the high-volume battery plant, the company has another high-volume battery plant in Uusikaupunki and a new plant in Kirchardt, Germany under development.

Valmet Automotive EV Systems Business Line is a Tier-1 system supplier of big OEMs. Producing high-voltage battery systems, battery modules and packs with different sizes opens the pave for Valmet Automotive to become a competent partner. The company gains huge experience in the entire process chain starting from project management to any type of mechanical, electrical, and thermal engineering activities related to battery technologies.

In addition to battery manufacturing, they also offer battery testing and battery system engineering which requires important technical know-how. Increased demand from customers always forces manufacturers to operate more reliably and efficiently. VA also handles its operations with increased capacity, high-tech and modern testing technology, coordination, and logistics.

Their testing activities can be adjusted to any situations such as engineering design to series production phase. They test the batteries against thermal conditions, high-voltage protection, and/or tightness based on the customer requirements. Therefore, they provide a particular testing plan for each battery model.

Moreover, VA EV Systems Business Line is aware of various requirements from different markets globally. Several laws, regulations, UN standards in addition to ever changing needs of the car manufacturers oblige the company to create explicit ways for their processes. They put effort to build a secure logistics network by cost-effective, safe and fast global transportation of high-voltage batteries as dangerous goods.

## 3.2 Research Strategy

In the scientific environment, scholars mainly describe two research approaches: qualitative research approach and quantitative research approach. Qualitative research approaches provide in-depth insights and realization of the research area by exploring and discovering phenomena (Thomas, 2003). On the other hand, quantitative research is suitable for analyzing cause-effect relationships between variables statistically to generalize the findings from large samples. According to Eriksson and Kovalainen (2008) although quantitative research is more prone to standardized and structured data gathering and examining techniques, qualitative research collects and analyze data more sensitive to the study context with the aim of comprehensive recognition of the object.

This thesis followed a qualitative research approach. Qualitative research approach is advisable for scientific research trying to explore, express and understand the meaning of phenomena and problems. Moreover, qualitative research addresses the importance of individuals or groups of people subjected to those phenomena and problems (Creswell

& Poth, 2018). Since this research aims to gather information about practices and challenges regarding compliance management of safety-related requirements by understanding a subject group's approach to the topic, qualitative research is adopted for the study.

Qualitative research allows researchers to conduct various methods such as a case study, hermeneutic phenomenology, narrative research, grounded theory research, ethnographic research and/or netnography (Ryan, 2017). In the context of case studies, a specific case or cases are investigated through an intensive analysis. This method is acceptable for generating an in-depth and extensive exploration of a specific phenomenon whilst providing diverse perspectives on a given issue. Moreover, a case study approach enables triangulation of data which increases the reliability and validity of the results (Farquhar et al., 2020). Hence, this thesis is proceeded as case study with an electric vehicle battery manufacturer company.

To clarify, in the framework of the thesis, 'case company' or 'the company' refers to Valmet Automotive and its EV Battery Systems Business Line. 'Requirement' refers to claims of regulations, standards, and customer specifications that the company must comply with. The research objectives, research questions in addition to the research tasks of the thesis study are explained briefly in Table 3 to better visualization.

***Table 3.*** *Research tasks corresponding to the research objectives and questions.*

| **Research Objective** | **Research Question** | **Research Tasks** |
|---|---|---|
| A | 1 | Analyze internal company materials<br>Interview case company experts |
| B | 2 | Analyze internal company materials<br>Interview case company experts |
| C | 3 | International Standards Review<br>Legislations Review<br>Literature review |
| C | 4 | Process and evaluate interview results and literature findings<br>Propose improvement opportunities |

## 3.3 Data Collection and Research Steps

Commonly used data gathering methods in qualitative research are interviews, observations, documents, workshops, and audiovisual materials (Creswell, 2009). For the case studies, combination of those methods is utilized as explained by Eisenhardt (1989). In this respect, this thesis applies descriptive case study approach by conducting semi-structured interviews as well as literature review, assessment of organizational reports, processes, and applications.

Descriptive research is a sort of research approach that intends to describe and summarize characteristics, behavior, or phenomena. The fundamental goal of this research approach is to provide a clear, accurate, and comprehensive picture of the subject under investigation (Nassaji, 2015). The researcher does not involve manipulating variables or establishing cause-and-effect relationships between variables. Instead, they focus on observing and measuring variables as they naturally occur in their environments. This approach is often used to gather information about a particular population or phenomenon, such as demographics, attitudes, opinions, behaviors, or experiences. Data collection is done through surveys, observations, case studies, and archival research during descriptive research. Collected data can then be analyzed using descriptive statistics and/or qualitative methods, such as content analysis, in order to obtain a more detailed understanding of the data.

The research process should be based on a robust methodology to compile the data and information needed for the development of the identified solution. The schematic research steps adopted in the thesis are illustrated in Figure 3.

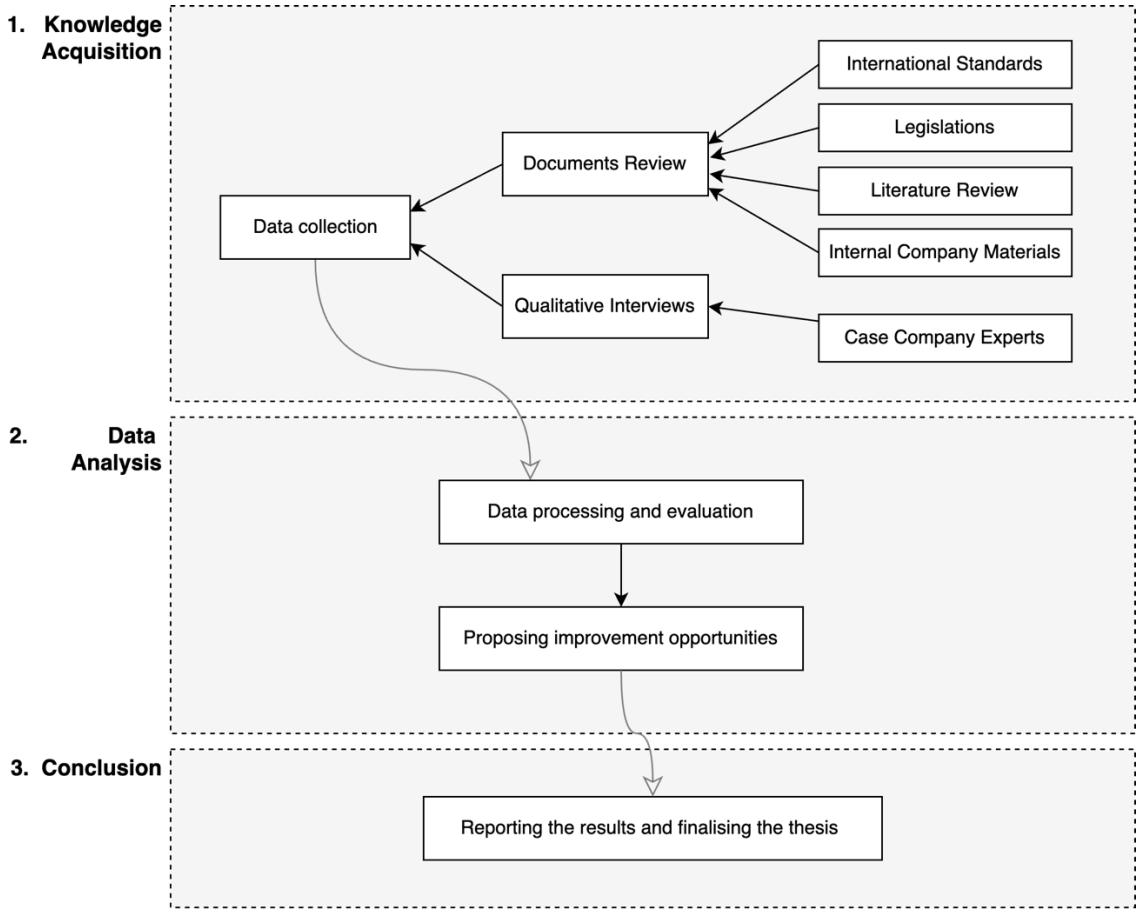


***Figure 3.*** *Research steps of the thesis study.*

As the Figure 3 shows, the research steps are categorized into three phases each of which consists of various activities:

1. Knowledge Acquisition

During scientific research, knowledge acquisition is critical to achieve reliable, meaningful, and useful results (Privitera, 2019). Firstly, research questions and objectives must be defined clearly. Although all the steps in the research process are important, the most critical step is framing the research questions (Ratan et al., 2019). The research question is an establishment of the study and sets a direction for the entire research process. It defines the problem to be investigated, identifies the aim of the research, and helps to discover the appropriate methods to be used. A well-formulated research question ensures that the study is focused, relevant, and feasible as well as having a clear objective and is aligned with the existing body of knowledge on the topic. Then, this will guide the selection of proper research methods, sampling methods, and data collection approaches. Depending on the research questions, a research design should be selected. There exist several research compositions that might be utilized in descriptive research, including cross-sectional, longitudinal, and case studies (Anastas & MacDonald, 2000).

Thereafter, sample selection is made by determining which group or population will be studied throughout the research. Finally, relevant data should be collected via surveys, interviews, observations or secondary sources during descriptive research (Wagh, 2023). International standards and legislation, existing literature resources in addition to interviews with industry experts within the case company are the main data sources of this thesis.

2. Data Analysis

Thereafter the data is collected, it should be organized, cleaned, and analyzed using appropriate statistical or qualitative methods since it provides insights into the key features of the studied group or phenomenon (Mack et al., 2005). By summarizing and understanding the data, the researcher can identify patterns and trends that may be useful for decision-making and intervention development. It also provides a precise picture of the characteristics of the case under study, such as demographic information, attitudes, behaviors, and preferences (Mack et al., 2005). Moreover, storing the data is another critical part of research. All the collected information should be sorted and categorized and recorded into a database or spreadsheet. Additionally, it can be kept as its hard copy formats with special attention to confidential information. During this thesis, collected data is analyzed, interpreted and processed in consideration of the above aspects.

3. Conclusion

Finally, the results should be interpreted in the consideration of the pre-determined research questions and any limitations of the research (Boru, 2018). The findings should be presented in a clear and concise manner with appropriate visuals and tables to support the results, when applicable. After careful planning, adopting a rigorous approach and paying attention to details, the results are presented and discussed objectively in this study. Feedback from the case company experts and university supervisor also guided the researcher to refine any issues that occurred during this process.

### 3.3.1 Interviews

In general, an interview involves a conversation where a set of questions is asked and answered for the purpose of gathering information about a subject (Eriksson & Kovalainen, 2008). Particularly in case study research, interviews are frequently used methods for collecting data. A research interview typically involves two or more people. One person is the interviewer who directs and plans the process of the conversation and asks questions, and the other person is the interviewee who replies back to the questions

(Gubrium & Holstein, 2001). In some cases, there may be multiple interviewers or multiple interviewees. However, the basic structure involves one person asking questions and the other person responding.

Qualitative interviews can be categorized as structured, semi-structured, and unstructured interviews (H. J. Rubin & I. Rubin, 2005). These types are also named as standardized, semi-standardized or guided, and non-standardized or informal/open/narrative interviews, respectively. Below Table 4 summarizes the types and features of qualitative interviews (Eriksson & Kovalainen, 2008).

***Table 4.*** *Types and features of qualitative interviews.*

| **Structured Interviews** *Standardized* | **Semi-Structured Interviews** *Semi-Standardized Guided* | **Unstructured Interviews** *Non-Standardized Informal/Open/Narrative* |
|---|---|---|
| Interviewer asks a set of predetermined questions | Interviewer uses a flexible set of predetermined questions and interviewee responds in their own words | No precise guidelines, restrictions, pre-determined questions or a list of options |
| Close-ended, pre-coded or fixed choice questions | Pre-specified questions can be adjusted during the interview | Allows flexibility to talk about the topic |
| No deviation from the order and wording of questions | Questions can be re-ordered, modified or new questions can be included for each interview | Few broad questions are asked to catch the interviewee in an open, causal, and spontaneous discussion |
| Often used in quantitative surveys | Interviewer can further probe interviewees based on their answers | Interviewer can shape the conversation in any direction |
| Preferably conducted by inexperienced interviewers | Useful to collect in-depth information systematically | Useful to understand interviewees' personal experiences narratively |
| | | Often adapted in biographical interviews |

Conducting structured interviews was not reasonable in the scope of this study. It was needed to interrogate further information from the interviewee in addition to having an option to ask additional questions in the case that the participant's information remains inadequate. Moreover, the research aimed neither to focus on personal stories behind participants' experiences nor to create a spontaneous discussion atmosphere. Hence, using unstructured interviews was also not considered as an option for the study. On the other hand, semi-structured interviews offer flexibility and in-depth exploration of research questions while still maintaining a structure to the interview process during qualitative research (Kvale, 1996). Consequently, data is collected through one-on-one semi-

structured interviews in this research. One-to-one execution of the interviews allowed the researcher to establish a personal connection with the participant which enhanced willingness to open up and to share personal perspectives about the research subject easier than in a group discussion setting.

