Regulatory and industry standards compliance in hardware technology startups

Qualitative interview study exploring the impact of legal and industry standards compliance on iterative development in hardware technology startups

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Regulatory and industry standards compliance in hardware technology startups - MOT Thesis

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Delft, 18th November, 2024

Acknowledgements

Dear reader,

A little over two years ago, my journey at Delft University of Technology began, following the completion of my bachelor's degree in Mechanical Engineering in the beautiful southern region of this country. After a few months of the Pre-master's program, I started the Management of Technology master's degree in February 2023. Throughout this journey, I have not only gained academic knowledge but learned a lot of important life lessons and experiences that I will carry forward. At first, the Management of Technology Master took some time to get used to since it challenged me to widen my perspective beyond technical problem-solving. This is also reflected in this thesis, as it is purely qualitative in nature despite my background being more quantitative-focused. The high-tech entrepreneurial focus of this research was so inspiring that I embraced it without hesitation.

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With due pride, I hereby present my master's thesis! I hope you enjoy reading this report.

Alex Dekkers
Delft, 18th November, 2024

Executive summary

In today's high-tech industries, technological innovation has become a crucial strategy for businesses seeking growth and expanding competitiveness. The growth of technology-based startups is especially notable, as they employ innovation processes that are often unfeasible within larger organizations. However, despite the abundance of talent and ideas, illustrated by the countless patents filed by entrepreneurs, many innovative companies struggle to translate their breakthrough technologies into commercial success. For startups developing hardware technology, the challenges are even more complex. These firms face significant hurdles in scaling up their operations, as regulatory and industry standards compliance add layers of complexity to their development processes. These startups often encounter conflicts between the iterative innovation process and the need to meet mandatory compliance requirements, leading to delays and increased costs.

Consequently, this research aims to examine the challenges associated with regulatory and industry standards compliance, as well as the landscape surrounding these regulations and standards. Thereby, this thesis aims to provide a scientific contribution to existing literature, and additional key insights for future hardware technology entrepreneurs and other stakeholders in this environment. This is done by analyzing the experiences and knowledge of established startups, seeking to uncover practices that can help others. The primary research question guiding this study is as follows:

"How can technology-based hardware startups include regulatory and industry standards compliance during the development process of their technology and products?"

To answer this question, a systematic literature review is carried out to map and thoughtfully understand the existing academic concepts related to this topic. Also, more specific exploratory research is performed to create a foundational understanding of the regulatory and industry standards landscape, faced by hardware-tech startups. Thirdly and most significantly, interviews were conducted with twelve hardware tech startups across various industries. These interviews provided knowledge of participants' experiences, motivations, and insights.

The findings of this study revealed that technology-based hardware startups find consensus in balancing validated learning principles i.e. hypothesis-driven entrepreneurship and hardware development, due to inherent hardware constraints. These challenges include restrictions in producing multiple MVPs, the inability to conduct pilot testing and long development cycles. However, all startups emphasize the importance of early market interaction for validating their business and customer assumptions. In addition, technology-based hardware startups face a complex regulatory landscape that requires adherence to both mandatory technology and product regulations, and additional industry standards, impacting their development processes. Awareness in startups of relevant regulations and standards varies, with some startups engaging external experts while others rely on market feedback. Overall, it is hard for startups to accurately estimate the real impact of compliance processes, especially since lead times for certification approvals, managed by notified bodies, do not align with rapid iterative development. Compliance processes can lead to increased costs and delays, requiring startups to build internal expertise to manage these requirements effectively. Furthermore, the timing of compliance efforts is critical, to align and implement requirements with product development phases.

While this study offers valuable insights, several areas could be further explored. Researchers could investigate whether hardware technology startups in different regions have similar experiences. Also, industry-specific research could provide deeper insights. Furthermore, academia could evaluate how compliance challenges intersect with other growth barriers; and how startups can be guided to overcome these. Ultimately, this research highlights the need for an integrated approach for compliance and product development, while stressing that the challenges that come with compliance, are often overlooked by startups, academia, and the broader ecosystem.

Abbreviations list

Abbreviation	Meaning
AI	Artificial Intelligence
B2B	Business to Business
B2C	Business to Customer
CE	Conformité Européenne
CRA	Cyber Resilience Act
DCE	Delft Centre of Entrepreneurship
EECC	European Electronic Communications Code
e.g.	Exempli Gratia, for example
EN	European Norms
EU	European Union
GDPR	General Data Protection Regulation
ISO	International Organisation for Standardization
i.e.	Id Est, in other words
IoT	Internet of Things
MDR	Medical Device Regulation
MiCA	Markets in Crypto Assets
MOT	Management of Technology
MVP	Minimal Viable Product
NEN	Netherlands Normalisation Institution
QCA	Qualitative Content Analysis
QMS	Quality Management System
RRI	Responsible Research and Innovation
SME	Small Medium Enterprises
SQ	Sub-Question
Tech	Technology
TRL	Technology Readiness Level
UL	Underwriters Laboratories
US	United States
VC	Venture Capital

Table 1: List of Abbreviations

List of Figures

List of Tables

Contents

1 Introduction

1.1 Balancing iteration and compliance: Lean startup principles in technology-based hardware startups

Over the last decade technology innovation has proven to be a key strategy for companies to grow their business and expand their market shares. Especially, the emergence of technology-based startups has shown significant development. Following Shewale (2024), over 50 million startups are launched globally each year. Out of this group, the survival rate for venture capital-backed companies is 25% according to (Kotashev, 2024). This highlights both the opportunities for innovation and the considerable challenges that startups face in sustaining growth. The surge in entrepreneurial activity has drawn the attention of investors, policymakers, incubators, and enthusiasts. Within this startup rise, lean startups show their competitive advantage by enabling rapid iteration, cost-effective scaling, and efficient resource allocation (Lizarelli et al., 2022). This lean-startup methodology guides startups to easily adapt to market demands and iterate their products or services to meet customer needs, resulting in growth and market penetration.

Following practices described in the lean startup methodology, startups have to test their business and technology-related hypothesis as quickly as possible and iterate their product based on the customer feedback they get (Ries, 2014). However, this iterative methodology best fits software products and services, as they can easily be redesigned. For hardware products this process is more difficult, each iteration will mean that another physical minimal viable product (MVP) has to be built. This process is time, and resource-consuming, resulting in a less agile development process, and potentially limited interaction possibilities (Nguyen-Duc et al., 2018).

Hardware startups that develop innovations based on technology advancements i.e. technology-based hardware startups, face even greater difficulties as they must balance developing complex technologies with market validation. Although these startups aim to apply lean startup principles, i.e. hypothesis-driven entrepreneurship (Eisenmann et al., 2011), their ability to do so is often constrained by slower and lack of iteration cycles. These companies have to find a balance between flexibility in responding to customer feedback, and complex development cycles. In addition to this, customers require products or services that ensure quality, accuracy, and reliability. This can be ensured via compliance with legal requirements and industry standards. However, compliance processes are challenging, resource-intensive, and time-consuming; therefore, they typically do not match iterative development. As also mentioned in Berg et al. (2020), agility in hardware startups is complex and not achieved through the adoption of fast-paced development practices alone. Currently, there is a noticeable gap in research exploring how technology-based hardware startups can integrate iterative development with compliance obligations. A practice must be found to allow for iteration, but ensure compliancy.

1.2 Thesis scope

Starting a technology-based hardware startup is not easy in itself. While developing new hardware technology, creating market traction, validating business models, searching for capital, and building a company, business owners also have to figure out regulatory and industry compliance, which their technology and product has to comply with. All this is a challenging task about which only little is known. **This thesis seeks answers on how startups manage regulatory and industry standards compliance throughout the phases of their development.** Specifically, it examines how startup founders use validated learning during their development process; how they acquire an understanding of relevant product compliance and specific industry standards; when this understanding is acquired during the development phases; and how compliance is implemented in the development process. This thesis is focused on technology-based hardware startups that are internationally orientated. However, the research group is limited to startups located in the Netherlands due to the researcher's physical and resource constraints.

1.3 Research questions

For a comprehensive understanding of the research scope. The following main research question has been formulated:

How can technology-based hardware startups include regulatory and industry standards compliance during the development process of their technology and products?

1.3.1 Sub-questions

The following sub-questions will be answered throughout the thesis to elaborate on aspects of the main research question.

1. **How do technology-based hardware startups use validated learning to test and refine their business and technical hypotheses during development stages?**

   This sub-question intends to provide a comprehensive understanding of how the practices from the lean startup method are implemented by actual hardware tech startups during their development process. It reveals the ease and challenges this method provides while developing hardware technology.

2. **How is the regulatory and industry standards landscape for technology-based hardware startups shaped?**

   The second sub-question aims to examine the overarching legislation governing technology and technology-based hardware products. The question provides a thorough understanding for the researcher and readers of the existing legal framework and regulatory requirements. Furthermore, it explains how industry standards are derived and what they require from companies.

3. **How do technology-based hardware startups identify relevant regulations and industry standards, applicable to their product and accessory industry?**

   To eventually advise future entrepreneurs on how to navigate the complexities of compliance, it is essential to understand how other entrepreneurs have overcome these challenges. Therefore, this sub-question focuses on how entrepreneurs gained insights into regulatory and industry standards compliance, as well as their approaches to adhering to these requirements.

4. **How do compliance processes affect iterative development and validation cycles in hardware startups during their development phases?**

   Regulatory compliance imposes constraints on the flexibility required to iterate and modify Minimum Viable Products (MVPs) during technology and product development. The process of obtaining compliance certifications is both time-consuming and resource-intensive, expected to conflict with the fast-paced, iterative nature of lean startup development. Therefore, it is crucial to understand how these compliance requirements impact the lean methodology, particularly in hardware startups, where rapid iteration and adaptation are key to validating business and technical hypotheses.