To assure a rigorous data gathering process, participants are carefully selected from the experts who have a deep understanding of the research topic inside the case company. The criteria for choosing participants for the semi-structured interviews were established in regard to the study of Lauriault et al., (2015). The authors highlight the importance of electing participants for semi-structured interviews in order to achieve relevant and informative data collection. They suggest including participants with different levels of experience and expertise in product safety to attain a more comprehensive perception of the topic. Additionally, the characteristics of population of interest and the research questions when selecting interviewees should be considered attentively. The researcher should also include a diverse range of participants to ensure that multiple perspectives are represented.

Ultimately, 6 senior professionals were decided based on the above-specified selection criteria as well as with the help of contact people from the case company. However, 2 of them resigned from the case company before starting to conduct the interviews. Therefore, only 4 senior professionals who have knowledge of product safety-related compliance management were interviewed for the research. Moreover, 1 additional expert from other areas of expertise was consulted to receive a deeper perception of some of the research questions. These additional experts were suggested by the main participants during the acquaintance meeting and the interviews upon the suggestion request of the researcher. Table 5 shows a list of people communicated inside the case company and their information on experience levels, locations, and current positions. The experiences column of the table demonstrates the expert's experience related to product safety in general. Even though the experienced industries vary between the automotive industry, electric vehicle battery industry, mobile phones production, and wind power industry, all the experiences are in the scope of the safety of the products.

***Table 5.*** *Information of the people communicated from the case company.*

| **Participants** | **Country** | **Business Line** | **Department** | **Position** | **Experience** (year) |
|---|---|---|---|---|---|
| IP01 | Finland | EVS | Engineering / CF Engineering | Functional Safety Manager / Lead Engineer, Battery Systems Functional Safety | 5 |
| IP02 | Germany | EVS | Engineering / CF Engineering | Manager, Requirements Engineering & Toolchain | 4,5 |
| IP03 | Germany | EVS | Engineering / CF Engineering | Key Specialist, Battery Safety | 3 |
| IP04 | Poland | RKS | Quality / CF Quality Management | Quality Manager | 12 |
| IP05 | Germany | EVS | Engineering / CF Engineering | Senior Manager, Systems Engineering | 11 |
| IP06 *(Resigned)* | Germany | EVS | Engineering / CF Engineering | Team Manager, Product Safety Battery Systems | 14 |
| IC | Germany | EVS | Engineering / CF Engineering | Requirements Engineer | 2 |
| CP1 *(Resigned)* | Finland | EVS | QHSE / CF Quality & HSE | Manager, Health and Safety | 25 |
| CP2 | Finland | EVS | QHSE / CF Quality & HSE | Director, Quality & HSE | 29 |

At the beginning of the research, the topic, purposes of the study, and the researcher were introduced to the related people of the case company in an acquaintance meeting via a Microsoft Teams meeting. The meeting was arranged with an informative email that covered the scope of the research briefly.

Thereafter, the researcher prepared a set of interview questions by searching relevant scientific contributions and literature survey related to product safety compliance management. The questions focus on discovering current practices inside the company, analyzing their existing product safety requirements compliance management system, identifying potential weaknesses, and opportunities for improvement. The interviews practically followed the interview questions presented in Appendix A. However, the researcher enabled a space for open discussion. Due to privacy of the data, complete answers of the interviewees are not included in the appendix.

After the researcher prepared a set of interview questions, all the possible participants were contacted again, and the interview process, possible duration, and the expected contribution of the participants was explained. The researcher also e-mailed the list of the interview questions to the main interviewees for their review and preparation to avoid exceeding the time limit. When both the researcher and the participant agreed on a suitable date and time, the researcher scheduled a Zoom meeting due to the technical convenience of recording the sessions.

Meeting links sent with an attachment of informed consent form. All the participants received informed consent so that they can clearly realize the fullest understanding of the research scope and that their participant is voluntary. Three interviewees returned the form to the researcher by electronically signing it.

The interviews lasted approximately 45-90 minutes depending on the conversation between the researcher and individual participant. The researcher shared the screen, which showed the interview questions, with the interviewee for an easy follow. The interview sessions were recorded in order to listen misheard explanations again and to transcribe. Before and during the interviews, the researcher obtained participants' permission to record the meeting. In total, 4 semi-structured interviews were conducted between January and March 2023. The date and duration information for each interview as well as the meetings with research consultants are tabulated in Table 6.

***Table 6.*** *List of meetings arranged with all the participants.*

| **Meeting** | **Participant** | **Date** [dd/mm/yyyy] | **Duration** [min] |
|---|---|---|---|
| AM | IP01, IP02, IP05, IP06, & CP1 | 09/11/2022 | 63 |
| NC | IC | 11/11/2022 | 70 |
| NI01 | IP01 | 23/01/2023 | 45 |
| NI02 | IP02 | 25/01/2023 | 46 |
| NI03 | IP03 | 17/02/2023 | 85 |
| NI04 | IP04 | 03/03/2023 | 42 |

One of the interviews was conducted in the Turkish language since both the researcher and the participant have Turkish as their mother tongue. During analyzing the interviews, the researcher translated this interview into English.

### 3.3.2 Interview Analysis

This thesis follows a qualitative research approach in order to analyze the case company regarding the product safety requirements compliance management process. Therefore, semi-structured interviews were conducted during the data collection. Thereafter collecting the data via interviews, the researcher analyzed it to present meaningful results for the readers. Firstly, the researcher transcribed the recorded meetings into text formats with the help of the *'dictate'* function of the Microsoft Word application. It is a practical service, especially for the researcher who implements a qualitative research approach. In total, 60 pages of data are created while transcribing the recorded meetings into text formats with an 11-point Arial font type and a spacing of 1.5. Both the meetings' recordings and text files are stored properly and accessible only by the researcher.

Later, the researcher went through all the open-ended interview responses and checked that they were relevant to the questions. This process necessitated to be done several times due to the intensity of the context and the amount of information. After gaining an overview of the gathered data, the researcher categorized the results based on the objectives of research questions. This categorization is formed according to the compliance management studies in the literature (Henson & Heasman, 1998; International Organization for Standardization, 2014) and consists of nine steps as shown in Figure 2. However, these steps are not directly imitated from the original titles rather, they are modified and re-named according to the researcher's discretion and the scope of the thesis. Namely these steps are as following: identifying and discovering the requirements, interpreting the requirements, identifying possible changes in products or operations, identifying and evaluating compliance risks, compliance decision, specifying methods of compliance, communication, implementation of requirements, and evaluation and monitoring. Then, under the mentioned steps, the researcher explained the case company's current applications and problems in their compliance management process for the safety-related requirements based on the open-ended answers of the experts.

### 3.3.3 Proposing Improvements

After conducting semi-structured interviews, collecting the required data, reviewing them for clarity, and analyzing them according to the first three research questions, the researcher answered the fourth research question as a final step of the thesis study. The last objective of the study was to recommend possible ways to improve the company's operations for compliance management. Hence, the researcher combined all the information obtained from semi-structured interviews and literature reviews to achieve the last objective.

Firstly, in reference to the interviews' results, the case company's difficulties during compliance management of product safety requirements are listed. In addition, their currently existent applications for this compliance process are summarized. Later, through a deep investigation of the literature, best practices regarding managing compliance with safety-related requirements are collected and reported in Chapter 4.3. Finally, possible improvement opportunities for the case company are defined by comparing all the findings. The researcher created a table where all the recommendations are shared in order to facilitate the reader's visualization. Subsequent to the table, improvement opportunities and suggestions are explained explicitly throughout Chapter 4.4.

# 4. RESULTS

The qualitative results in this chapter are obtained from the semi-structured interviews conducted with the chosen participants inside the case company as well as from the information gathered by literature research regarding product safety compliance management processes in the global context. All the compiled data is analyzed and used in accordance with the benefits and the goals of the case company. The following subchapters present the company's current state and challenges during managing compliance with the product safety requirements, and opportunities for improvements by comparing the most applicable practices in the field. Accordingly, the results of the thesis are structured in the order of research questions. In this chapter, the word ´requirements` implies regulations, standards, and customer specific requirements unless another information is specified.

## 4.1 Current Applications for Management of Compliance with Product Safety Requirements

In this chapter, the researcher aims to answer the first research question. The results are based on the semi-structured interviews conducted with the case company participants. The current state of the case company regarding product safety requirements management practices in global framework is presented and subtitled in the following parts in accordance with the investigation of the literature and previous scientific research. As shown in Figure 2, the subtitles are decided based on compliance management processes found in the literature (Henson & Heasman, 1998) and ISO 19600:2014 compliance management system (International Organization for Standardization, 2014).

Figure 4 provides a structure for the reader to easily visualize how the upcoming results are presented.

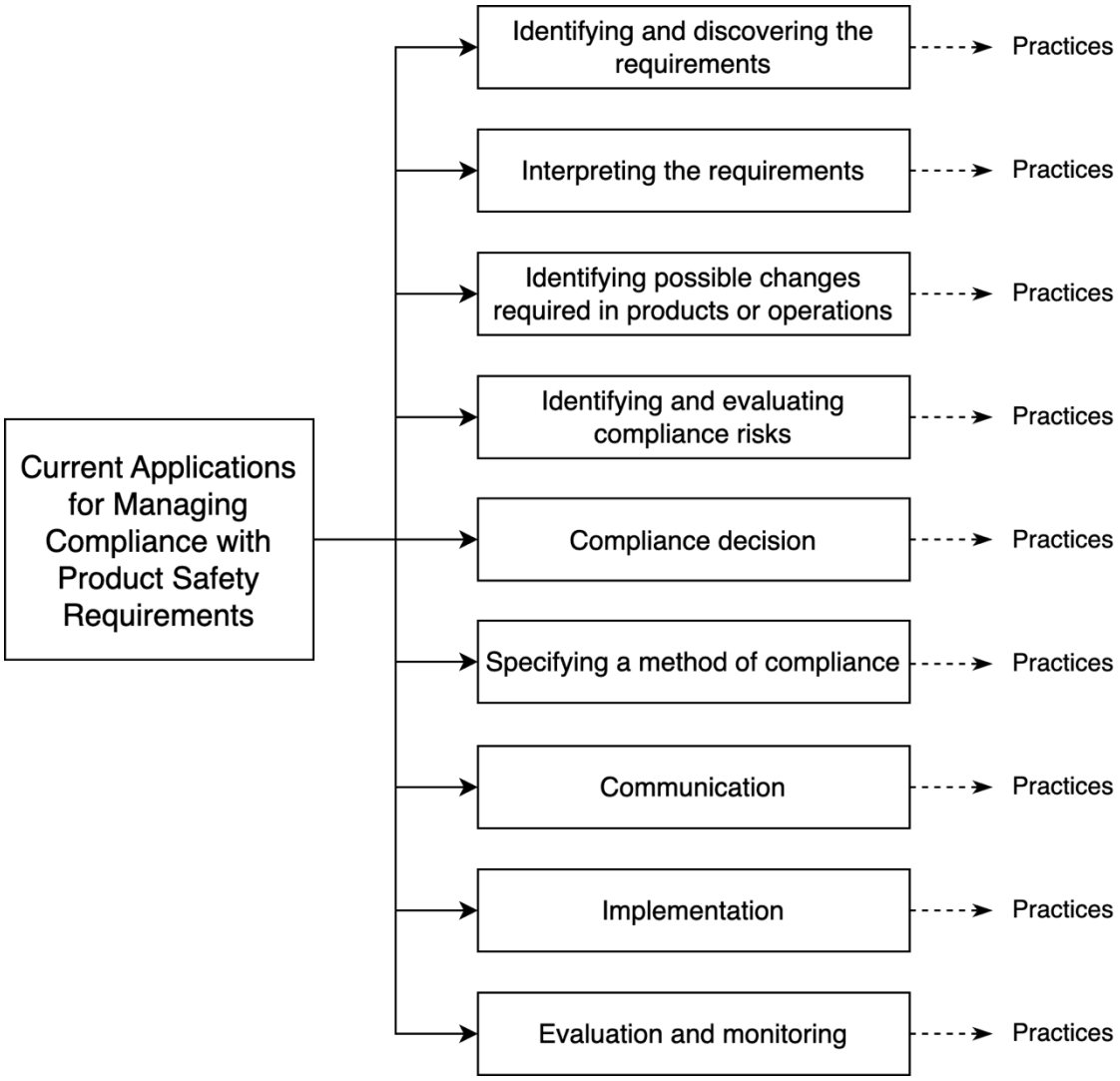


***Figure 4.*** *Structure of current applications for managing compliance with product safety requirements.*

**Identifying and discovering the requirements**

According to four experts from the case company, global standards and regulations are handled mainly by responsible people who screen the market requirements regularly. As the interviewees stated, this group of people keeps the library of the standards up to date. The library is an organization-wide standard database. In this process, some retailers of standards send email notifications when a new revision of the standard is available. Even though there exist processes for getting updates for regulations and standards, there is no specific source within the company only for product safety requirements. Therefore, it is needed to extract safety-related requirements from all information.