5. **When do startups initiate actions to achieve regulatory and industry standards compliance?**
   Lastly, understanding the timing of compliance is crucial. The point at which a startup becomes aware of, and adheres to specific regulations and industry standards can be significant. Certain common practices or pivotal moments may highlight the importance of these regulations. By examining these factors, a timeline and strategy can potentially be developed to guide future entrepreneurs in navigating regulatory and industry standards compliance.

1.4 Objectives

The rise of technology-based startups is widely seen, with a specific focus on the lean method for rapid iteration and market adaptation. However, hardware startups face unique challenges compared to their software colleagues. The iterative process for hardware products is time and resource-intensive, hindering agility and market responsiveness. Moreover, product regulation requirements add complexity, not aligning with iterative development, risking potential delays and increased costs. Several challenges have to be addressed to provide meaningful answers. This includes the understanding of how hardware startups apply hypothesis-driven i.e. practices from lean startup methodology, to validate business and technology; what product certification and other regulatory compliance influence the development process for startups; and how these companies streamline their technology, and business validation processes, and compliance processes. The objective of this research is to provide answers to the challenges described. In addition, it seeks to help future entrepreneurs by providing recommendations to effectively overcome compliance complexities. This is done via an in-depth literature review. Hereafter, an explorative study into the regulatory and industry standards landscape was conducted, to gain a comprehensive understanding of the challenges startups face. Finally, and most significantly, a questionnaire is developed to gain complementary information from startup founders via semi-structured interviews. After the interviews were conducted, the data was coded and analysed to provide structured and substantiated answers. These answers were thereafter discussed with a startup investor and notified body consultant, to validate and substantiate the results found.

1.5 Scientific and social relevance

This study is part of the Master's degree in Management of Technology, representing a significant component of the researcher's academic journey. Its findings not only contribute to science, but also offer valuable insights for the startup environment, policymakers, and industry professionals.

1.5.1 Academic relevance

The MSc. Management of Technology program values engineering and technology as valuable corporate resources. Technology advancement is broadly used to gain a competitive advantage over competitors. Especially, technology-based startups create unique opportunities to provide disruptive solutions to existing or even upcoming challenges in existing and new industries. This research provides knowledge that has until this moment been missing from the available business literature on lean startup methodology and compliance with regulatory and industry standards. Overall, only recognition is given that compliance can be challenging. However, based on available studies, there appears to be no guidance on how and when to navigate this. Furthermore, the impact of compliance efforts in a startup context is something that has not yet been extensively covered in academic papers. For these reasons, this study can be seen as foundational, exploring how tech-based hardware startups comply with regulations and industry standards during their development.

1.5.2 Societal relevance

This research holds significant societal relevance by addressing the unique challenges faced by hardware startups within the technology ecosystem, with a particular focus on contributing to the entrepreneurship landscape surrounding Delft. By documenting the experiences and strategies of startup founders, this study acts as a repository of knowledge that can guide and inspire new entrepreneurs, providing insights into navigating between iterative hardware technology development and compliance with regulatory and industry standards. Besides future entrepreneurs, other stakeholders such as academia, incubators, venture capitalists, advisors and policymakers, could value this research. Since they can also learn from the best practices, shared

within this research. This is particularly relevant when considering the context of introducing new technologies to the market and their efficient adoption within society, which can enhance the global competitive landscape. A much-discussed topic by governmental bodies these days.

1.6 Report structure

The thesis is subsequently structured as follows. Chapter 2 provides an in-depth literature review wherein several influencing concepts are described and examined. In addition, a synthesis of development methodologies is made as a foundation for structuring the interviews. Within chapter 3 the theoretical framework for this research is introduced and elaborated on. Chapter 4 presents an exploratory study that examines how the landscape of regulations and industry standards is shaped and how they relate to one another, by which it answers one of the sub-questions. In Chapter 5 the methodology utilised in the study is elaborated, highlighting the research design, data analysis and sampling strategy, and assessment of validity and reliability. Chapter 6 presents an overview of the gathered data, and delves deeper into the coding and analysis methods. Chapter 7 includes the results found within the analysis. Chapter 8 provides an in-depth discussion of the results, along with their implications for academia, entrepreneurs, investors and incubators. In Chapter 9, the findings of the overall study are concluded, and recommendations for further research are given.

2 Literature review

This chapter examines the existing literature concerning all relevant academic concepts covered in this thesis. The concepts are derived from the problem analysis and directly linked to the research and sub-questions. The purpose of this section is to provide a clear and comprehensive foundation to understand the academic concepts upon which this study is built. This includes an overview of key theories in existing literature, a definitions overview, and an explanation of the literature gap. It must be noted that the existing literature concerning hardware technology-based startups and interference with regulatory and industry compliance is limited. Therefore, relevant literature is searched from a broader perspective. This will be further elucidated in chapter 5.1 methodology.

Firstly, different standardized development methods are discussed, after which the implication of regulatory compliance on these development methods is explored. Furthermore, the literature related to the lean startup methodology is reviewed, including its limitations for hardware development and regulatory compliance. Subsequently, the levels of technology readiness are challenged for the development of technology and innovation. Afterwards, the Collingridge dilemma and its similarities to startup uncertainty are challenged. Finally, a timeline synthesis is done for further use during the data acquisition of this thesis. In figure 1, a visualisation of the covered concepts in this chapter is given.

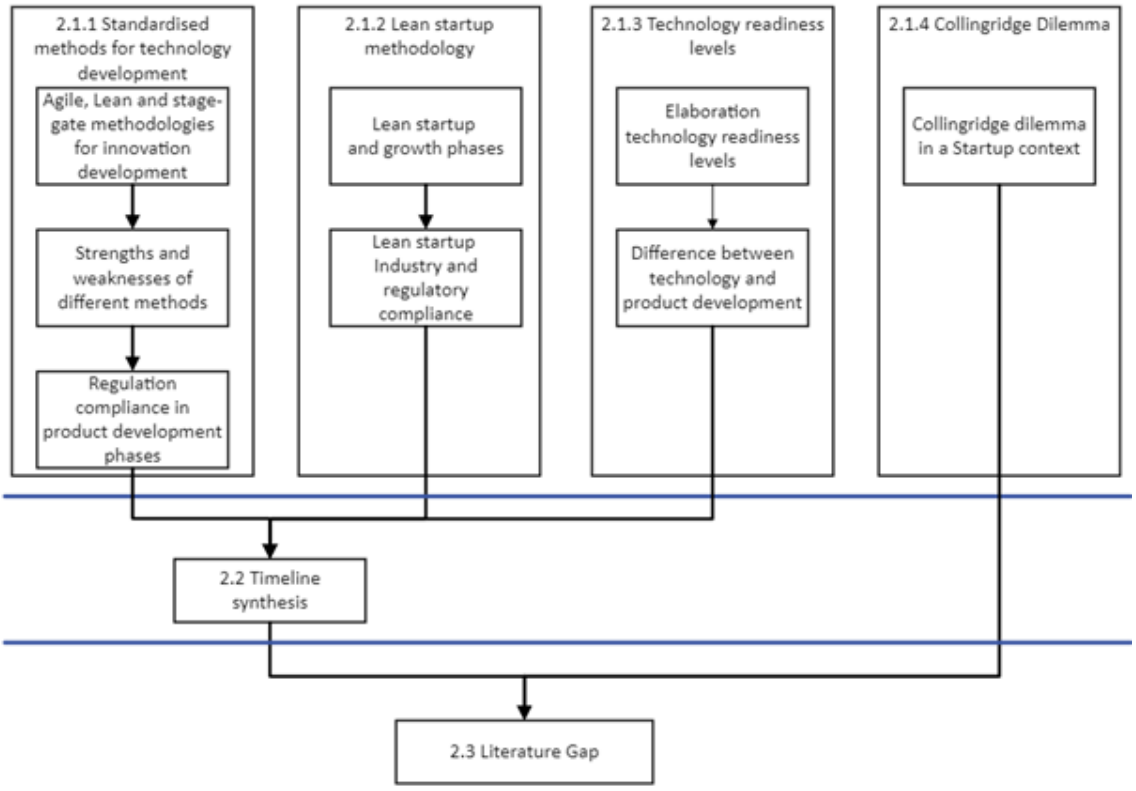


Figure 1: Outline research concepts discussed in this chapter (Outline made by the researcher)

2.1 Research concepts

2.1.1 Standardised methods for new technology development

This section of the literature review delves into standardised methodologies for innovation development. It especially focuses on how compliance with regulatory and industry standards

interferes with these methodologies. Although innovation processes are not entirely synonymous with development processes within startups, it remains important to consider these concepts due to their inherent similarities. Furthermore, existing literature more thoroughly explores the implications of regulatory compliance and industry standards on development methods, making this an essential area of study.

Innovation development is done via a range of standardized methods, whereby it is regularly seen that parts of different methods are used interchangeably. Traditionally stage-gate methods have been common practices, but those have been increasingly exchanged for hybrid models such as agile and lean methods (Cocchi et al., 2021). Agile and lean methods have a lot in common, they both focus on iterative processes, continuous feedback, and the goal of delivering products more efficiently (Narasimhan et al., 2006). However, there are also significant differences. Agile is applicable in situations where requirements and solutions evolve during the process, and self-organizing teams collaborate cross-functional (Cooper & Sommer, 2016). The method aims for flexibility, customer feedback, and rapid delivery of product sections. Lean, on the other hand, comes from manufacturing and looks to minimize waste and improve the process. This method aims for continuous improvement, efficiency, and delivering what the customer needs (Power, 2014). Both methods prioritize customer satisfaction and are used together to complement each other.