During one of the interviews, the participant explained that there is a possibility of communicating with a consulting company regarding updates to certain market regulations.

However, the primary aim of the collaboration with the consulting company will not be discovering the updates:

> ‘But we are not talking about this update issue, but rather so that they can support us about the tests we will do in that country.’

One of the experts from the case company mentioned their membership of the national body committee for automotive industry standardization. Few people from the company act as expert members of global standardization with the help of this membership to identify new standardizations.

Ordinarily, company experts are aware of how rapidly the regulations are changing. Satisfying the regulatory requirements is even more complicated when operating in a global market. As highlighted by a company expert:

> ‘It [handling compliance with regulations globally] is a tough question, mainly because the regulatory field and standards representing state-of-the-art are developing quite fast pacing. It [keeping the state-of-the-art up to date] is hard and something also beyond the standards and regulations]’

For the customer specific requirements perspective, the main application is direct access to OEMs’ internal portals. The company receives the updated information by registering the customers’ portals.

One interviewee working in a different business line of the case company described a similar application during identifying and discovering the product safety requirements. They also mentioned that they are still developing this process.

> ‘…there is big topic still under development, but at first we are checking customer portals and we have information from customer purchasing department.’

**Interpreting the requirements**

In principle, interpreting the updates and changes on the product safety requirements is a part of expert judgements according to the interviewees. When some outdated standard or norm is found out, they reviewed and checked the compliance against their current capabilities in the requirement at that moment. Moreover, how the product is affected by this requirement and whether it can be fulfilled or not require a checking by the experts.

Therefore, directly applying the updates into the operations is not the case for the company.

> ‘Of course, it might be that the new requirements might be even more challenging or even impossible.’

Firstly, they ensure that the requirement and the aim of the standard is within the company’s scope development and EV batteries. One of the interviewees explained the following step:

> ‘If it is clear written, then we can copy and paste to our requirements book or at least make fast requirement out of it and if there are some unclarity, then we are discussing it internally.’

One of the interviewees noted this process as delta evaluation. Interpretations of the update's effects may lead to design change or delta validation. However, it is also mentioned that there is no sharp process when the related people come together. The judgement of the interpretation evolves via back and forth e-mailing and discussing about different viewpoints regarding the update.

Some of the interviewees also addressed that they sometimes utilize external consultants for the interpretation of requirements. Depending on the project type, scope and size, as well as the available sources, they hire consultancy to help them sort the requirements and to create the specifications.

> ‘There is some level of utilization of external employees also.’

In addition, one interviewee emphasized that meeting the safety requirements is not open to interpretation from the target market viewpoint. They must satisfy the regulations mandatorily if they aim to operate in that trade market. The only issue remains finding the effects and results of compliance:

> ‘If there is an update in the market regulations, you normally have no chance of accepting it or not if you want to produce this car and to sell it here [target market].’

The interviewee working in a different business line of the case company mentioned reviewing the norm and defining the requirements from Quality Department. They are also responsible for checking if this specific change is related to their process quality or not.

**Identifying possible changes required in products or operations**

The required changes are evaluated based on the company’s capability, project scope, and industry area when there is an update in the requirements as explained by the inter-

viewees. All the valid product requirements are defined at the start of the product development process. When there is a change in the requirement, its effect on the current design is assessed. Even though there is no need to change the design, it might be necessary to repeat the validation tests for the specific requirement after the changes.

Moreover, the company discusses the effects of the change with the supplier when there is a supply chain operation. Sometimes, the supplier side is already aware of this change before the case company. Therefore, the supplier acts as an external consultant regarding the topic.

> '…suppliers tell us what kind of change they have to do to achieve this [updated] requirement. The suppliers are also aware of this kind of change. We communicated what kind of changes is required with the suppliers.'

If there should be a design change, the company examines and analyzes the situation with the design teams internally.

**Identifying and evaluating compliance risks**

Identifying and evaluating the compliance risks at the start of the project is crucial for the company. When they think about internal products, they can decide how they will deal with the European market regulations. However, if they work in big projects required by different OEMs, they normally operate in the global market. In this case, they must comply with every available standard regardless of European region or US market or Chinese market. If they lack the ability to evaluate compliance risks before entering the project, they might be fined a lot of money, a huge reputation lost, and even bankruptcy.

> 'We have to be really sure that we know with the start of the project if we are capable of fulfilling all these different standards worldwide. Because if we are not fulfilling these standards then we are in a big mess because the customer is forcing us to comply with that and if they are not capable of going to certain markets because our product is not good enough.'

For this reason, the company experts believe that they have to be cautious and deeply investigate different markets, and possible risks to comply with the different markets.

Based on the engineering judgement inside the company, the requirements are evaluated after which risk evaluation emerges. If there are no test results at hand, then they will either fulfill the requirement or emphasize the problem which is in turn a risk definition.

> 'Risk management [process] exist as well through the project lifecycle.'

One of the interviewees called this process a change request process. When the product reaches a certain level of development, then any changes will be delivered to the change request.

> ‘The impact of change is read and reviewed against the already executed testing. For example, some pre-verification or revalidation testing or maybe some specification updates or design updates has to be done.’

The other business line expert also reported the utilization of risk assessments for the changes.

**Compliance decision**

Companies must select whether to satisfy the changed requirements once it has been determined that changes are necessary for the company to meet the regulations' criteria. In European regions, existent standards are not mandatory. However, authorities appreciate and recommend that the products are designed according to the standards.

The case company decides compliance depending on cases under discussion with several stakeholders such as product management, project management, and technical compliance representatives.

Additionally, if the requirement is related to a market regulation, then compliance is a must without arguing to operate in the market. In each market, regulations and state-of-the-art norms are already defined and well-known.

> ‘This [compliance] is most of the time not according to wish or decision.’

> ‘By law, you have to comply with the safety standards, otherwise you [may] have big risks and some liability lawsuits.’

> ‘You have to change. You have no other way. This is against the law.’

For instance, noncompliance with the state-of-the-art product safety requirements in the US market may cost millions and billions of dollars.

From the customer specific requirements point of view, the case company experts stated that they also have to comply with them. Since the contract between the customer and the company ensures that the company has to comply with every requirement, there will be no other chance to decide not to comply.

According to the company’s own production safety, the decision depends on how safe they want to be. As a battery manufacturing company, if they decide to their employees need special protection equipment then they might not develop it in accordance with

some safety standards. It is because their employees have special protection or special level of training or knowledge. On the other hand, one interviewee noted:

> ‘If we are saying that our workers don’t have the special training, then we need to develop a bit more than we need…that our product is complying with additional safety standards…that we have no harm to our workers.’

Hence, deciding compliance with the changed requirements is done according to the circumstances by the company experts.

**Specifying a method of compliance**

Companies must choose how to comply with the regulation after deciding to comply. The adjustments that companies must perform are indicated in detail in various circumstances. There may be little or no room for discretion in this phase of compliance process. However, the corporation sometimes may have a variety of alternative compliance methods since the adjustments needed to comply with the legislation are complicated and susceptible to interpretation.

The case company experts stated that they follow some models from several standards such as VDA Product Integrity, IATF 16949, Automotive SPICE, and V-Model in order to test the requirements during product development. They review testing requirements from multiple sources and then compile them into a testing strategy. To reduce the huge amount of test scenarios, they select the most stringent ones.

However, the company manages the compliance method mainly with the change management process.

> ‘When we start with the change, we need to track it. We have separate documentation for this. It is managed by change management until implementation.’

Moreover, they seek technical and engineering judgement for the product development process. Based on the know-how they perform more development tests if they foresee risks for upcoming compliance homologation tests. Hence, they try to assure that they will comply with the later tests and requirements as early as possible in the beginning of development.

In the cases of global operations, the company tries to outsource some of the tasks as described by one interviewee. The reason for external guidance is mainly the fact that providing a complete compliance process for every country and each target market is almost impossible for a single group in the organization.

> ‘At the moment we [the case company] are not maybe capable or don’t have the knowledge about it [Chinese market] completely. Therefore, we are trying to outsource some of the tasks.’

**Communication**

After establishing a compliance method, companies must communicate this to all parties involved in implementing the necessary changes. For small-scale organizations building an effective communication system may be relatively easy, simple, and economical. However, for large-scale organizations with complex managerial structures and many employees, the burden of communicating the selected compliance strategy may be immense.

As a large-scale manufacturer, the case company experts described different systems to handle all the requirements and product information in addition to documentation of the project phases from the different departments. For instance, one of the experts stated that requirements are communicated through the Siemens-Polarion software tool by the requirements engineering teams. When they become aware of updated regulations, the requirements are also updated in this system. Updates in these systems trigger the change management process.

> ‘Change management is done [supported] via software. All documentation related to change management are archived and stored in the software.’

The case company has a change board where these compliance changes are discussed for all projects. This board consists of a variety of participants from every area such as logistics, mass production, development, etc. In case of updates, each representative explains what kind of effects this change brings out to their own operations in addition to adding the cost effectiveness of the change.

Furthermore, the company utilizes the GUKSA tool for ensuring an effective process management approach. Process descriptions, explanations, and all the information related to processes are collected and recorded to make them accessible and understandable by all employees.

Together with the formal processes, people are communicating during the meetings and e-mail conversations as disclosed by the interviewee. These meetings and e-mails are also data for the company and different levels of decisions are made in those conversations. However, it is challenging to keep all the voices and decision-makers up to date about what is already discussed because of the difficulties in encouraging people to document all the discussions and in making them follow the decisions from the main tool.

> ‘There are meetings in place where you could have the opportunity to speak about it [problems] and some new tasks.’

The experts also admitted that they are taking steps to make truly open and transparent communication in their operations even though it is always quite difficult.

> ‘The PSCR organization is one huge step ahead.’

**Implementation**

The implementation step of the compliance management process is closely linked to the evaluation and monitoring step. Companies generally perform required changes to comply with the regulations and then deliberately adjust these in consideration of monitoring efforts and feedback from external organizations.

Implementation of the requirements is done through a change management process after nomination inside the case company. They aim to define impact analysis of the change starting from the change, informing production and logistics units, and ensuring any stock levels if necessary.

> ‘Each change is evaluated by the responsible representative from each department.’

Additionally, it is crucial to have a clear understanding of responsibilities between all the related departments such as design, production, product safety, and local lines, etc. in the phase of implementation. For example, some companies recruit employees only to deal with compliance issues in their daily activities. However, one of the interviewees claimed that some of the responsibilities should be separated from the normal project work due to increased pressure and reduced efficiency of outcome.

> ‘Especially if it comes to safety related compliance requirements then they [compliance management teams] have a big responsibility.’

> ‘Often this responsibility is on the shoulder of some project leads, maybe, that's not where it should be.’

**Evaluation and monitoring**

The last step in compliance management process is evaluation and monitoring of compliance after implementing the updated regulation. Most of the time, companies are unwilling to routinely monitor compliance with regulations until they are forced to comply. It may be due to the launch of a new product development or a change in production processes. Generally, larger-scale companies have a specific unit whose tasks are monitoring compliance with regulatory requirements.

The case company does not have a written down process to evaluate and monitor compliance after the implementation of global requirements as stated by the interviewees.

> ‘It is more on-the-fly processes [for worldwide requirements that are not in the main target market] and fingers crossed that we are monitoring everything and that nothing will come up when it's too late.’

Currently, existent solutions are mainly based on external consultancy solutions, and some employees investigate the market and discover what new norms and standards are available. The so-called V-Model structure is utilized for all engineering activities.

> ‘Also, there is implemented monitoring sheet on requirements management tool where active status can be tracked.’

The case company also has different milestones or project gates in the projects. These milestones include requirement review and sample validation sessions as mentioned by one of the experts.

> ‘PDP (Product Development Process) covers all important milestones and reviews.’

During the product development process, the company reviews the requirements for each sample based on their configuration management. Throughout the process, samples are changed to different versions all of which are tested with different prototypes.

> ‘So, you review the requirements on each sample plus you get the validation result of those requirements by testing.’

## 4.2 Problems Regarding Product Safety Compliance Management

In this chapter, the researcher targets to answer the second research question. The results are based on the semi-structured interviews organized with the case company participants. Different types of problems that the company confronts while handling compliance with safety-associated requirements are introduced and subtitled in the following parts in accordance with the investigation of the literature and previous scientific research. As shown in Figure 2, the subtitles are decided based on compliance management processes found in the literature (Henson & Heasman, 1998) and ISO 19600:2014 compliance management system (International Organization for Standardization, 2014).