Besides agile and lean methods for product development, stage-gate methods have also been widely adopted. The stage-gate method has its origin in the late 80s. The method is based on the success of intrapreneurs within major corporations that have proven that a stage-gate-idea-to-launch system was most efficient for developing innovations (Cooper, 1990; Cooper, 2014). This original model stated innovation as a process. The process is divided into several stages and quality checkpoints also called gates. A set of deliverables is specified for each gate, as is a set of quality criteria that the product must pass before moving on to the next step. The stages are where the work is done, and the gates ensure the quality (Cooper, 1990; Ettlie & Elsenbach, 2007).

The three methodologies have their strengths and weaknesses, which have been concisely set out in table 2, based on (DelVecchio et al., 2014; Cocchi et al., 2021), and (Cooper, 1990). This table shows that all methodologies differ and their applicability is dependent on the type of innovation and organisation that is proceeding with the development process.

Methodology	Strengths	Weaknesses
Agile	+ Flexibility and responsiveness to change + Reduced time-to-market with iterative sprints + Enhanced team collaboration and cross-functional work	- Resource intensive, requiring continuous customer involvement - Scalability issues in larger organizations or complex projects
Lean	+ Focus on waste reduction and efficiency + Customer-centric development ensures value addition + Promotes a culture of continuous improvement	- Implementation challenges requiring cultural shifts - Risk of overemphasis on efficiency, potentially stifling innovation
Stage-Gate	+ Structured and disciplined process reduces risk + Risk management through evaluation at each gate + Predictable outcomes aligned with strategic objectives	- Lack of flexibility can slow down processes in dynamic markets - Resource intensive due to thorough evaluation requirements

Table 2: Strengths and weaknesses of development processes (Researchers synthesis on discussed literature)

The hybrid development methodologies agile and lean do not have a pre-planned, sequential staged path for the innovation process, allowing for their strengths. This is in contrast to stage-gate, which does provide a structured process. Over time, the original Stage-Gate process has been adapted to modern innovation practices. It is almost no longer possible for businesses to have a stable product definition early in the process. Customers simply may not be clear on what they want or need. Therefore, build-test-revise cycles have been implemented during the stages (Cooper, 2014; Cooper, 2017). This revised stage-gate model has implemented practices seen in agile and lean methods since it includes continuous feedback from the market over time. This process has been visualised in figure 2.

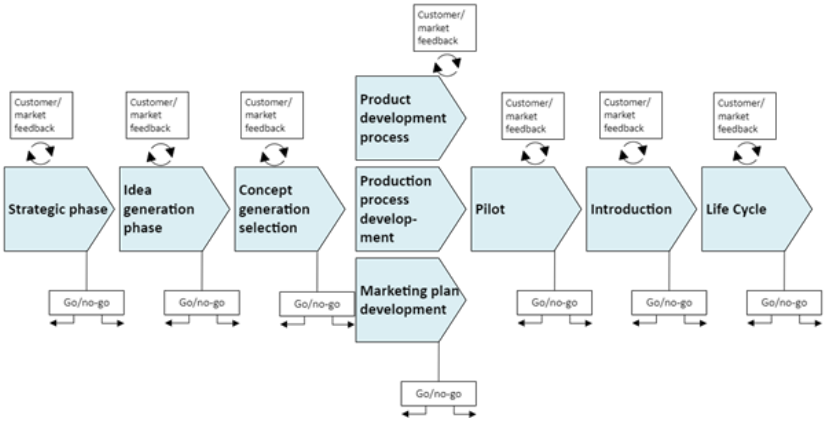


Figure 2: Stage-gate process with continuous market feedback in all stages (Cooper, 2017)

All three development methods show a form of iterative development over the process. Due to the success of this, the methods have seen significant implementation over the past time (Ghani & Bello, 2015). Agile methods have especially shown massive adoption within companies that focus on software development (Zorzetti et al., 2022). However, agile software development has its challenges while complying with regulations specific to industries (Karrenbauer et al., 2019). As mentioned in Cawley et al. (2010), agile practices do not seem to suit regulated environments fully, but rather tailored agile versions combined with more plan-based practices seem to be needed. Typical regulated industries are automotive, aviation, financial services, food, medical devices, nuclear, and pharmaceutical (Fitzgerald et al., 2013a). Regulations that can influence the agile development process are product or service certification, process certification, and person certification (Ministerie van Algemene Zaken, 2023). These regulations don't just play a role in the agile development process but also certainly play a role in lean and stage-gate processes.

The challenges seen with regulatory compliance in iterative development methods are multifaceted. Firstly, handling regulations and industry standards requires the need for specialized knowledge and even prior experience (Fitzgerald et al., 2013b). Furthermore, compliance processes demand rigid frameworks and extensive documentation requirements from companies to prove adherence to all standards and procedures (Fitzgerald et al., 2013a). This disrupts the flexible and speedy process implied by agile methods. Also, the process of compliance review by regulatory bodies can be extensive and time-consuming, further hindering the efficiency of the iterative development method. After compliance is acquired and certificates are given, changing aspects of the product results in re-certification of the section or even the whole thing. This results in slowing down development cycles and requires additional resources to maintain compliance, making it challenging to fully adopt iterative methods in such settings (Fitzgerald et al., 2013b).

The discussed development methods are used not only in software development but are also increasingly adopted within hardware development. Adopting the methods enhances flexibility and responsiveness in product design and manufacturing (Kaisti et al., 2013). However, it is important to highlight that iterative hardware development becomes more complex due to challenges, including documentation and certification (Atzberger & Paetzold, 2019). Other factors that are recognized to make iterative hardware development difficult are the technical feasibility of producing prototypes, external dependencies, the inability to create modules of the product, and proper education and training (Atzberger & Paetzold, 2019). Also, ensuring quality in hardware products is considered more difficult than for software. Achieving both iterative development and quality creates significant challenges for hardware developing companies (Berg et al., 2020). Therefore can be said that iterative development methods are not easily adoptable for hardware development since they pose challenges.

After the hardware is developed, the market introduction phase begins. During this phase, customers must adopt the new product. This phase is also referred to as the adoption phase or life cycle phase, as seen in figure 2. The study by (Ortt & Egyedi, 2014) found that pre-existing standards and regulations can significantly shorten the adoption phase of innovations. This is due to the principle that standards and regulations ease customer use and implementation. This suggests that addressing regulatory compliance challenges during the development phase leads to faster market adoption. Therefore, integrating compliance early in the development process can provide a strategic advantage.

2.1.2 Lean startup methodology

The next section of the literature review delves into the lean startup methodology, widely covered in existing research. In addition, there is a specific focus on the differences between software and hardware startups applying this method, especially towards technology-based hardware startups seeking to adopt these practices. Furthermore, the limitations of regulations and industry standards within this iterative method are covered.

Technology-based lean startups are a specific segment of businesses. These entrepreneurs aim at scaling their business, by developing innovative technologies with limited human and financial resources (Ries, 2014). The lean startup method provides a systematic lean and agile process for startup companies to accomplish the development of new technologies in an efficient way (Yordanova, 2018). This startup method has seen wide adoption over the past decades. The core of the methodology is the startup roadmap, including five consecutive stages. During all these stages iterative development is seen, including rapid prototyping, and continuous market feedback to validate a product's market fit as quickly as possible (Lizarelli et al., 2022). Furthermore, startups bringing a new technology to market must validate if their technology works and have to assimilate this into a product. The roadmap allows startups to pivot or preserve based on market feedback, and testing the product, which helps them to manage uncertainty while optimizing resources.

However, startups face challenges not seen by other established companies (Unterkalmsteiner et al., 2016). Especially, while searching for sustainable and scalable business models while having time frames and limited resources (Berg et al., 2020). These challenges are particularly difficult to manage for lean-based hardware startups, due to the intrinsic nature of hardware development. Iterative hardware development requires companies to produce multiple variations of their products, a process that is both costly and time-consuming. All while startups often lack the necessary resources, time, regulatory knowledge, and experience to manage the complexities of hardware development effectively (Nguyen-Duc et al., 2018). Consequently, they face even greater challenges in iterating their product development processes, while simultaneously ensuring compliance with complex regulations and certifications (Fitzgerald et al., 2013a). This situation makes the integration of iterative development methods and quality insurance even more challenging (Tisma, 2024). Hardware developing startups are rapidly developing their new technology, while simultaneously validating their business case all in an agile and lean way (Eisenmann et al., 2011). During that, they also have to comply with product regulations to test their product in the industry. These difficulties of having to comply with product regulations, while simultaneously in an iterative way developing the hardware product, are not yet broadly covered in the existing literature.

Within this thesis, the growth phases of startups will play a central role. These growth phases are seen in software as well as in hardware startups. Each company must go through five consecutive phases, each characterized by a non-linear iterative development process (Vohora et al., 2004). As startups transition from one growth phase to the next, they face critical junctures. These junctures involve challenges related to resources, knowledge, mindset, market adaptability, and dependencies on external entities. The initial phases focus on product development and market entry, while the later stages focus on scaling operations and optimizing business models. During the phases, the rate of mortality of the startup decreases. The development in all stages is crucial for startups to achieve growth and long-term success. Regulation and industry compliance can be seen as knowledge that needs to be acquired by a startup. However, it can also be seen as a barrier to entry into the market since a product has to comply with the regulations before a market can be entered. In the recently published report by the European Commission Draghi (2024), it is described that 'regulatory complexity and excessive requirements, such as licensing or compliance with multiple standards, can prevent companies from entering markets. This particularly affects small businesses and startups that lack the resources to navigate these regulations.' Furthermore, it is mentioned that Europe claims to favour innovation, but it continuously adds regulatory burdens on European companies, which are especially costly and difficult for SMEs and startups. More than half of SMEs in Europe flag regulatory obstacles and the administrative burden as their largest challenge (Draghi, 2024). This underlines the challenges startups face in bringing their products to market.

According to Vohora et al. (2002), start-up incubators and facilitators play an important role in helping startups through the different challenges that are seen at the end of each phase. They especially provide valuable help by providing a network (Khodaei et al., 2022). However, it

remains unclear whether these facilitators can also provide expertise in product regulatory and industry standards compliance and requirements. As mentioned in Salgado-Criado et al. (2024), venture capitalists should have an advisory role, they should mentor startup owners in regulations, allowing the startup team to focus primarily on market penetration and company growth.

2.1.3 Technology readiness levels

Earlier several frameworks that map innovation development have been discussed. Thereby, the specific context of startup development, which has an intercorrelation between business development, and innovation development has been challenged. However, within the context of lean startups, businesses can also be working on entirely new technologies. To manage the complexity of technology advancement, NASA engineers developed the Technology Readiness Levels (TRL) (Hicks et al., 2009; Buchner et al., 2019). This framework allows engineers to evaluate the progress of a technology from its inception towards a proven technology. Although these levels were first developed to streamline NASA's technology management processes, TRLs have since been adopted across various industries to help managers. In the EU and US, the TRLs have become a standard communication tool for research, capital funding and research extensions (Buchner et al., 2019; Gerdsri & Manotungvorapun, 2021). Also, it is used for a variety of other purposes, such as technology management and technology transfer (Gerdsri & Manotungvorapun, 2021). The levels are divided into nine distinct levels and further elaborated can be found in appendix A.

The technology readiness levels provide a clear roadmap for technological maturation. However, applying them to product development reveals a more complex relationship. Technology development often focuses on refining a specific solution, and proving the solution meets operational requirements. In contrast, product development is a broader concept that involves market research, customer satisfaction, and the need to provide added value (Olechowski et al., 2020). As an example, if a technology reaches TRL 7, it shows a working prototype in a relevant environment, which is not straightforwardly turned into a successful product. A successful product namely requires more than technological readiness. It demands market validation, continuous feedback implementation, and a sustainable business model. The TRL framework, although valuable, doesn't capture these aspects, underscoring the difference between technology development and developing a product or innovation (Olechowski et al., 2020).

2.1.4 Collingridge dilemma and startup uncertainty

A well-known dilemma in socio-technology studies is the so-called Collingridge dilemma. When a new technology is still at an early stage of development, it is still possible to influence the direction of its development, but it is unclear what regulation is in order, or there isn't even any regulation developed. However, when the technology has become embedded in the industry and society, and its implications are known, it is very difficult to influence its development (Collingridge, 1980). The dilemma is one of the biggest challenges for responsible design and innovation (Kudina & Verbeek, 2019; Genus & Stirling, 2018). Collingridge also attempted to overcome the dilemma on his own. He proposed two strategies to overcome the dilemma. Firstly, the upstream governance approach aims to deepen and broaden the knowledge base about a technology's potential societal impact, while it is still in its infancy. However, this approach is criticised due to the assumption that harmful effects can't be understood before the technology is fully developed and diffused (Winickoff & Pfotenhauer, 2018). Thereby, the unpredictability of human actions and the inherent complexity of socio-technological systems limit the effectiveness of the strategy (Liebert & Schmidt, 2010). The second strategy is the control-oriented strategy. This approach focuses on maintaining and enhancing the ability to control technology even after it is fully developed and adopted. This includes increasing the power of scientists, policymakers, and institutions to make and revise decisions throughout the innovation process (Liebert & Schmidt, 2010). Both approaches prescribe early interactions between governance bodies and industries to

aim for the elimination of the dilemma. This interaction will result in a shift from managing the risks by regulatory bodies, to managing the innovation process itself. Furthermore, the industry is generally ahead and developing faster than the speed at which regulatory entities develop regulations.

The context of this thesis is focused on the uncertainty that a startup founder faces regarding the regulations their new technology must comply with. This regulatory uncertainty can significantly impact the strategic decisions made by the startup. As found in the study of Norval et al. (2021) focussing on exploring the attitudes and preparedness of tech startups to data protection issues. Startups often felt that it was unclear how, and in some cases, whether their technology could be reconciled with the EU General Data Protection Regulation (GDPR). They also saw startups questioning whether aspects of the GDPR applied to them, with some indicating complacency, by first waiting to see if and how the regulation is enforced before acting.

The uncertainty surrounding regulations causes startups to delay critical decisions, impacting their growth and development. This hesitation is often due to the lack of clarity and the potential costs associated with compliance (Salgado-Criado et al., 2024). As a result, startups may defer the integration of data governance mechanisms until later stages when their technology is more established and the risks are better understood. This problem of when to comply with regulations, aligns with the Collingridge "dilemma of control," allowing startups to prioritize immediate growth without the distractions of regulatory compliance. Venture capitalists (VCs) also recognize these challenges, understanding that regulatory uncertainty hinders a startup's ability to innovate and compete in the market (Salgado-Criado et al., 2024).

2.2 Synthesis of technology, product and startup development timelines

Different methods for new technology development have been mentioned so far in chapter 2.1.1. However, in the context of a hardware startup, this process is different from what is seen in established businesses. A startup has its unique process, they are developing a technology that has to translate into a product, while also building a business simultaneously. Existing literature has not yet prescribed a framework for the technology development process within a hardware startup context. Therefore, a synthesised timeline is proposed. This timeline incorporates all frameworks previously discussed. This includes the hybrid stage-gate model, as discussed in 2.1.1. Furthermore, the growth phases of the startups, discussed in 2.1.2, are represented in the synthesis. Lastly, the technology readiness levels have been included. These consecutive steps describing technology maturation have been discussed in section 2.1.3.

2.2.1 Synthesized timelines

In the sequel of this thesis, product development processes, technology readiness levels (TRLs), as well as the growth phases of a lean startup, are used and synthesized to understand the development of the technology and startup uniformly. The earlier discussed stage-gate process with continuous market feedback, and the startup growth phases have been set parallel in figure 3. Thereby, the TRLs have been placed logically suited to the timelines. Throughout the interviews conducted for the data collection of this thesis, the synthesized timeline is used to sketch interference moments with the participants about when certain aspects of regulatory compliance became urgent in their development processes.

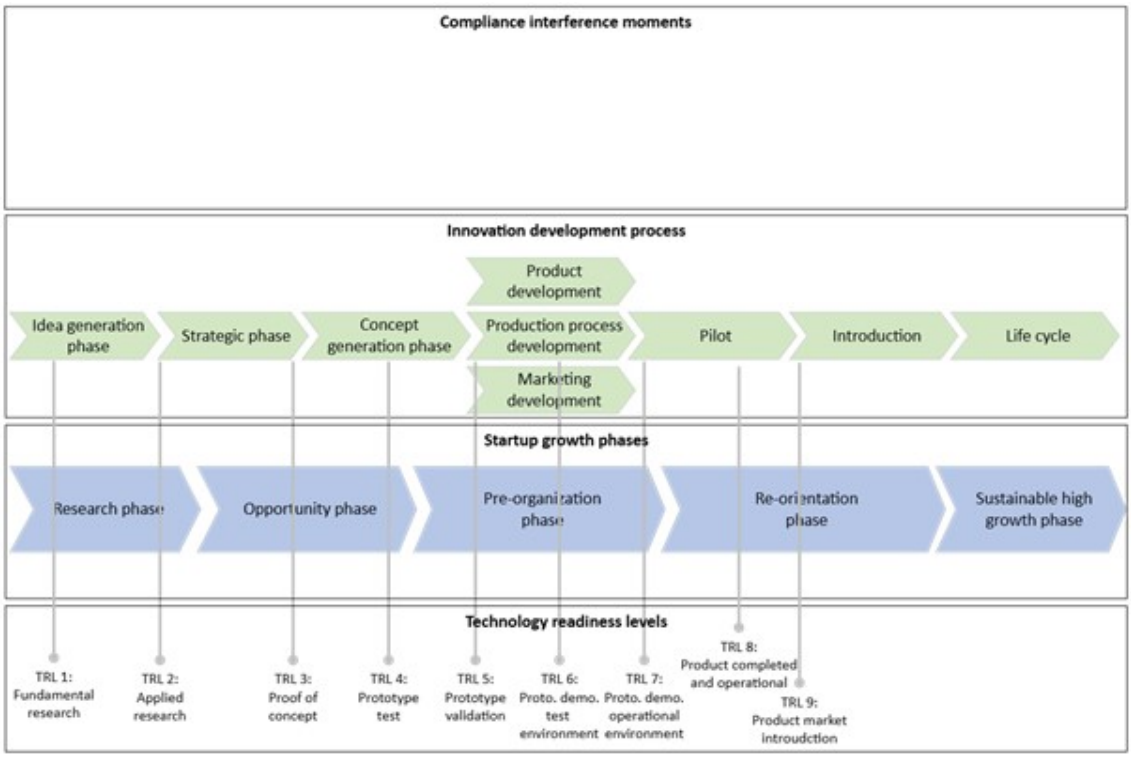


Figure 3: Synthesized timeline of startup development and product development, with technology readiness levels indicated (Synthesis by researcher)

The timelines have been synthesized in such a way that phases are overlapping as realistically as possible. The timelines illustrate how product development is intrinsically tied to the startup's growth trajectory. Also, the TRLs have been indicated throughout the timelines, to include all management practices. Regulatory compliance influences both timelines, as it is crucial at various points when the startup transitions from development to market introduction and growth.