Figure 5 provides a structure for the reader to easily visualize how the upcoming results are presented.

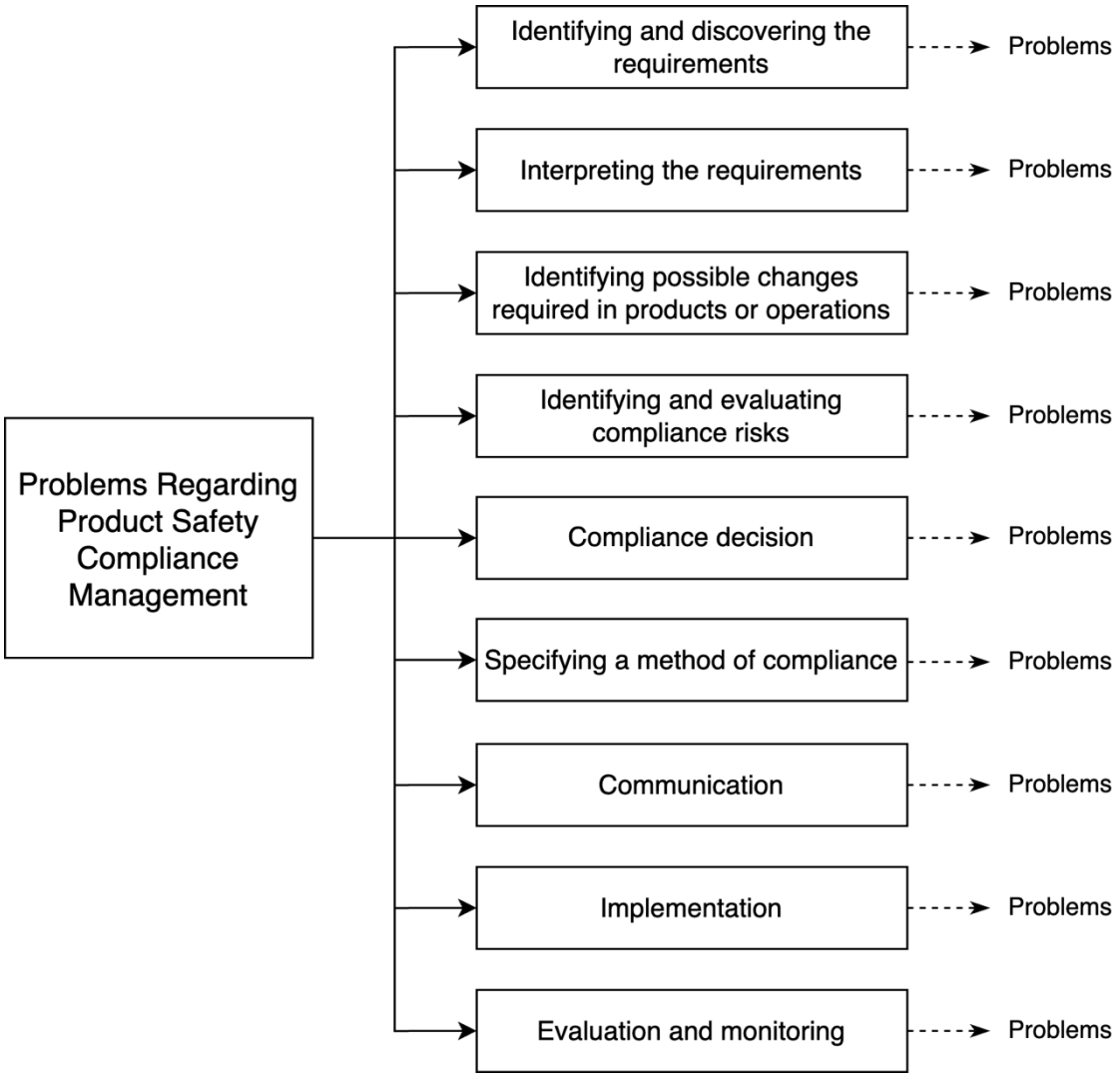


***Figure 5.*** *Structure of problems regarding product safety compliance management.*

**Identifying and discovering the requirements**

The semi-structured interviews showed that the case company experts generally have difficulties in dealing with the continuously changing environment and expectations from regulatory issues and customers. It is also mentioned that lack of centralized data bank related to product safety requirements is another problem.

> ‘There is no single source for all global standards and norms like DIN, ISO, GB/T, SAE, UL, and etc.’

Additionally, language issues are a huge problem for discovering the global requirements. Sometimes, even the customer demands working on their language while identifying the standards as explained by one interviewee.

> ‘Some standards are hard to get in hand in English version’

Although EU member countries have harmonization in the legislation requirements for product safety, company experts stated that how they practice the requirements and what their demands in compliance differ between EU countries. Especially, automotive manufacturer dominance in German market may have specific wishes:

> ‘OEMs are claiming that German version of their internal standard is the legally applicable one.’

Two interviewees agreed that identifying any changes and discovering safety-related requirements would be easier if there was an automatized notification system. For instance, this can be an internal database or an external paid support where you give your e-mail address, and they supply the information simultaneously.

> ‘It would be great if a system or a service provider which provides automatic updates for standards and recent publications exists.’

Moreover, unawareness of the upcoming standards and not being able to discover them before it is already officially published is another big challenge as explained by the interviewees.

Following the up-to-dateness of global requirements and understanding their main goals are challenging for the company. This requires a huge process about all norms for whole countries around the world, which is also quite complicated.

> ‘The biggest challenge is to have worldwide overview about every upcoming standard.’

More problems also mentioned about the customer requirements. Since the case company operates in the global market, their products are delivered more than 70 countries. Often time, customers clearly specify the market where the products will be sold. However, sometimes the customers just write worldwide operational requirements.

> ‘The customer can forget to inform us, or someone skipped checking their e-mail from the portal, so the challenge is to be up to date with the changing norms, standards.’

As explained by one of the experts, besides product safety requirements, there should also be official requirements for safe handling and storing procedures for the product. It is because, currently there are quite little standardizations for these phases. The company basically drafts these procedures with in-house expertise.

**Interpreting the requirements**

During the interpretation of the product safety-related requirements, there may be issues such as the absence of internal guidance or supportive external bodies, language barriers, lack of guidance, difficulties in new market areas, etc. The case company experts also emphasized the language problem in this phase of the compliance management process. For example, China is market dominant for producing EV batteries. Their regulations and standards are published in the Chinese language at first. Therefore, to operate in this region, companies must interpret and comply with these requirements as well.

> 'So, for us, a European company, it [Chinese market] is quite hard.'

There are companies where special people are hired in specific regions. Their duties are translating the country-specific requirements into at least English. This requires huge amounts of time and cost allocations. For the case company, the limited timing during the requests for information and quotation phases forces the company to allocate limited time for translation activities in some cases.

Moreover, German market is also dominant in producing automobiles with many large-scaled OEMs. The country puts difficulties for nondomestic organizations who are planning to operate in Germany. Their internal standard is written in Germany and even many OEMs have German as their official language. The case company has German OEMs as its customers and this situation is also a problem for them.

> 'We need a process in place for how we are translating all these [different customers'] requirements for our internal development because our language is English.'

Additionally, the case company experts explained that they make a selection to how many requirements they should comply with. In nature, application specific standards are not normative while there are also mandatory standards. For example, the legal position of the result in term terms of machinery, there is a classification of A-, B-, and C-level standards. A-level is basically a regulation in the machinery sector. Receiving marking is also mandatory and the C-type standards are basically the application specific standards. In general, companies should check what standards might be applicable, and when they start developing new products.

It is clear that the number of requirements, regulations, proposals, recommendations, and all kinds of information from different sources, from customers is extremely huge. As mentioned by one of the interviewees that one simply cannot fulfill all the standards that might be applicable to the product.

> ‘Let’s say we have 350 standards [requirements] that might be applicable for the product. Let's think about what the priority is, maybe 100 or maybe 50 or maybe even 15 out of these 350 standards [requirements], which are legislative or otherwise seen as crucial for the product. And then the rest of the standards [requirements], let's say 250 or 350 are mostly considered as a nice to have or somehow informative information.’

Therefore, they agreed on prioritizing the requirements.

> ‘Sometimes the requirements are overlapping or even contradicting between each other.’

**Identifying possible changes in products and operations**

Companies might face difficulties if they cannot identify what kind of changes must be made to meet the needs of new or updated regulations. Typically, when companies acquire sufficient information about the specific changes demanded for compliance with the regulation, they are less likely to confront monetary losses. Therefore, they should reserve adequate resources for a compliance process in order to prevent potentially bigger risks in the future.

According to the case company experts, it is also mentioned that the cost of changes is always a big challenge. They must repeat the validation tests for the requirements, even though the requirement is already passed before the changes occurred. This means an obvious increase in the cost of expenses for the project.

One interviewee stated that during the identification of changes in product safety requirements, it would be beneficial to give clear boundaries and guidelines related to how to proceed and what sort of compliance their products need to achieve. They mentioned the need for stronger management understanding to solve this issue.

> ‘More trainings and resources would be welcomed.’

**Identifying and evaluating compliance risks**

According to the company experts, compliance risks are defined mostly by testing results. Additionally, they review and verify what kind of impact the change will bring. Therefore, it is important to conduct revisions and verification activities with sufficient reserve.

> ‘[The problem is] mostly lacking resources to perform all necessary review and verification actions on time.’

Hence, they should pay attention to training employees. However, one of the interviewees mentioned that it is not meaningful to train only engineers across the company. They should also train at the management and top-management level of people inside the company. Logically, higher level of technical and managerial experiences derives a better awareness of the state-of-the-art, know-how about the requirements and regulations in addition to judgment about what the challenges and possible cons and pros might be while aiming to product safety and liability.

> ‘It has to be a cross organizations company understanding.’

**Compliance decision**

Since the investigation area of this thesis is product safety, mainly all the case company experts are aware of the importance of safety towards human-beings, environment, and structures. Thus, when their product safety-related requirements change, they believe that they should directly adapt to this change.

> ‘To be honest, you have no chance to decline.’

When they proceed with the compliance decision on a case-by-case basis, the distinction between different market areas and customer expectations might be challenging for the company. Especially US market poses difficulties for the company. The US regulations always consider a production with the highest degree of safety to satisfy the requirements for operating within their markets.

> ‘You have the UL certification process what's really hard to fulfill at the moment. It is a big challenge for our company.’

**Specifying a method of compliance**

After the decision of complying with the requirements, companies should specify how to implement it through their processes. Even though there are several ways of implementing the regulations, companies may choose the one with minimum changes and efforts. However, this may also result in insufficient capability for dealing with possible issues that might occur in the future.

The case company representatives mainly found it difficult to evaluation of cost of change during the change management process. At this part, this process can be said the main approach to implement compliance changes.

> ‘We need to be really careful of each department to evaluate the cost of change. We need to be sure that each time we take into account every area where the cost will rise because of the change.’

**Communication**

Most of the time, companies face difficulties while creating an effective communication approach for each person involved in a specific topic. The case company interviewees also expressed the same difficulties for their company.

> ‘To establish truly open and transparent communication which does not lack any steps or information directions is always a bit difficult.’

It should be a must to cooperatively exchange information between different project units. When the company fails to create systematic awareness, then it may cause resource and time losses such as repetition of the same task, searching the same topic unnecessarily, or doubling the documentation, etc.

One of the experts reported that involving each related person and getting their opinions is challenging. Moreover, they should be kept up-to-date about what is already discussed, what is decided and what is the background of all the decisions or what is recommended in the meetings, and what level of decisions are made in meetings. However, the company is lacking to obtain a robust communication system within the organization.

> ‘Of course, meeting notes is one of the places to document the decisions and background, but people are in hurry and all the meetings are overlapping each other, so it is sometimes difficult to keep all the meeting sources up to date. It is challenging.’

It is also mentioned that currently, they are lacking in a process description regarding communication inside the company.

> ‘The problems will come up when we have defined the processes and then it will show how good the processes are.’

**Implementation of requirements**

During the implementation of the requirements, the company experts mainly affirmed that there exist non-uniform practices in their projects.

Additionally, the change management process that they utilize to implement project changes still needs improvement.

> ‘It [change management process] is not perfect but a lot better than some time ago.’

Moreover, one of the interviewees mentioned unclear responsibilities within the company. Particularly for some new roles, the company is lacking in complete description of

what these roles should be responsible for. Job descriptions are not clearly acknowledged by the company as described by the interviewee.

> ‘Maybe a lessons-learned or a process [for] what we have to improve to [make] position descriptions are known to the company and also to done according to a special process.’

It is also noted that due to the importance of this problem, different departments should collaborate side-by-side. The case company experts expect to improve process and job descriptions by starting from human resources to the different development teams. At least, they should go hand in hand. The case company should realize as a whole how the company sets up the projects, how they define development structure, and how the teams are structured.

**Evaluation and monitoring**

Evaluating and monitoring compliance with the requirements is an important step of the compliance management process. This step may involve obstacles if companies are ignorant about the challenges and if they are insufficient to define the risks of compliance. According to the company experts, the case company poses inadequacy in this step.

> ‘These people [who are searching for new norms and standards into the market] are not capable to check it with our existing requirements.’

As explained by one of the interviewees when there is a changing requirement related to product safety, then those people who are doing market checks do not have the expertise to evaluate them properly. The judgement of whether the change will have a huge impact or not, what the background and origin of the change is and what kind of meanings that change has on their projects cannot be done with these people.

> ‘Therefore, we need more skilled people to do this evaluation.’

Moreover, even if this kind of expertise level is reached, there might be still some duty allocation issues. When people are trained to evaluate and monitor the requirements, whether they should work in the engineering team or there should be a compliance management teams with deeper technical understanding about the upcoming safety requirements still pose problems.

## 4.3 Most Applicable Compliance Management Practices for Product Safety Requirements

The target of this chapter is to provide answers to the third research question. By investigating the literature and previous scientific research regarding the most applicable compliance management practices of product safety requirements for product manufacturer companies, the researcher listed the following essential solutions (OPSS & BEIS, 2021; NERC, 2021; Encona, 2021; Rincon, 2010; IBM, n.d.; Association of Equipment Manufacturers, 2022; European Commission, 2011; United States Consumer Product Safety Commission, n.d.; Harmon, 2003) throughout Chapter 4.3. These solutions are mainly formed based on the previously utilized compliance management process steps as a whole. For example, one of the solutions may be useful for only one step of compliance management or may be applied to all steps. Therefore, the researcher recorded the practices without separating the different steps.

Below Figure 6 shows a map for several practices of compliance management processes. This figure helps to easily visualize what kind of compliance management practices for product safety requirements are available in the literature. Each practice is discussed in detail following the figure.

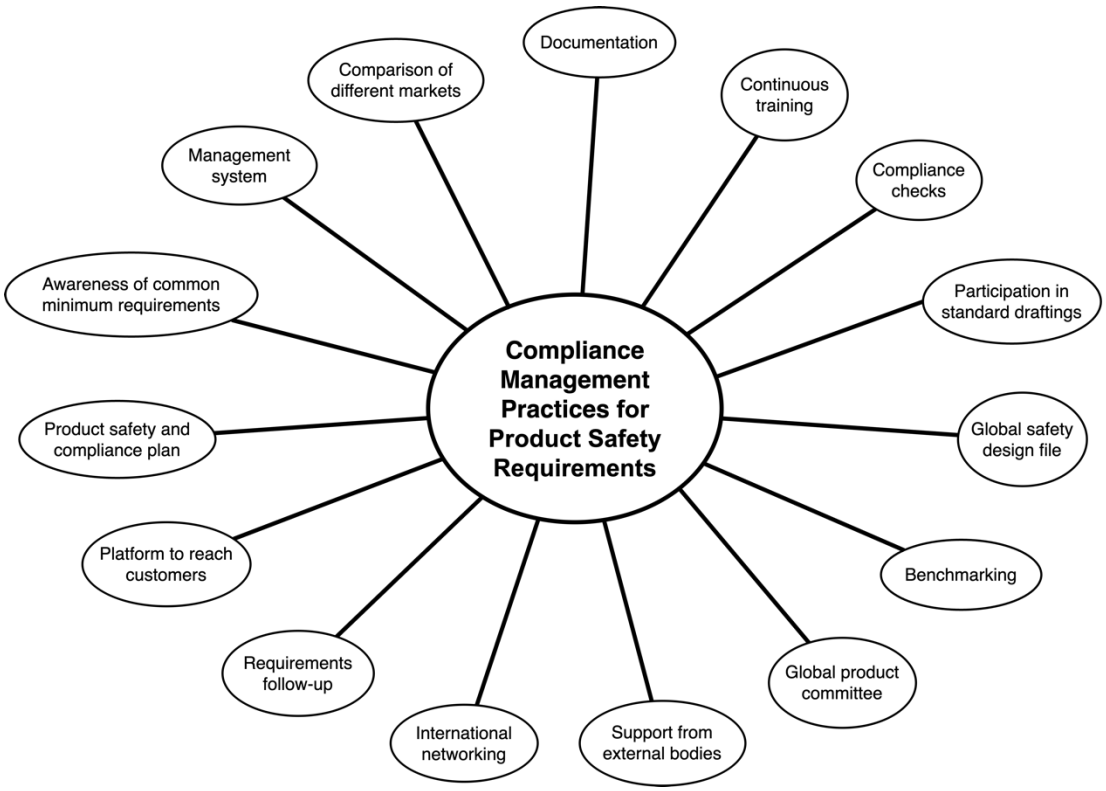


***Figure 6.*** *Compliance management practices map.*

**Management system for the requirements**

In order to guarantee product design and development aims are favorably satisfied, having a management system for the requirements is essential. Especially, complex products with various intended use, such as batteries, are more interdependent throughout the entire life cycle. The requirements management system enables project people to control each phase of the product, to analyze the requirements, and to prioritize them. It also provides an agile communication network with the stakeholders while monitoring any changes in the product requirements. Generally, digital requirements management systems are embraced within the companies. It creates a transparent way of working by reducing the duplication between teams.

**Efficient documentation of activities**

Documentation of compliance activities to meet product safety requirements is an important practice for manufacturers. Having a robust and flowing documentation process allows companies to investigate retroactively in case of any problem with the product. Additionally, documentation improves the understanding of safety and compliance concerns of the company for future actions as well as helps to avoid possible product recalls. Documentation of activities includes paper-based documentations, electronic or audio-visual media. Overall, efficient documentation inside a company ensures that all the actions are established, controlled, monitored and recorded.

**Compliance checks throughout the projects**

Checking the product safety compliance throughout the entire life duration ensures that the product is designed, produced, integrated, transported, and disposed safely. Any failure to demonstrate compliance with the regulatory issues could cause undesirable results for the company. Therefore, they must check product safety compliance before it is too late for recovery. These checks can be done for each project milestone. Reviewing of current situation, and verification and recording the information should be performed during the checks. By this way, the company makes sure that the next project phase will not continue unless the current product meet compliance requirements.

**Global safety design file**

Developing product safety design files may assist the design engineers in their duty of sharing the information with other people involved in projects. These files are part of technical documentations and may consist of information such as hazardous substances, flammable materials, accessibility risks, features to safe operation, or heavy

elements that may create handling risks, etc. Furthermore, there might be safety reports, risk registrations, safety data sheets, handbooks and policies for safe maintenance, and all appropriate safety information the designers prepared in the design process. These files help to increase awareness of any risks and to minimize the likelihood of safety features included in the design.

**Benchmarking from other companies**

Every company has their special set of rules and regulations for risk management and product safety. For instance, high-profile big companies put primary emphasis on product safety while considering their organizational strategies and processes. They also allocate more resources on this topic, and they face quite less product recalls compared to smaller and less successful companies. Additionally, they are more likely to have dedicated experts who focus priorly on safety and regulatory issues. Hence, benchmarking or comparing own parameters to other businesses to analyze effectiveness of the practices is essential for the companies.

**Employment of external bodies**

Utilization of additional support from external bodies is helpful during product safety compliance management process. These bodies include research institutions, business consultancies, industrial associations, inspection agencies etc. Sometimes companies cannot have adequate resources to form specific units and train them to manage product safety compliance with the highest expertise knowledge. On the other hand, they can spend for hiring support from external bodies who can reserve more time and more experience related to these issues. Therefore, employing external support can be also considered as an important practice.

**Requirements follow-up by product safety person**

Companies should employ people who are primarily dedicated to managing product safety requirements. Since there exists a huge number of regulations, legislations, standards, and customer requirements in global environment, focusing on them apart from other tasks is not sufficient. There should be a committed group of people who follow-up product safety requirements, discover new or changing requirements, understand their background and meaning, and pass the information to the related people.

**Platform to reach all customers**

It is necessary for companies to create a platform to contact all the customers. Generally, alike system is a digitalized technological action where the company and the customers

can mutually benefit. Not only technical communication with the requirements, but also marketing, sales and service units can share information and collaborate. With this platform, companies can gather feedback related to products or operations from the customer easily. Moreover, they can inform customers about any detection of hazardous event or deficiency of the product. In the case of recalls, companies can organize a smooth process through this platform.

**International networking for knowledge acquisition**

Globally operating companies can build international networking in order to share information between different units. Every country has their own policies and regulations related to product safety. Even the customers from different regions may have different requirements for the same product type. Therefore, arranging regular meetings with the global units may enhance the knowledge acquisition and utilized practices which result in improved compliance management processes.

**Product safety and compliance plan**

Having a practical product safety and compliance program decreases the possible accidents and recalls caused by the product. Creating a plan for product safety and compliance improves the safety and quality of the product for customers as well as ensures an accessible market globally. This plan may involve risk elimination actions and tracking them to the completion, identifying people who will be responsible from the entire process, deciding the product/operations/process risks, and determining what kinds of trainings people should attend. Moreover, companies should clearly develop policies, procedures, standards and/or guidelines for their daily operations in order to meet their safety purposes.

**Attending to standards drafting processes**

Companies may assign some of their personnel to the participation of standard drafting process. This participation can be directly by covering national, European and international drafting committees for standardization. However, generally companies participate in the process by national standardization committees. The drafting meetings are mainly open to all interested parties and their schedules are publicly shared. By registering themselves prior to the drafting meetings, industry experts can attend the process. Eventually, participation in these activities provides a significant opportunity to become familiar with the standard, to enhance interpreting the requirements and understanding what their background is and how it will apply to their products.

**Comparison between different market standards**

Globally operating companies may have various product safety solutions for different markets. Companies operating in a different country but in a similar industry may have completely diversified product safety standards, safer product understanding, and compliance management processes. Additionally, supply chain activities within a company requires a systematic examination between different market standards. Unimaginatively, some countries set up higher and tighter safety related standards. Therefore, comparing and analyzing those requirements between different markets as early as possible brings advantages to the company.

**Global product committee for knowledge sharing**

Sharing knowledge between global operations is an essential practice for successful compliance management. Companies can build a global product committee where the members share information with each other, for example in knowledge sharing workshops involving each unit around the world. During these sessions they may have several objectives such as any changed or new requirements, acquisition of new practices related to product safety compliance, strategical improvements, and any knowledge gained during the implementation of co-decided activities. Moreover, they can discuss good practices and lessons learnt in addition to exchanging perspectives on how to ensure and maintain achievements in the future.

**Definition of common minimum requirements**

Investigating which product safety standards and regulations apply to their products is challenging for manufacturers. There are various safety-related requirements depending on the product type, target market, and/or customer interests. However, there are also minimum common requirements universally assessed to demonstrate product safety compliance. Hence, companies should at least create a checklist to evaluate applicable common product safety requirements for their target market.

**Continuous training for people involved in product safety**

Companies should commit to providing appropriate training for their product safety personnel. Since product safety is the most crucial part for the industries, any deviation from the regulatory requirements causes the people responsible to be held questionable. Therefore, product safety people should have a comprehensive understanding on main-

taining safety and conformity of products. For this, companies provide or allocate resources to train product safety people sufficiently in the pursuit of obtaining necessary qualification and competency level.

## 4.4 Improvement Opportunities for Managing Compliance with Product Safety Requirements

The target of this chapter is to provide answers to the fourth research question. Throughout Chapter 4.4, improvement opportunities for the case company regarding compliance management practices for safety related requirements will be presented. Previous findings of the Chapter 4.1 and Chapter 4.2 featured the current practices of compliance management of product safety requirements and confronted problems during this process inside the case company. As regards to the problems obtained by the semi-structured interviews, the case company's potential improvement areas are defined by combining them with the existent literature findings presented in Chapter 4.3.

Below Table 7 demonstrates both the improvement opportunities of the case company to manage compliance with the product safety requirements and proposals for an improved compliance process. This table was created by summarizing all findings under the Results Chapter 4 to ensure a smooth reading. Following the table, improvement opportunities and suggestions are described in detail.