1. Idea generation and research phase: These stages mark the inception of both product ideas and the business itself. The startup's 'research phase' is aligned with the 'idea generation' and 'strategic phases' in product development. Both processes focus on identifying viable technological solutions and market opportunities. During these phases, TRL 1 and 2 are seen. Indicating fundamental and applied research marking the initial exploration of new concepts.
2. Concept generation and Opportunity phase: As the startup identifies a viable business opportunity, the team is simultaneously conceptualizing how the product should be formed. This overlap prescribes that the concept generation is influenced by market needs and business viability. TRL 3 and 4 are passed in these phases, ensuring proof of concept and technological validity within a mock environment.
3. Development and pre-organization phase: During the pre-organization phase, the startup begins formalizing its structure, which parallels the product, production and marketing development phases in the innovation process. All processes involve refining the core product and establishing the means to scale the sales and company. Within these phases, TRLs 5, 6, and 7 are marked as they respectively prescribe technology validation and demonstration in a relevant market, as well as a prototype demonstration in an operational environment. TRL 7 also marked the end of those phases, as it indicates a pilot to start.
4. Pilot/introduction phases and re-orientation phase: Both the re-orientation and

pilot/introduction phases involve feedback loops. The startup needs to adapt the product based on market reactions, which can involve modifying the product, marketing strategy, or even the business model. Readiness level 8 is checked during these phases, as the technology is fully developed, paralleling the introduction of the product to the market. Therefore, also TRL 9 is achieved, which prescribes an actual proven system in an operational environment.

5. Life cycle and sustainable growth phase: In the final stage, the startup's sustainable growth phase aligns with the technology's life cycle phase. The phases align because, startups typically start with the development of one technology, around which they build up the company. Within these phases, product market fit is achieved and the sales increase.

2.2.2 Acknowledgement synthesis

While the proposed synthesized timeline effectively integrated the discussed frameworks, it is important to acknowledge its inherent limitations. The timeline is solely intended as a universal understanding of business, technology, and product development over time in the unique context of a tech-based hardware startup. This timeline is a theoretical construct and will not fully capture the unique development path startups actually follow. The synthesis assumes a sequential progression through the stages, which may not align with the iterative path seen in startups. Additionally, the synthesis does not account for industry-specific variations or external factors like market dynamics that could impact the timeline. The generalized approach also may not fully represent the variability in available resources, team expertise, or unforeseen challenges that startups face.

During the interviews with entrepreneurs, feedback will be collected to identify any discrepancies between the proposed timeline and their experiences. This feedback will be used for refining the timeline and will be discussed in more detail later in the thesis.

2.3 Literature gap

In the existing literature, there is a noticeable gap regarding the applicability of hypothesis-driven development i.e. lean startup methodology, to hardware technology-based startups. Unlike software development, hardware products face significant challenges in fast iteration and redevelopment due to regulatory constraints and physical production limitations. Thereby, these hardware tech startups often lack the resources and regulatory knowledge to effectively overcome these challenges. This process is conceptualised as a funnel process, in which initial market conditions, industry standards, and regulatory compliance requirements are highly uncertain, gradually becoming clearer as the startup approaches sustainable market adoption.

These regulatory challenges have not yet been recognised in research regarding startup growth phases and critical junctures. Research has not defined when startups face these regulatory challenges and how they should overcome them. Therefore this research aims to explore and address the unique challenges faced by technology-based hardware startups using hypothesis-driven development; thereby contributing valuable knowledge and practical solutions for entrepreneurs. Within figure 4, a conceptual representation of the processes and the knowledge gap between them is visualized.

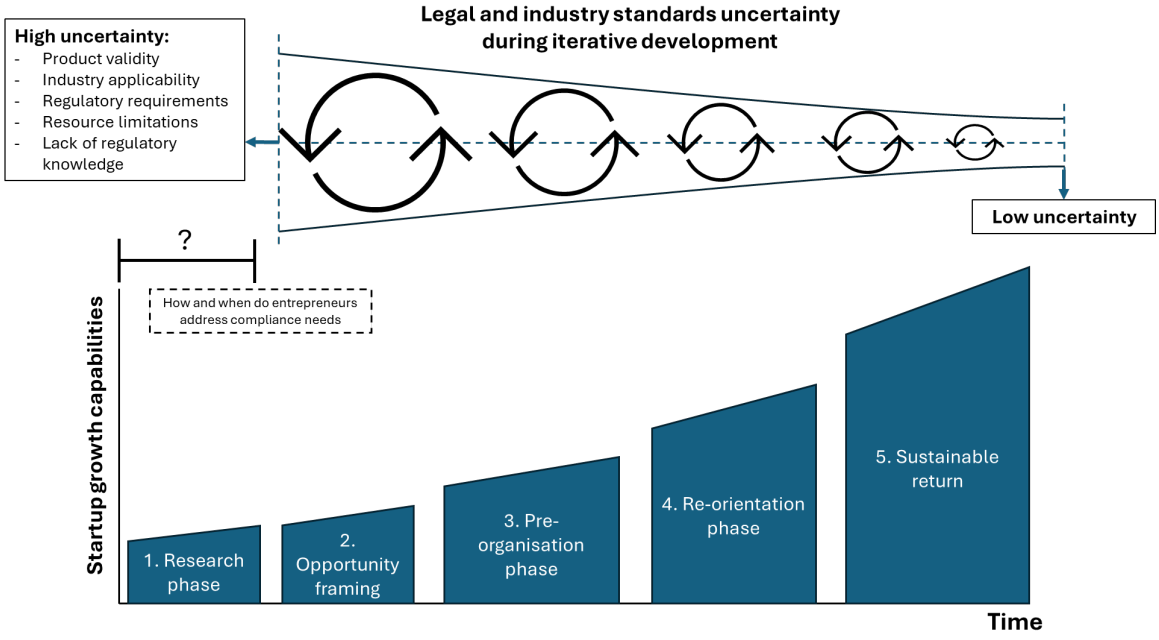


Figure 4: Conceptualisation knowledge gap (Created by the researcher)

A solid grasp of the concepts discussed is essential for both the researcher and the readers to fully understand the subject. To support this, a table summarizing the key concepts has been created. The table 3, provides detailed explanations of these concepts.

Key concepts	Explanation
Agile methodology	Iterative approach to project management and product development that uses sprints to emphasize flexibility, collaboration, and customer feedback.
Lean methodology	Approach that focuses on maximizing value by eliminating waste and improving processes continuously to deliver products efficiently.
Stage-gate methodology	Innovation development methodology which prescribes steps from idea generation through development and launch, with decision points (gates) where progress is reviewed and only the best ideas are advanced to the next stage.
The Lean Startup	Business approach prescribes developing products based on validated learning, experimentation, and customer feedback to shorten product development cycles.
Technology-based hardware startup	A technology-based hardware startup is a starting business focused on creating and bringing to market innovative tangible products that incorporate advanced or emerging technologies.
Technology	Technology refers to the fundamental innovation developed to solve a specific problem or perform a particular function. It is often the underlying mechanism or scientific principle that makes a solution possible, such as microprocessors, sensors, and robotics, as well as advanced systems like AI, IoT, or big data analytics.
Product	A product is the specific application of a technology that is designed, packaged, and offered to the market to meet customer needs. It's the tangible or intangible item that consumers can purchase or use, often subject to regulatory standards to ensure safety, quality, and compliance.
Regulatory compliance	Refers to the adherence to laws, regulations, and government-issued guidelines that are mandatory. These can vary in different regions. Examples are GDPR, NIS2, DSA, the AI Act, Blockchain Act, etc.
Industry standards compliance	Refers to adherence to standards and guidelines that are typically established by standards organizations like ISO. This is done to align with the expectations of the industry, customers, and partners, even though these standards are not legally required.
Hardware development	Process of design, engineering, prototyping, and production of physical electronic devices and components.
Production limitations	Constraints and challenges that affect the development process, such as capacity, resources, knowledge, expertise, and time.
Regulatory knowledge	The understanding of laws, guidelines, and standards relevant to specific industries that ensure compliance and legal operation.
Growth phases of tech-based startups	Five sequential stages that tech-based lean startups must proceed, each involving a non-linear iterative development process and presenting unique challenges.

Table 3: Key literature concepts and their explanations (Created by the researcher)

3 Theoretical framework

This chapter introduces a theoretical framework developed by the researcher, based on concepts from existing literature, which is studied in chapter 2. The purpose of this framework is to clarify the relationships among the research concepts. The research concepts originate from the research outline and literature review. Each connection is detailed through specific research sub-questions that are aimed at exploring the underlying relationships. Overall, this framework provides the context necessary for addressing the main research question.