***Table 7.*** *Improvement opportunities for the case company to manage compliance*

| **Problems and Challenges** | **Compliance Process Steps** | **Suggestions** |
|---|---|---|
| Keeping the data bank for standards and norms up-to-date globally and to extract relevant safety requirements | Step 1 | Compliance management system where all the responsibilities are allocated |
| | Step 2 | |
| Evaluating the impact of the changes for the company | Step 5 | Urgent need to make proper arrangements in PSCR organization |

| Problems and Challenges | Compliance Process Steps | Suggestions |
|---|---|---|
| Unawareness about upcoming standards beforehand<br>Lack of worldwide overview about every upcoming standard | Step 1<br>Step 2 | Reaching the same safety understanding level in each operating location, international collaboration within company units<br><br>Collaborating with multiple service providers to obtain automatic notifications about the updates<br><br>Internal company action plans for attending in standards and requirements drafting activities<br>- place in mailing list of relevant regulators<br>- be a member of professional groups<br>- subscribe to relevant information services<br>- attend industrial forums, seminars, workshops<br>- monitor the websites of regulators<br>- meet with regulators and legal advisors<br><br>Lobbying with external parties |
| Language barriers between other markets and customers, even inside the EU | Step 1<br>Step 2 | More time and resource allocation to translation services or a local unit employment in those regions to collect and document identification and engineering clarification in safety issues<br><br>Compliance management committee for cross functional knowledge acquisition |
| Lack of inspection of cost of changes | Step 3<br>Step 6 | Clear boundaries and guidelines about how to proceed in compliance process, a compliance framework<br><br>Strong managerial understanding<br><br>More resources and training in order to improve employees' qualification<br><br>Implementing a compliance process method which is compatible with company' visions, context, product, and organizational structure |

| Problems and Challenges | Compliance Process Steps | Suggestions |
|---|---|---|
| Lack to perform all necessary review and verification actions for safety concerns on time | Step 4 | More resources for testing activities and training not only for engineers but also for top management<br><br>Cross organizational understanding about product safety requirements and complying with them<br><br>Risk assessments in accordance with risk situations, company's context, size, and objectives<br><br>Monitoring further actions after risk identification process<br><br>Prioritization the high-risk situations about safety related requirements compliance<br><br>Encouraging all employees to properly documenting and regular reviewing of findings |
| Mostly unquestioned compliance with product safety requirements | Step 5 | Assessment of company's own strategies before the compliance decision<br><br>Understand legislations, bureaucratic policies, local culture about compliance management |
| Lack of communication<br>No process description for effective communication<br>Unnecessary repetitions<br>Difficulties to update everyone involved in the safety requirements | Step 3<br>Step 7 | Truly open and transparent, reliable, easily accessible communication channels<br><br>Reaching the same safety understanding level in each operating location<br><br>Effectively exchange of information<br>- Informal discussion sessions<br>- Focus group meetings for sharing ideas about safety requirements and their compliance<br><br>Reduction in unnecessary meetings and increasing documentation meeting minutes and sharing them with related persons |

| Problems and Challenges | Compliance Process Steps | Suggestions |
|---|---|---|
| Non-uniform practices<br>Change management process is not sufficient<br>Unclear responsibilities within the company regarding compliance management<br>New roles are not described clearly<br>Collaboration between different departments | Step 8<br>Step 9 | Lessons-learned process from challenges confronted in compliance process<br>Clear and bounded job position descriptions<br>More resource allocation to compliance management activities<br>Structured teams where each member know their tasks and responsibilities<br>Continuous and periodical reviews about compliance process<br>Increased top management involvement<br>Urgent need to make proper arrangements in PSCR organization<br>External support identification related to regulations, standards, laws, customers, etc. |
| Not qualified to check and compare existing and outside requirements<br>Cannot properly evaluate changing requirements from the market<br>Lack of judgement | Step 9 | More resource allocation to compliance management activities<br>More trainings through a periodical program for each level of experience<br>Employing competent and skilled people who have the ability to guide and take the lead of product safety requirements compliance process<br>Feedback receiving from different sources internally and externally |

**Step 1: Identifying and discovering the requirements**

As responded by the case company experts, the company faces some problems in systematically identifying and discovering and reaching all requirements regarding their products' safety. They mentioned the challenge of keeping their data bank for standards and norms up-to-date globally. Although they emphasized a software tool to track all the requirements, it is still a challenge for them to extract relevant safety requirements. It is proposed in the ISO 19600:2014 standard that depending on the companies' nature, organizational structures, and activities, each requirement and their validation methods should be defined consistently through a compliance management system.

This system may also solve language problems with the help of assigning a responsible person to guide this system. Even though EU countries have harmonized product safety requirements, there are still communication problems due to local languages. Since the case company encounters time and budget difficulties while translating every global requirement, this system may also contribute to putting appropriate attention to translating those requirements and making comparisons with other requirements in various markets. It may also trigger employing people in those locations who will identify the requirements and insert them into the centralized systems.

Additionally, this system may offer early awareness about upcoming changes. Since it is better to understand the regulatory requirements before it is officially published, the case company requires identification and discovery of them as early as possible. Even sometimes, their customers may forget to inform them about the locally changing requirements. Hence, the company may also adopt local units for their industrial areas. However, in order not to pose language difficulties again, their centralized requirements management system should still be in utilization.

Moreover, the case company may involve in standard generations process. This would be beneficial to have an overview about upcoming requirements and even to attempt to influence the regulation in favor of their own requirements. In order to attend those sessions, the company may be placed in mailing list of relevant regulators, be a member of professional groups, subscribe to relevant information services, attend industrial forums, seminars, monitor the websites of regulators, and meet with legal advisors as recommended by the ISO 19600:2014. Support from multiple service providers may also increase the earlier awareness of the changes since they automatically make the company up-to-date about recent situations of the product safety requirements.

**Step 2: Interpreting the requirements**

After gaining awareness about the requirements, they should be interpreted according to the companies' own products. The task is to justify whether the company is liable to the regulation, what will be the effects of compliance, and how many products will be affected. If the interpretation results in liability and several impacts on the products, then the organization proceeds to the next step. Hence, it is essential to understand upcoming requirements even while they are in the drafting phase to be prepared beforehand. This apparently requires adopting competent information channels and lobbying with external parties.

As stated by the case company experts, they face some problems during the interpretation of the product safety requirements. One of them is the different language barriers with other countries. Especially market dominant organizations from different countries publish their regulations and standards in their own language. Moreover, customers from other countries have written their internal standards and requirements in their official language. These are the challenges for the case company to interpret the information and decide to comply with them.

There should be a committee or a compliance person responsible for interpreting the requirements inside the company. This compliance committee should be responsible for the effective translation process of non-English documents from other parties, or even assign people from those countries to deliver and receive cross-functional compliance information. This committee may also create a special setting for organizations to start the exchange of information with their opponents. Furthermore, any possibility of overlapped or contradictory safety-related requirements can be resolved and processed with the help of the committee or compliance responsible person.

**Step 3: Identifying possible changes in products and operations**

Identification of possible changes in products and operations during the compliance management process could involve external changes such as financial situations, market conditions, liabilities, and customer relationships apart from the regulatory changes. Moreover, there should be internal changes such as policy descriptions, procedures, position or responsibility changes, and activity or service changes emerging from the requirements updates. The impact of the identified changes on the organizations and actions to meet new requirements should also be evaluated.

According to the case company experts, there is a need for clearly defined boundaries and guidelines related to progressing further in compliance management. This requires

a stronger managerial understanding, which eventually leads to the need for more training and resources. Special attention should be given to this need since any misunderstanding and uncertainty related to changes in compliance may trigger to end up with irrelevant or repetitive tasks. For instance, there might be unrealistic comments, falsehoods, and gossip within the company related to required changes. This may create time-wasting actions. Hence, acquiring trustworthy information regarding particular changes required to obtain compliance with requirements is critical for the company (Henson & Heasman, 1998).

**Step 4: Identifying and evaluating compliance risks**

Identification and evaluation of compliance risks is a crucial step for companies. This step requires the allocation of appropriate and adequate resources and processes in accordance with the implementation of a compliance management system. As regards the risk situations, context, size, and objectives of the organization the extent and detail level of the compliance risk assessment can vary as noted by ISO 19600:2014.

Compliance risks are defined by test results inside the case company. However, due to the lack of resources, there might exist time limitations to performing all necessary review and verification actions on schedule. There should be periodic risk assessments for managing compliance with product safety requirements for the company in the event of new or changed operations, changes in the organizational strategy, updates in compliance obligations, and any noncompliance regarding safety-related requirements. Moreover, there should also exist a monitoring and corrective approach after the identification of compliance risks.

The case company should plan actions to address compliance risks in its compliance management process. These actions can only be taken by people who have sufficient expertise and knowledge about these concepts. Therefore, training for all levels from engineers to top management as a cross-company understanding should be implemented within the company.

Obviously, assessing the risks of compliance will help the organization to prioritize their resources and pay attention to the most significant areas. For example, they can focus primarily on higher risks cases and allocate their resources accordingly. By this way, they can gradually cover all the compliance risks. Eventually, all of these assessments should be documented properly and reviewed regularly.

**Step 5: Compliance decision**

It was equally understood by the case company experts that manufacturing safe products is critical for the company, environment, customers, and world. They regard safety primarily in all their operations. This should be maintained in all their operational areas in every country with an identical safety degree. Thus, they mainly decide with no chance to comply when any changes arise in product safety requirements. This fully accepting compliance behavior is also explained in Henson & Heasman's (1998) study. Companies believe regulation is an opportunity and decide on industrial compliance in the case of full compliance. This behavior tries to discover the benefits of the regulations and by complying, they may even open the pave for other companies to comply. This situation may reinforce the competitive advantage in the market. However, it is more beneficial for the organizations to embrace a combined approach between defending to comply and fully complying by assessing the company's own in-house organizational strategies.

Sometimes, in the event of deciding to comply or not, the company faces difficulties with the expectations of different market areas and customer expectations. Especially some countries lay obstacles for the organizations that are willing to operate in their territory. In these cases, the company should decide whether or not to satisfy the required highest degree of safety in their products.

In order to have the ability to make the decision of compliance, companies should understand legislation, bureaucratic policies, and local lifestyle. As reported by ISO 19600:2014, deciding to comply or not should be evaluated in accordance with analyzing compliance risks. Additionally, companies should handle the requirements of products by creating a system where all the regulatory issues are described throughout the project steps. Therefore, it is critical to have a comprehensive compliance framework/system which is strengthened with audits rather than only complying with individual requirements.

**Step 6: Specifying a method of compliance**

Companies should select a method of compliance to implement the required changes easily and systematically after deciding to comply. A specific method is advantageous for the organization to provide framework for establishing compliance objectives and scope, and to which level the compliance will be embedded into operational tasks.

Due to not adopting a specific method of compliance with the safety-related requirements, in which way those decisions should be implemented in the project activities remains insufficient. There exist various standardizations that promote different solutions for compliance method selection and how to perform tasks accordingly.

Additionally, evaluating the cost of change is problematic for the case company. Hence, having a compliance framework will be useful for the company to evaluate the harms and benefits of the complying decision (Henson & Heasman, 1998). With the results of this evaluation, the company can choose the option with optimum benefits and minimum costs of change.

**Step 7: Communication**

The international standard of compliance management systems ISO 19600:2014 acknowledges the importance of communicating internally and externally in the process of compliance management. As explained by the case company experts, another challenge during compliance management of product safety requirements is building truly open and transparent communication within the company. Therefore, the company should embrace a proper method for communicating the compliance process to all parties involved. This method should clearly define what is expected from the personnel, how the escalation should be done when necessary, and what kind of situations create this escalation. Meeting minutes and e-mailed information should be seen as a source of communication inside the company.

From the external communication viewpoint, the case company should also put emphasis on delivering the information to the interested parties. One of these external parties can be the customers, which is the most important connection for the case company. In order to create a healthy communication strategy, the company should pass the changed or updated compliance situation to the customer as well as act fast to the ever-changing requirements of the customers. They should attain a specific structure for communicating apart from their daily duties.

There may be compliance management information channels for product safety-specific topics. For example, informal discussion sessions, focus groups for brainstorming, etc. They should have the ability to gather, document, properly store and make the information on international and regional product safety requirements and their handlings accessible to the related parties. These solutions are also effective for obtaining employees' engagement for communication internally and externally.

**Step 8: Implementation of requirements**

According to Henson & Heasman (1998), implementation of the required changes in the compliance management process requires a long time and periodic reviews. The case company's biggest problem is not having a uniform process for implementation of the changes in compliance management of safety-related requirements.

The case company also faces unclear responsibilities during compliance management. Obviously, imprecise responsibility allocation between team members will create disruptions in the implementation of the changed requirements. Therefore, top management should be involved actively in governing the compliance process and defining the responsibilities. Job descriptions should also be clearly defined by the top management as proposed by ISO 19600:2014. It is the duty of top management to assign people who will be responsible for reporting, developing, implementing, evaluating, and maintaining the compliance activities.

There may be a compliance officer, or in the case of the case company a PSCR, who is responsible for daily compliance management process. Even though this kind of responsibility exists in the company, the PSCR organization still needs to be arranged properly as soon as possible. This person should act as a contact person within the cross-functional compliance committees and coordinates compliance management. However, there should be also external consultation related to regulations, standards, and laws related to their product's safety in order to improve implementation steps.