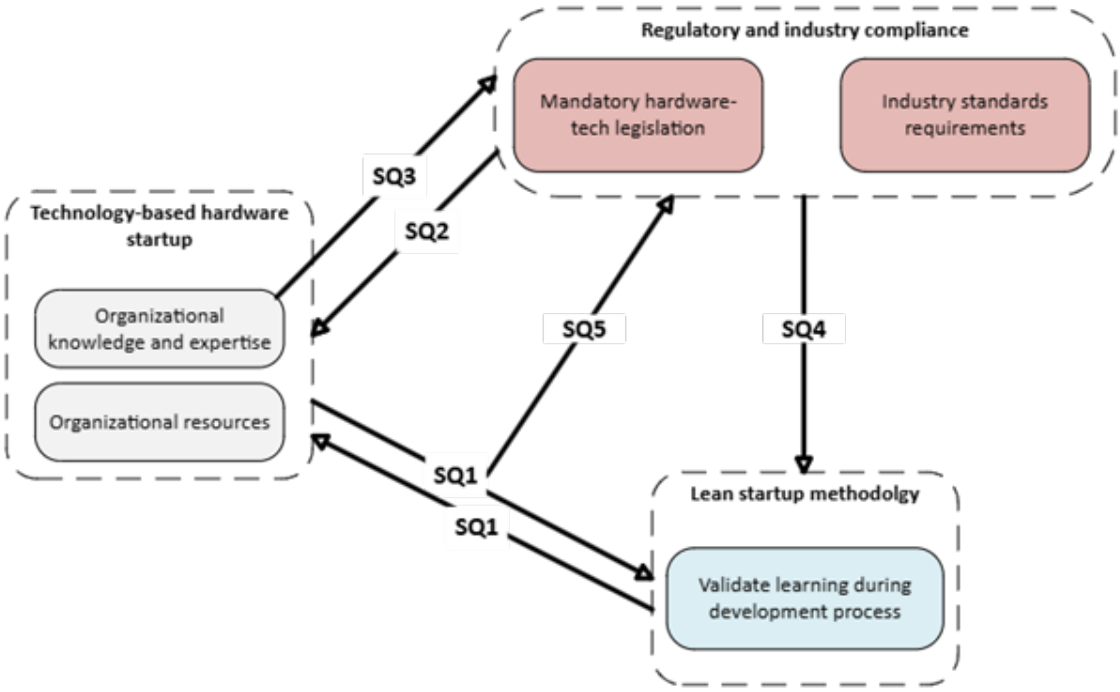


Figure 5: Theoretical framework indicating the sub-questions exploring relations in literature concepts (Researchers own model)

The theoretical framework demonstrates the relationships between the different components derived from the literature review. Hereafter, the directions of the sub-questions between the concepts are discussed, and assumptions made have been discussed. Assumptions were made to guarantee quality and clarity and keep the focus on answering the research question.

Influence lean startup methodology on technology-based hardware startups (SQ1)
The lean startup methodology is the practice startups follow to most efficiently bring their innovation to market, meaning within a short section of time, and without wasting resources (Ries, 2014; Eisenmann et al., 2011). As for a hardware technology-based startup, these practices are more difficult, due to challenges discussed in 2.1.2. Hardware startups that decide to develop their product using the lean development practice, will encounter challenges that must be dealt with. The hardware tech startup itself has its knowledge and resources such as time, venture capital investments, network, and human capital (Sevilla-Bernardo et al., 2022), which influences the way they applies the lean startup methodology. This relationship is denoted as a bi-directional relation since both concepts affect one another.

Sub-question one (SQ1) is about this relationship. It explores how the technology-based hardware startup applies the lean startup methodology in its development. It addresses the iterative process of refining ideas based on real-world feedback. While continuously building new minimal viable products (MVPs), to test hypotheses. Furthermore, it seeks to understand how this methodology

shapes the startup itself. What added value does the startup get out of applying this methodology? Both directions together, provide an understanding of the practices and stages at which validated learning is utilized, this question helps in understanding how hardware startups adapt their strategies and products to meet market needs.

Influence of obligated regulatory and industry standards compliance on hardware tech startups (SQ2)
Legislation and industry standards are norms expected by the market (Legal Nodes, 2024). The specific legal requirements and industry standards necessary for hardware technology are examined more deeply in Chapter 4. However, it can already be said that the legislation surrounding hardware technology is extremely complex (Fitzgerald et al., 2013a), especially in the context of a startup, where experiences, knowledge and resources are lagging. The regulations that come with the legislation around hardware technology restrict the development of startup technology and business (Unterkalmsteiner et al., 2016; Legal Nodes, 2024). They are as every other business, obligated to comply with the regulations. In addition, some emerging industries may lack appropriate regulations, making compliance impossible and leading to separate ethical and responsible innovation discussions (de Bakker et al., 2014). These cases are outside the scope of this thesis.

In addition to legislation, industry standards are also common practice in B2B markets. Industry standards are drafted by standardisation bodies, such as ISO, in cooperation with industry experts, stakeholders, and research organisations to establish consensus on best practices and guidelines. Businesses decide by themselves if they want to be certified for standards. However, customers demand businesses to already comply with these rules, before engaging with them (Legal Nodes, 2024).

Sub-question 2 (SQ2), explores the regulatory and industry standards landscape that hardware startups have to confront. It identifies legislation for hardware technologies that affect product development and it recognises required industry standards, providing a foundation for understanding compliance challenges and necessary adjustments in the development process. This sub-question is not answered via semi-structured interviews, as other questions are. In contrast, it is answered by a literature review and additional knowledge gathered from notified body consultants. This sub-question direction is indicated in one way, as legislation and industry standards constrain product development within hardware startups. Furthermore, if any changes in legislation or standards occur, startups have to adapt and shift along with these changing regulatory and standards frameworks.

The influence of startups knowledge and expertise on regulations and industry standards (SQ3)
Clarifying and understanding the complex world of regulations and industry standards is challenging. Especially, prior or lack of experience can significantly influence how these challenges are navigated (Salgado-Criado et al., 2024). The knowledge concept stands for the knowledge of the collective knowledge of the startup team, and potential consultants such as venture capitalists or other advisors (Khodaei et al., 2022; Unterkalmsteiner et al., 2016). Within this sub-question relation, It is important to understand the prior knowledge the startup had and the additional knowledge they gained over time. The ”regulatory and industry compliance” concept, as discussed earlier, encompasses all existing legislation and industry standards relevant to the industry in which the startup operates. The direction of this sub-question is one way since knowledge and resources impact a startup’s ability to understand and comply with regulations and standards. With this sub-question, certain influencing variables can emerge, namely the complexity of the regulated industry, as well as, the prior experience and external support startup teams have.

The third sub-question (SQ3), examines the processes startups use to determine which regulations and standards are relevant to their product. It identifies the mechanisms and resources startups employ to navigate regulatory landscapes. This knowledge is valuable to test if there exist certain

common practices, used by startup teams, to assess regulatory compliance. Furthermore, different techniques to assess compliance can be helpful for other entrepreneurs to learn from.

Impact of regulatory and industry compliance on hypothesis-driven entrepreneurship (SQ4)
Legislation and industry standards set hard boundaries in which an innovation has to be developed. The impact of these requirements can potentially influence the development process of the innovation significantly. The lean startup methodology prescribes startups try to iterate as much as possible, also called validated learning or hypothesis-driven entrepreneurship, to most efficiently make progress in development. This methodology encourages startups to create minimum viable products (MVPs) and test them in the market (Ries, 2014). However, in regulated industries, products must comply with regulations and industry standards. Ensuring that each MVP meets and is validated against industry standards is both costly and time-consuming, which contrasts with the principles of the lean startup methodology (Nguyen-Duc et al., 2018; Fitzgerald et al., 2013b). It is therefore interesting to gain a deeper understanding of how startup teams apply the methodology while ensuring compliance. The sub-question direction is uni-directional since strict regulatory requirements can constrain how freely startups can iterate on their products. Potential influencing variables are identified, namely market pressure and type of industry. The urgency to bring a product to market might push startups to bypass or delay compliance, influencing the relationship. Thereby, the nature of the industry itself (e.g., medical devices, or consumer electronics) can interfere due to varying regulations.

Sub-question 4 (SQ4) seeks to provide solutions for the discussed contradiction, as it explores to learn about the impact of regulatory requirements on the validation processes of business and technical hypotheses. It helps understand how compliance considerations shape the validation process. This can help other entrepreneurs potentially alter the approach they take to test and refine their ideas.

Interference moments by startups on compliance during the development process (SQ5)
Lastly, there is a sub-question about the startup's decision-making process regarding regulatory and industry standards compliance. Knowing about regulations and deciding to comply with them are two separate things. It is crucial to identify and map the moments when teams begin to take specific compliance actions during different phases of development. Within existing literature, no research was found on when hardware startups should confront compliance efforts, during their development.

The direction of the sub-question is seen as uni-directional, due to the ability of the startup team to decide when to interfere. There have been potential influencing variables identified, including expectations from investors and stakeholders, as well as the operational scale of the company, and market expectations. If stakeholders expect or demand compliance, it could influence the allocation of resources and the timing of compliance activities. Additionally, the operational scale may interfere, as larger teams with more resources might experience a reduced relative impact from the compliance process. Finally, different markets most likely influence the startup's incentive to comply with regulations and industry standards.

The last sub-question (SQ5) focuses on this relationship. It directly challenges when the team adopts certain design specifications during the development process. Sketching this out over the earlier discussed timeline 2.2, will provide comprehensive knowledge for future startups starting their development process.

4 Technology regulations and standards landscape

4.1 The critical role of timely compliance

Crafting a robust compliance framework is a challenging task for a startup, especially in the earlier stages of development. However, not complying with regulations means that startups face potentially costly consequences and delays. Therefore, a startup needs to understand the different types of regulations together with how to comply with them. Regulatory compliance generally refers to adherence to laws, regulation guidelines, and industry-specific guidelines or norms. In the context of hardware products, this typically includes quality assurance, safety and security, effectiveness, traceability, and certification and validation (Fitzgerald et al., 2013b), which must be met before the product can be legally sold or used in markets. Besides the legal aspects, customers in industries value products that adhere to regulations (Gallagher, 2007). Therefore, startups not only have to comply with regulations due to legal reasons, but certainly also to grow their businesses.

Lean startups are continuously trying to learn as much about their customers and technology as possible, i.e. hypothesis-driven entrepreneurship. Doing this means that they continuously have to pivot between business plans, concepts, and markets. Entering a new market and bringing a new product to market are distinct strategies, which acquire regulatory compliance adoption. When proceeding on one of those strategies, three main compliance pillars must be considered (Legal Nodes, 2024). Firstly, men must consider if the business or product triggers any criteria for regulated activity. This would result in the need to get authorization or licenses to remain compliant. Secondly, if the business collects any personal data it must adhere to general data protection laws. Finally, the type of target customers determines what type of customer protection compliance the business and product must have compliance with.