Moreover, companies should provide financial and non-financial incentives in order for their employees to collaborate in the implementation process. The case company experts mentioned that their current change management process is still in need of improvement. Hence, they should establish a compliance function with clear and unambiguous support from the top management, uninterrupted accessibility to them, when necessary, in addition to accessibility to any information and data required to carry out compliance duties.

**Step 9: Evaluation and monitoring**

As a final step of the compliance management process, companies should evaluate and monitor the effectiveness of the compliance system. This step includes not only assessing the effectiveness of the process, controls, duty allocations, and identifying compliance deficiencies but also assessing any noncompliance issues, unachieved objectives, exceeding deadlines, and delays.

One of the problems mentioned by the case company is having inadequacies in this step. For instance, people who are searching for new norms and standards related to product safety are not fully capable of comparing them with the existing requirements. This is the problem of lack of competence level to apply knowledge and skill. Hence, it is critical for the case company to allocate resources to people who are committed to the compliance process, who have effective communication and influencing skills, who can command and guide, and who can demonstrate related competence.

Furthermore, the case company should schedule regular training sessions for product safety requirements management-related employees. It is strongly recommended to design and execute a training program to make sure employees are competent to perform their tasks within the framework of the company's compliance management process. Their existing practice for training or education is insufficient.

Especially for the case company where any noncompliance in product safety may cause severe results, the best training method will be interactive training as described in ISO 19600:2014. This training should aim to provide practical and easily understandable know-how related to managing compliance with product safety requirements. They should be planned continuously and included in the company's annual training plans.

Moreover, while evaluating the performance of the compliance management process, sources of feedback are also important. These sources include customers, suppliers, regulatory issues, employees, and digital or paper-based activity logs. Any feedback from these sources is critical to improving performance. For example, the case company may include feedback receiving for assessing the product safety compliance process via their whistle-blowing channels or idea management sessions. In this way, people's engagement to monitor and evaluate the compliance process can be increased positively.

# 5. DISCUSSION

## 5.1 Summary of Key Findings

Throughout the thesis, an EV battery manufacturer company's compliance management practices regarding product safety requirements were discussed. Even though the current status of the company was not of poor quality in this context, it was found that there are still various opportunities for improvement for the company. In order to enhance management of complying with product safety requirements globally, the case company needs more systematic and coherent practices with a cross-organizational understanding.

The three objectives for this study are defined as follows. Firstly, identifying what kind of practices are embraced within the case company related to managing product safety requirements compliance. Secondly, investigating what kind of challenges the case company encounters in the management of compliance with product safety requirements. Then evaluating the outcomes of the first two objectives and literature, recommending possible ways to improve the company's operations for compliance management. These objectives lead to the following four research questions:

1. What is the current state of the case company regarding product safety requirements management practices in the global framework?
2. What kind of problems does the company encounter in managing compliance with product safety requirements?
3. What are the most applicable procedures regarding product safety requirements compliance management?
4. How to improve compliance management practices of safety related requirements inside the case company?

Throughout the thesis, these research questions were answered to provide common knowledge about practices and problems related to the research topic and to contribute uncovering improvement opportunities for the company. Firstly, analysis of existent application to manage compliance with product safety requirements inside the case company demonstrated that the company focuses on producing safe products and tries to comply with regulations, legislation, and customer requirements. They utilize engineering judgements, a centralized data bank for all product related standards and norms, and risk assessments for evaluation of compliance process. However, due to the large

amount of product safety requirements, especially for a globally operating company, handling all the compliance cycle creates difficulties and several needs.

During analyzing the problems confronted in managing compliance with safety-related requirements, it is recognized that existence of different languages of the customers around world for a global company, keeping the data bank for standards and norms up-to-date globally and evaluating the impact of the changes were posing difficulties for the company. Additionally, they need independence from the customers to let them know about the updated requirements. Rather, they should be able to identify updates and changes internally. They were also lacking the obtain a systematic process for implementing changes in complying with safety-related requirements in their projects. It was mentioned that maintaining effective communication with all the interested parties is not handled properly. Moreover, there was inadequacy in evaluating and monitoring compliance due to a lack of skilled employees in this area of interest.

Thereafter, the researcher collected the best practices by investigating literature, and previously conducted scientific research related to compliance management of product safety requirements. By combining the best practices with the case company's needs, improvement ideas are proposed for the company. In each compliance management process phase, the company needed more resources, more skilled people in this context, and more planned training for different experience levels. Collaboration with external parties, making each employee understand about adoption of a compliance management method, providing clear responsibility allocation between related people, obtaining an efficient communication process, and increasing top management involvement were some of the recommended actions for the company.

Achieving product safety understanding throughout the entire life cycle of the product is essential for the company. Without satisfying the safety related expectations, they cannot operate in the market. Even worse, they may cause harmful or catastrophic situations to human living and environment because of insufficient product safety applications. Hence, they should responsibly and seriously align their activities with safety first awareness in each phase of the projects without any exception.

## 5.2 Limitations and Criticism

In the data collection step of this research study, semi-structured interviews with the case company experts were held. In total, there were four interviews with durations of 45-90 minutes. At the beginning of the research, a possible number of interviewees were planned with six company experts. However, before starting data collection, two of them

resigned from the company. Even though the research still had their contact information, conducting interviews with them for Valmet Automotive was not appropriate since they had already started to work for another company. Hence, the data collection was limited to four people that are working related to product safety, requirements management, and battery technologies. To overcome this limitation, the researcher designed more comprehensive semi-structured interview questions and in a way that the participants can provide in-depth responses regarding the research topic.

## 5.3 Overall Trustworthiness (Qualitative Rigor) of the Research

Evaluation of qualitative and quantitative research are separated in terms of their nature. In general, quantitative research is evaluated based on validity and reliability concepts which respectively refer to the accuracy and consistency of quantitative research (Liu, 2018). On the other hand, the concept of trustworthiness is relatively more suitable for evaluating qualitative research than validity and reliability criteria. These two concepts are re-established through strategies of addressing credibility, transferability, dependability, and confirmability in order to evaluate qualitative rigor of the research study (Thomas & Magilvy, 2011). Although their practicality of trustworthiness may differ depending on the specific framework of each research study, combination of these four concepts contribute to an evaluation of overall trustworthiness.

Firstly, credibility or truth-value evaluates research by checking the truthfulness of obtained findings. Credible research should enable discovering and representing participants' experiences as sufficiently as possible. To strengthen credibility in a qualitative study, a researcher can implement various strategies such as prolonged engagement with research sites, persistent observation, triangulation of methods, sources, and investigators, peer debriefing, stakeholder or member checks, collecting referential adequacy materials, and conducting negative case analysis (Liu, 2018).

The main data of this thesis were literature investigations and semi-structured interviews with the case company participants. Conducting in-person interviews with the company expert is the greatest proof of the credibility of the research. The interviews were lengthy and consisted of precise and repetitive questions. This helped the researcher to collect subject-oriented true experiences of the participants. Recognizing similarities between participants' responses also increases the credibility of the research activities. After conducting the interviews, the researcher checks the collected data as a whole in order to obtain meaningful results. Reviewing each interviewee's transcription and searching for

similarities between participants is also evidence for research credibility (Thomas & Magilvy, 2011).

Additionally, case study approaches with an organization enhance the data triangulation which is another strategy for credibility. With the case study approach, the researcher obtained both individual perceptions of the participants regarding the research topic and the internal archive and organizational know-how of the case company. For example, when interviewees mentioned particular applications inside the company related to product safety compliance management, then the researcher had a chance to corroborate the provided information by accessing the internal system of the company.

Moreover, since the researcher worked as a thesis worker for eight months at the case company, prolonged engagement at research site is achieved. In addition to the thesis work, the researcher was a summer intern at the same company for four months before the thesis work. Therefore, the researcher interacted with the case company firsthand which helped to observe unbiased characteristics throughout the year. Furthermore, the researcher delivered the final version of the thesis to one of the case company experts for a review. This way, any confidential data could be excluded from the thesis ensuring protection of the privacy of the company's internal information. Also, with this member checking strategy, the researcher obtained informant feedback for assessing the credibility of the findings. Hence, the thesis findings are justified with credible evidence and the research is reasonably conducted.

Secondly, transferability or applicability assesses research by checking how applicable the research findings of a particular study are with other similar contexts. To enhance the transferability in qualitative research, the researcher can collect thick descriptive data, employ purposive and theoretical sampling, and/or conduct peer debriefing (Liu, 2018).

The results of this thesis are mainly specific to Valmet Automotive company due to the pre-determined objectives of the study. However, overall research topics and compliance management processes are generally investigated in the literature. For instance, the semi-structured interview questions are not specific to the case company rather the researcher designed them based on a generic compliance management process for product safety requirements. However, there is no concern about generalization in qualitative research approach. Therefore, a similar framework can be utilized for other companies working in the same industry or in the other industries where product safety is important.

Consequently, it can be said that the findings of this research are transferable, and relevant for a given study context although there might be some modifications for another industrial areas.

Thirdly, dependability or consistency evaluates research by inspecting how consistent the results of the research are when it is redone in the same context with the same participants. To reinforce the dependability in qualitative research, the researcher can utilize overlapping methods, conduct stepwise replications and/or audits, and make processes of research traceable, documented, and justified (Thomas & Magilvy, 2011).

Throughout the thesis, the researcher clearly explained all the research phases in detail. The objectives and research questions are described in Chapter 1, Introduction. In Chapter 3, the researcher presented the case company and the participants. Additionally, the reasons behind the selection of those interviewees are discussed. Later, the researcher precisely explained the entire data collection process and why a descriptive qualitative research approach is selected. Moreover, transcribing of the responses, and answering each research question are described. Finally, all the research findings are presented in a reader-friendly way. Thus, this research can be repeated by the same processes.

However, this research was conducted by only one researcher as a master's thesis work. Thus, step-by-step replications were not possible in the context of this research. In addition, during the semi-structured interviews, there were additional questions and comments apart from the answers to the pre-prepared questions. When another researcher conducts the same study, these extra discussions may naturally vary. Nevertheless, it is not expected from consistent research that the results will be exactly the same when conducted again. Therefore, this research will generate stable findings when another researcher repeats the study.

Fourthly, confirmability or neutrality evaluates research by checking if the conclusions are obtained as regard to the data from the respondents rather than the biases, motivations, and interests of the researcher (Liu, 2018). The main focus is on the objectivity of the data. To strengthen confirmability in qualitative research, the researcher can carry out confirmability audit, use code book, keep reflexive journal, use triangulation, provide sufficient justification for all methodological and theoretical choices, disclose sufficient information on the specific methods, procedures, and processes in data collection and analysis.

During the whole study, the researcher was working with the case company as a thesis worker. This situation might be seen as the researcher could be affected by prejudice and interests in favor of the company. However, the participants of the research were

completely different from the researcher's employed team. The researcher met most of them only during interviews for the data collection process. Furthermore, the researcher committed to understanding the direction of the interviews by asking for clarifications, repeating missing words, and seeking for clearer explanations whenever needed.

Finally, according to Thomas and Magilvy (2011), research is confirmable when credibility, transferability, and dependability are achieved. In conclusion, together with the above-mentioned reasons and accomplishing the first three criteria of overall trustworthiness or qualitative rigor, it can be said that the research is a researcher-free and confirmable study.

## 5.4 Ethical Considerations

In addition to evaluation of overall trustworthiness, ethical considerations of research should be investigated based on the nature and the targets of the research. Due to the increased competency, security risks, unethical practices in peer-reviews, frauds because of information and communication technologies, and decreased trust in scientific self-regulations, conducting ethical research becomes critical (Tracy, 2010).

In order to focus on designing ethical research effectively, a researcher should discuss the following points as stated by the study of Bryman and Bell (2007):

- Ensuring voluntary participation of the subjects so that they can freely choose to attend or leave the study.
- Providing informed consent so that the attendants understand the targets of the research, benefits and risks if any.
- Anonymity of attendants by not collecting any personally identifiable data.
- If participants are known by the researcher, guaranteeing confidentiality of them from everyone else.
- Avoiding any types of physical, social and mental harm and keeping them at unquestionable bottom level.
- Establishing plagiarism-free research, avoiding inaccuracy and misleading information in presenting the results.

Throughout this research, the researcher paid attention to ethical issues due to the data collection process conducted with external participants. Firstly, each participant is provided with an informed consent form which is also placed in the Appendix section. This form includes the contact information of the researcher, the purpose of the study, and

the procedures for the interviews. Moreover, it is clearly stated that their attendance in the thesis study is completely voluntary, and they can withdraw their consent to attend the study at any time without any punishment. Three out of four interviewees digitally signed and returned the form to the researcher. Only one interviewee was not willing to sign the document even though all the information written in the informed consent is understood by them. Hence, the researcher obtained full consent of the participants prior to the interviews.