Additionally, it is important to distinguish between regulations pertaining to technology and those applicable to products. Many startups are developing new technologies or basing their products on innovations or advancements of existing technologies. Technology may be subject to its own set of regulations. For instance, consider artificial intelligence (AI), for which general regulations are currently being developed to provide a clear regulatory framework for all companies and products utilizing this technology (Wirtz et al., 2020). However, for products based on a particular technology, additional regulations may apply that are specific to the product's intended use. For example, consider regulations related self-driving cars. They may use AI technology to automate decision-making, however, they must also comply with other regulations regarding the safety of vehicles. The different layers of legal regulations, industry standards, and best practices have been visualized in figure 6.

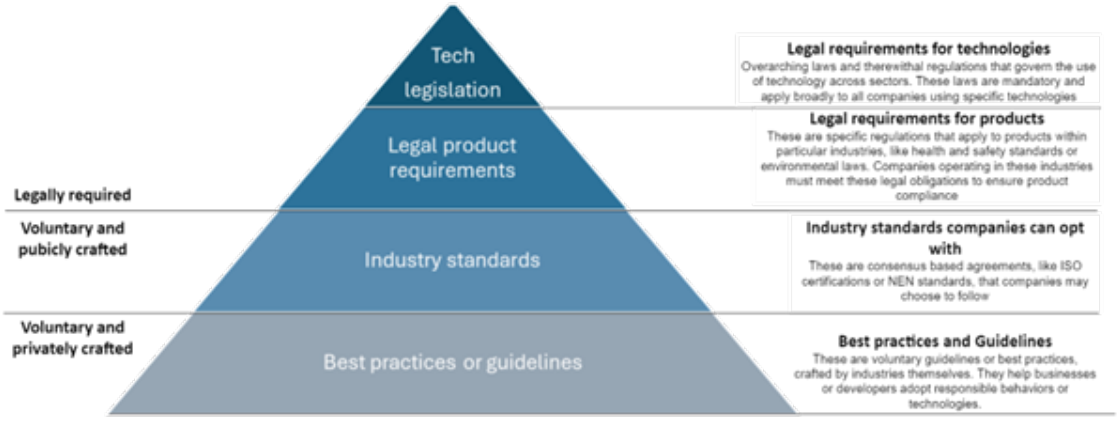


Figure 6: Regulations pyramid: Explaining the levels of regulatory compliance and industry standards (Framework based on insights NEN consultants and enriched with researcher's findings)

The significance of legal requirements and standards varies between industries and markets, reflecting the unique operational, safety, and ethical challenges seen. Strictly regulated industries such as automotive, aviation, finance, food, medical, nuclear and pharmaceuticals are examples of markets with stringent compliance measures to protect consumers, ensure safety, and maintain market integrity (Fitzgerald et al., 2013b). For startups, it is important to understand how strictly their targeted market is regulated, so they can understand the compliance efforts they will go through.

4.2 Legislation for technologies

Legislation concerning technology determines the first set of regulations startups must comply with during their development. Legislation is the set of laws or legal rules that are enacted by a governing body. In the context of technology, these regulations aim to regulate the components, systems, or processes that form the building blocks of various products, ensuring that these technologies are reliable, secure, and interoperable (McDermott et al., 2022). Within this section, the general concepts regarding technology regulations are discussed, and some examples are given.

Science or technology regulations were initially crafted to strengthen public confidence in science. This is considered a practice of responsible research and innovation (RRI) (Burget et al., 2017). RRI considers more than only legislation and the associated regulations. Following Burget et al. (2017), it implies governing research and innovation in order to include all the stakeholders and the public in the early stages of research and development. All this is to ensure a comprehensive ethical, safe and socially desirable innovation process (Zwart et al., 2014; Burget et al., 2017). RRI emphasizes the importance of aligning research and innovation activities with the needs, values, and expectations of society. However, as argued in de Bakker et al. (2014) the willingness of industries to take responsibility can be reluctant. Therefore, technology legislation and therewithal regulations are needed to enforce industries to ensure these needs are practised.

Depending on the type of industry, other legislation and regulations are in place. However, most general regulations, which are seen in almost every industry, are mentioned below.

- Cybersecurity: Cybersecurity legislation is in all probability required based on the global location. For example, the European Union has implemented the NIS2 directive. This directive enforces stringent security standards and mandates the reporting of significant cybersecurity incidents within 24 hours across various sectors. Additionally, it requires the appointment of supervisory authorities to ensure compliance with these regulations across all relevant sectors. (Rijksoverheid, 2024).
- European Chips Act: This legislation is currently being made. It contains certification procedures for the semiconductor industry, ensuring energy efficiency, trusted chips, and quality and safety requirements. In addition, it offers funding for startups, scale-ups and SMEs. The Act is applicable for all industries that use semiconductor technology (European Parliament, 2023a).
- Data protection and privacy: Hardware technology that collects, stores, or transmits personal data, compliance with data protection laws such as the General Data Protection Regulation (GDPR) is mandatory. This is particularly relevant for Internet of Things (IoT) devices. On top of that, the Cyber Resilience Act (CRA) requires producers and resellers of IoT products to meet stringent cybersecurity standards to protect consumers from potential threats. This act is in place as of mid-2024, requiring producers and resellers to enhance their security levels (Cyberveilig Nederland, 2024).
- Tech-specific Legislation: Besides legislation that is in place to be used in different industries, there are also industry-specific legislations. Examples of specific technology legislation within the EU are:

- AI Act, which is the first major regulation specifically focused on artificial intelligence. It focuses on ensuring AI systems are transparent, and respect fundamental rights (European Parliament, 2024), so that it is not only seen as a black box.
- Blockchain technology, the markets in Crypto-Assets Regulation (MiCA) have been created. These form a comprehensive framework for crypto-assets and blockchain technology to ensure market integrity and consumer protection (European Parliament, 2023b).
- Telecommunications infrastructure, within the EU the European Electronic Communications Code (EECC) regulates the telecom networks and services, aiming to ensure universal access to high-quality and secure communications (European Parliament, 2018).

4.3 Legislation for hardware products

In addition to overarching technology regulations, specific product regulations can also impact development. Although this thesis focuses on how startups navigate the regulatory landscape relevant to their industry, it is also crucial to recognise that product legislation applies to all hardware products sold in markets.

While technology regulations emphasize the safe and ethical use of technology within society, product regulations focus on maintaining quality, safety, and environmental standards. Additionally, these regulations ensure that new market entrants meet required standards, thereby preventing low-quality or unsafe products from undermining competitors (Minchin, 2023). Furthermore, they provide customer confidence, by ensuring that a product adheres to set standards. For startups, this is important to recognise, since it can influence the purchasing decisions of customers.

The landscape of product regulations varies significantly across industries, creating a spectrum from highly regulated sectors to those with less impactful requirements. In industries such as automotive, aviation, food, medical and health devices, nuclear, and pharmaceutical (Fitzgerald et al., 2013b), rigorous regulations are essential due to the potential risks associated with product failures. These sectors often require comprehensive compliance with multiple standards, including pre-market approvals and extensive testing protocols, which can prolong the development cycle and increase costs for startups. In contrast, less regulated industries may require only basic certifications, such as the CE mark in Europe, which signals compliance with essential safety and quality standards. These differences result in less stringent regulatory compliance requirements for startups in these industries, in comparison to the higher-regulated ones. However, even in these less regulated areas, adherence to relevant product regulations remains vital. Non-compliance does restrict market entry due to legal requirements.

General product regulations include various government-mandated certifications that can vary significantly not only by industry but also in different regions, meaning that many markets require specific regulations. It is important for companies to map out the differences in regulations in different parts of the world, i.e. countries. For example, for European startups, it is common to expand sales to the US markets, which requires adherence to UL certification instead of CE certification. Not adhering to the specific product regulations in global arise, can prohibit companies from entering the targeted market. To illustrate, the primary regulations that hardware products sold in Europe must generally comply with are listed below.

- Safety standards and certification: Hardware products in a variety of industries must meet specific safety standards. Compliance with standards such as the CE marking in Europe proves that a product follows required safety-, health-, and environmental regulations (Rijksoverheid, 2022).
- Environmental compliances: Regulations such as the Restriction of Hazardous Substances

(RoHS) (European Parliament, 2011) and Waste Electrical and Electronic Equipment (WEEE) (European Parliament, 2012) directives in Europe mandate that electronic products be free of certain materials that harm the environment, and that they are collected and recycled after usage. Startups should integrate these requirements into their product design from the beginning.

- Medical Device Regulations (MDR), the MDR in the EU regulates the safety and performance of medical devices to ensure high-quality standards to ensure patient safety (McDermott et al., 2022). Within the US these are the FDA regulations.
- Machinery directive: The goal of this directive is to establish safety requirements for machinery and equipment in various industries, sold within the European Union. It ensures that machines are designed and constructed to minimize risks to operators and users (European Parliament, 2006).
- Electromagnetic Compatibility (EMC) Directive: regulates the electromagnetic emissions and immunity of electrical and electronic equipment, ensuring they do not generate electromagnetic disturbances that exceed a certain level, such that they can influence other materials (European Parliament, 2014).

The above-mentioned regulations pertain specifically to the European market. However, as emerging startups often aim to expand globally, it is essential to recognize that regulatory frameworks vary across different regions. Compliance with these diverse legal requirements is critical for market entry and long-term success. Therefore, startups must thoroughly investigate and understand the specific regulations and standards applicable to the target markets they intend to enter.

4.4 Industry standards and best practices

Enterprises are obligated to comply with technology legislation and general product regulations discussed above. In addition, companies can opt to comply with specific industry certifications, such as European Norms (EN), country-specific norms such as the Dutch norms (NEN), and standards from the International Organization for Standardization (ISO). These standards are created by standardisation organizations collaborating with industry stakeholders, and research organisations to establish consensus on general guidelines and requirements. International standards are technical specifications about the design, dimensions, interactivity, and performance of products and processes. In short, they specify how something should operate or interact with others to create a universal language between producers, suppliers, and consumers.