Due to conducting in-person semi-structured interviews, the anonymity of the participants was not possible. However, the researcher avoided revealing any personal information about the participants throughout the research to ensure confidentiality. To secure data privacy, instead of introducing their identity, the researcher coded them by abbreviated numbers with respect to the interview orders. After collecting their responses, the video records and transcriptions are protected and stored confidentially with a multifactor authentication system. This system provides an additional layer of security for account holders. All the collected data is accessible only by the researcher. Also, sending the final version of the thesis to the case company expert ensured that company-specific confidential data, if any, were excluded before publicly publishing the thesis.

Furthermore, in the framework of the thesis study, there were no sensitive questions that may have a negative impact on the participant's emotions or create embarrassment and no painful or injured situations. Also, the researcher put great effort to insert each citation and referenced papers throughout the research to avoid harming other researchers. Each literature survey's findings are paraphrased properly, acknowledged, and linked in the bibliography list with the APA referencing system. The results and evaluation of the research are also presented trustfully. Overall, it can be said that the researcher strictly avoided violating ethical considerations while designing and conducting this thesis research.

## 5.5 Research Contributions

### 5.5.1 Scientific Contribution

This thesis contributes to the scientific society by investigating applications and problems during compliance management processes related to product safety requirements of a case company. In the literature, there is a large amount of research regarding product safety of batteries and manufacturing operations, importance of product safety, and how

it is handled internationally. Throughout the thesis, these literature investigations are presented which can be seen as a source for further research.

Moreover, challenges that companies encountered while operating globally and specific product safety requirements for EV battery producers are summarized in this thesis. Both international level, European region level, and other countries level which are market dominant in manufacturing battery technologies are described and listed properly.

Previously established compliance management methods are utilized for accomplishing compliance management in product safety-related requirements. However, these applications are conducted specifically for EV battery production. With the increased attention to EV batteries throughout the scientific area, this thesis provides a thorough explanation of complying with EV battery regulations, standards, and customer requirements as a whole. With the combination of theoretical areas such as product safety, compliance management, EV battery production, and global operations, this thesis acts as a scientific resource for future scholars.

### 5.5.2 Practical Contribution

This thesis is conducted to answer the case company's needs regarding product safety requirements compliance management processes. Based on gathering the best practices and analyzing the company's current status and problems, improvement opportunities are proposed for the case company in the context of the research.

The case company was Valmet Automotive EV Systems Business Line where EV batteries are designed, tested, and manufactured. Since the thesis is shaped around EV battery industry, results and research process can be implemented for other automotive battery manufacturer companies. For the contributions of the outcome of this thesis to the case company's practicalities, several advancements are recommended to increase competitiveness of the company regarding complying with safety requirements in global market. By applying these solutions to their operational activities, the company will ensure robust, structured, and enduring compliance with product safety regulations, standards, and customer requirements.

Furthermore, revealing the company's problems and needs regarding this topic opened the pave for increased awareness inside the company. Rather than only talking about the problems, conducting structured and comprehensive research, discovering the best practices, and combining them with the company needs enabling to implement them more easily for future practices.

In addition to the EVS business line, other business lines of the company can apply the information collected throughout the research. RKS and VCM business lines can then perform a self-assessment in order to determine if any of the solutions or knowledge presented in the research may be compatible to their activities.

Finally, all the data collection steps and results findings are not strict to only one industrial area. On the opposite, they can be utilized for other machinery or electronics manufacturers industries with some slight modifications on the context and literature review. Therefore, not only does the cooperated case company benefit from the outcomes of this thesis but also other organizations may adopt the solutions into their practices.

## 5.6 Implications for Future Research

Throughout this thesis, the case company's existent practices and encountered problems related to managing compliance of safety related problems were analyzed and presented as regards to the findings from the scientific research and the interviews with the company. It could be recommended to investigate also other global EV battery manufacturer companies to assess whether the applications and problems are similar and whether the proposed practices would be applicable for them as well.

Additionally, Valmet Automotive is a growing company and planning to extend its operational area in the following years. When the company enlarges its operations within various countries, similar research can be performed with the company. This kind of research may raise different perspectives regarding compliance management in product safety requirements for each location.

Furthermore, developing a compliance management model specifically to the case company could be an interesting research topic. Since the company already lacks this kind of process description, one can design research to generate a process model with the help of the outcome of this thesis.

Finally, in the context of this thesis, various regulations and standards were investigated globally. In the future, that official information is prone to change and broaden. In addition, EV battery technologies are also improving rapidly. There is an increased popularity of electric vehicles in the world, which also escalates the attention to manufacturing batteries. This will result that regulations and standards for EV batteries also tend to vary and be more stringent. Therefore, the topic of management for compliance with global product safety requirements necessitates to be continuously updated for potential revisions.

# 6. CONCLUSIONS

The target of this thesis is to gain an understanding of how an internally operating EV battery manufacturing company handles product safety requirements compliance in their operations, how efficient their current status is, and how they can be improved for future actions. The thesis utilizes a qualitative research approach with a descriptive case study method with Valmet Automotive company EVS business line. Data collection for the thesis is performed by detailed literature review for regulations, standards, customer requirements, and previous scientific works related to the thesis topic including the semi-structured interviews conducted with the case company experts.

Analyzing of the research questions are structured based on the compliance management model adopted by combining literature findings and compliance management standards. This process consists of *identifying and discovering the requirements*, *interpreting the requirements*, *identifying possible changes required in products or operations*, *identifying and evaluating compliance risks*, *compliance decision*, *specifying a method of compliance*, *communication*, *implementation*, and *evaluation and monitoring*.

Answering the first two questions brings out that even though the existent practices of the case company in management of compliance with product safety requirements are not in poor quality, there are still a few gaps to fulfill their inefficiencies and lacking points. For instance, the company mainly handles discovering any changes in the requirements by responsible people. However, this falls short due to a lack of experience in interpreting and comparing the findings with the company's operations in addition to confronting language differences in identifying global requirements.

In order to explore possible improvement ideas for the company, literature and previous scientific research regarding the best practices in compliance management of product safety requirements are investigated while answering the third question. Various solutions are found as following: *management system adoption for the requirements*, *efficient documentation of activities*, *compliance checks throughout the projects*, *having a global design file*, *benchmarking from other companies*, *employment of external bodies*, *requirements follow-up by product safety people*, *having a platform to reach all customers*, *international networking for knowledge acquisition*, hav*ing a product safety and compliance plan*, *attending to standards drafting processes*, *comparison between different market standards*, *global product committee for knowledge sharing*, *defining common minimum requirements*, and *continuous training for people involved in product safety*.

To conclude, improvement ideas are proposed for the case organization in light of the findings. Emphasizing more resource allocation and training of the relevant personnel to increase compliance management understanding of product safety requirements seems important for the company. Collaborating with external parties, increasing top management involvement, and clearly defining the responsibilities and job descriptions can be given as some of the recommendations for the company to improve its practices. In summary, the thesis contributes to the company and scholars in the context of managing compliance with safety-related requirements for product manufacturers operating globally by examining previous studies, regulations, standards, and an EV battery producer organization.

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# APPENDIX A: SEMI-STRUCTURED INTERVIEW QUESTIONS

**Opening**

- I would like to record this interview session as a clarification of conducting this interview as well as for further review to ensure the accuracy of the context.

  Do you have permission to record this interview?

- If citing directly in your own words improves the clarity, I would like to quote your answers in the research.

  Do you have permission to share your answers anonymously?

**Background of the interviewee**

1. Name
2. Position/Role
3. Experience in your current position / in Valmet Automotive?

**Background of the interviewee**

4. Do you have any safety plan/procedures in place for handling and stroking EV batteries?
5. Do you think having a safety plan is/would be useful in structuring requirements?
6. Is there any person responsible for identifying product safety requirements for the product?

**Compliance Management in Global Context**

7. How do you handle compliance with regulations, standards and customer requirements in the global business market?
8. Are EV battery components and materials sourced from suppliers that meet safety regulations?

**Compliance Management in Global Context**

9. What is the current compliance management process inside the company?

   *E.g., collection of information, benchmarking, follow-ups, data management system, et cetera.*

10. How are EV battery design and production processes reviewed for compliance with safety regulations?

11. How are EV battery safety concerns addressed during the development and implementation of new technologies?

12. Are there any training sessions/materials for employees related to product safety requirement management procedures and regulations?

13. How are EV batteries tested for compliance with safety requirements?

14. Does VA have any certification for battery safety approval?

15. What is your process for addressing and resolving safety-related incidents or customer complaints?

**Identifying and discovering the requirements**

16. How do you discover new product safety requirements?

    *Awareness? Any commissioning to track and discover requirements beforehand?*

    a. Any challenges/problems/wishes?

       *E.g., overlaps, no data bank, distinctions in global market, markets outside the EU et cetera.*

17. How do you stay informed about updates and changes in product safety requirements?

    a. Any challenges/problems/wishes?

**Interpreting the requirements**

18. How do you interpret the updates/changes on the product safety requirements?

    a. Any challenges/problems/wishes?

       *E.g., Lack of guidance, poor alignment, language issues, absence of supportive external bodies, difficulties in new market areas, no internal guidelines et cetera.*

**Identifying possible changes in products or operations**

19. How do you identify which changes must be made to meet the new/updated product-safety requirement?

    a. Any challenges/problems/wishes?

**Identifying and evaluating compliance risks**

20. Do you define and evaluate the compliance risks before deciding to comply with any changes?

    a. Any challenges/problems/wishes?

**Compliance decision**

21. How do you decide whether to satisfy updated/new product safety requirements or not?

    a. Any challenges/problems/wishes?

       *E.g., checking affordability by the customer, testing the solutions et cetera.*

**Specifying method of compliance**

22. Are you following any specified compliance method inside the company after the compliance decision?

    *E.g., to decrease the cost of compliance, to reduce the interpretation, or to reduce the complexity of changes…*

    a. Any challenges/problems/wishes?

**Communication**

23. How do you communicate inside the company to the employees who are involved in the implementation of the required changes in the compliance management process?

    a. Any challenges/problems/wishes?

       *E.g., insufficient competencies of related people, lack of information exchange between designers and sales & marketing, unawareness…*

**Implementation of requirements**

24. How do you implement any changes in product safety requirements?

    a. Any challenges/problems/wishes?

       *E.g., unsystematic activities in projects processes, unclear responsibilities and operations...*

**Evaluation and Monitoring**

25. Do you have any process to routinely monitor and evaluate the requirement compliance?

    a. Any challenges/problems/wishes?

       *E.g., the uncertainty of updated requirements, invalid translations, late realization, different evaluation criteria of different market areas et cetera.*

**Problems**

26. What type of problems/challenges do you encounter while handling compliance with the requirements related to product safety?

27. Do you recognize any specific EV battery safety requirements that are particularly challenging for VA to comply with?

**Reflection**

28. Are there any best practices that VA follows in terms of product safety requirement compliance management that you would recommend to others in the industry?

29. Do you have any ideas to improve the current EV battery safety compliance management practices in the future?

30. Do you have any further comments and corrections related to the topic?

31. Do you recommend any other persons that might also participate in this interview?

Thank you so much for your time and help!

# APPENDIX B: INFORMED CONSENT FORM

**INFORMED CONSENT FORM FOR MASTER'S THESIS RESEARCH**

Title of the Study: Improvements for Product Safety Requirements Compliance Management Practices – Case Study: Automotive Battery Industry

Researcher: Eda Ulku Sahin, eda.ulku@tuni.fi, Safety Engineering and Management, Tampere University

Supervisor: Prof. Jouni Kivistö-Rahnasto, Tampere University

Purpose Of the Study: The purpose of this study is to gather information about current practices applied for product safety requirements management in the case company. Furthermore, this study aims to discover what kind of problems the company confronts in managing compliance in a global context as well as to reveal the most applicable procedures in the literature. With the help of results of the study, the researcher intends to propose improvements ideas of the current practices.

Procedures: If you agree to participate, you will be asked to participate in a one-on-one interview that will last approximately 1 hour. The interview will be conducted by Eda Ulku Sahin and may be recorded for transcription and analysis.

Benefits: The benefits of participating in this study include the potential for increased understanding of the topic and contributing to academic research. Please note that there will be no direct benefit to you for your participation in this study.

Confidentiality: All information that is collected from you during this study will be kept confidential. Your name will not be used in any publications or presentations resulting from this study. Instead, you will be assigned a code number to protect your identity. The recording will only be available for the researcher and will not be shared with other parties.

Voluntary Participation: Your participation in this study is voluntary and you may choose not to participate or to stop participating at any time without penalty. During the interview, you may reject to answer any questions. After you sign the consent form, you are still free to withdraw at any time without giving a reason. Withdrawing from this study will not affect the relationship you have with the researcher. If you withdraw from the study before data collection is completed, your data will be returned to you.

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**CONSENT**

I have read and I understand the information provided in this consent form. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving a reason and without cost. I voluntarily agree to take part in this study.

**Participant's Signature** **Researcher's Signature**