Besides industry standards, there is also a fourth level of best practices and guidelines. These are informal recommendations or guidelines, often created by industry experts or advocacy groups, and not based on consensus. These are created by private companies or certification bodies, seeking to sell the best practices or guidelines to make a profit, which is in contrast to the industry standards mentioned earlier. Best practices and guidelines are recommendations or strategies that are widely accepted as the most effective and efficient ways to achieve desired outcomes. They serve as non-binding advice rather than formal requirements.

Companies themselves have the option to comply with industry standards, best practices or guidelines, a decision that can be driven by internal capabilities as well as external market forces. Internally, organizations may leverage their strengths, such as robust quality management systems or conscious environmental impact, to meet these standards. Externally, compliance is often pursued because it enhances customer satisfaction and aligns with market expectations. Customers increasingly demand that products and services adhere to recognized standards (Benner & Veloso, 2008; Tomic & Spasojevic Brkic, 2019). Some examples of regularly seen industry standards are:

- Quality management systems (QMS): Implementing a QMS like ISO 9001 is one of the main

practices seen in industries (International Organization for Standardization, 2015). This standardised framework helps maintain safety, reliability and quality across products and services. By complying with this type of framework businesses can convince customers and regulatory bodies that the company adheres to globally recognized standards.

- Information security management: Industry standards provide frameworks to set, implement, preserve and continually improve information management systems. One of those frameworks is the ISO 27001 standard, which is globally recognised as an information security standard (Nederlands Normalisatie-Instituut, 2023). This norm is commonly seen in IT, finance, healthcare, and other industries dealing with sensitive data.
- Industry-specific norms: In addition to standards that apply across various industries, there are also specialized norms tailored for specific sectors. For example, IATF 16949:2016 focuses on the automotive industry, setting stringent requirements for quality management systems to ensure the production of qualitative components (International automotive task force, 2016). Similarly, AS9100 is a standard developed for the aerospace industry, emphasizing the quality and safety of aerospace products (SAE international, 2016). It is important to note that these are just a few examples, as there are many more standards designed to address the specific needs and challenges of different industries.

Globally, several organizations are dedicated to the development and publication of standards. These bodies by themselves can challenge businesses to comply with the standards. In addition, other companies specialize in conducting assessments and audits to ensure adherence to these standards. The most well-known international standardization bodies include the International Organization for Standardization (ISO), the American National Standards Institute (ANSI), and in Europe the European Committee for Standardization (CEN). Additionally, countries have their national standardization organizations, such as the British Standards Institution (BSI), the Deutsches Institut für Normung (DIN), and the Netherlands Normalisation Institute (NEN), which focus on standards specific to their respective countries.

Within the context of this thesis, the focus is on how tech-based hardware startups could navigate and comply with all these regulations, industry standards, and best practices. As seen, the amount of regulations is large, and navigating all is complex, especially in the lean startup context where startups experience additional resource, time and expertise challenges in comparison to more established firms. According to Legal Nodes (2024), startups should aim for early engagement and may also benefit from employing external consultants to effectively navigate complex regulations. Additionally, adopting an iterative approach to compliance can assist them in achieving various compliance requirements.

5 Methodology

Within this chapter, the research methodology for the thesis is discussed. This research is qualitative in nature, ensuring that the complexity and context-specific situation of each startup's environment is captured comprehensively. The research methodology consists of three parts. Starting with, the systematic literature review which is performed to explore the research concepts of interest. This method is described in section 5.1. For the second section, an explorative study on technology legislation, product regulations, and industry standards is performed. This is done to give the researcher and reader an understanding of the regulatory landscape, see section 5.2. In the third and primary section of this study, semi-structured interviews have been conducted to gain qualitative data. The data is aimed to bridge gaps in existing literature. The methodology for primary data acquisition is discussed in section 5.3. By combining the knowledge gained from interviews with the knowledge gained from the literature review and regulation study, data is combined and triangulated to strengthen the insights gained. The overall research methodology has been visualised in figure 7.

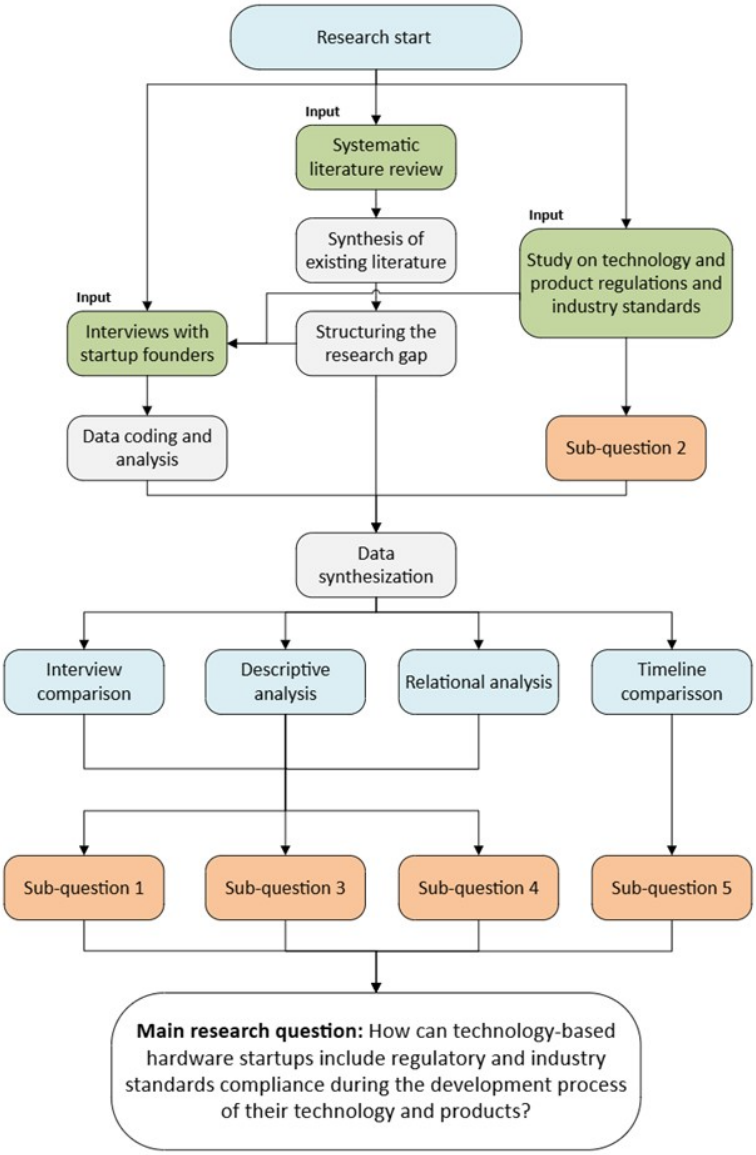


Figure 7: Graphical representation of the research approach

5.1 Literature review

Gathering data based on existing literature is the first step within this master thesis. The literature is extensively discussed in chapter 2. Existing literature covering topics regarding technology-based hardware startups is limited, especially literature that covers the challenges related to hardware tech startups and regulation and standards compliance. The literature scarcity necessitates a broadened systematic literature review to address this gap. Given the limited existing research, the review incorporates related concepts such as the impact of regulatory compliance on general technology development processes and the Collingridge dilemma of control, aiming to draw insights from these areas. The systematic review is structured with clearly defined search concepts.

Scopus was primarily used as the main search engine, due to the fact only peer-reviewed journal articles, conference papers, and academic books are published. After the initial systematic search discussed below, a snowball strategy was used to identify more relevant research papers (Wohlin, 2014). The search strategy utilized Boolean operators, particularly AND, to combine research terms that describe the main concepts in this thesis. After the search, titles and abstracts of the search results were then reviewed to assess their relevance and quality. The inclusion criteria applied in Scopus are listed below.

1. **Topic Relevance:** Articles were included if explicitly discussed topics related to the lean startup methodology, standardized development methods, technology readiness levels, Collingridge dilemma, and their relevance to regulatory compliance in tech-based startups.
2. **Publication date:** To capture a comprehensive understanding, the review focused on literature published from 2005 onwards. However, seminal works that are foundational to the field, were also included, regardless of their publication date.
3. **Language:** Only publications in English or Dutch were included, given the capabilities of the researcher and the time constraints of this thesis.
4. **Accesability:** Literature must be accessible through the Delft University of Technology institutional login at publishers, or accessible in the database of the university.

The Snowball method has been applied for further literature searches. Within the following table, all concepts and search terms have been listed:

Key words	**Search terms**	**Number of articles found**
Regulatory compliance	Regulatory AND Compliance AND startups	67
Lean startup	Lean startups AND Hardware development	6
Hardware startup	Hardware AND Startups AND challenges	81
Technology development process	Technology development process AND startups AND Regulations	20
Startup challenges	Startup challenges AND Hardware OR Software AND Regulations	11
Technology Readiness Levels	Technology readiness levels AND Startups	26
Collingridge Dilemma	Collingridge AND dilemma, Collingridge AND Startups OR challenges	40
Regulated environments and Agile	Regulated AND Environments AND Agile	53

Table 4: Search Terms by Keyword utilized in Scopus

The initial search in Scopus provided 304 results. These articles were quickly screened based on their titles and abstracts. Articles that appeared to meet the criteria were read in full and further evaluated for their relevance and quality. The selected papers were categorized according to their thematic relevance, as seen in the outline of chapter 3. The concepts provide the theoretical background to answer the research questions and objectives of the thesis. The following thematic differentiation is made:

- **Standardized methods for new technology development:** Common development methods Agile, lean, and stage-gate are explored. Furthermore, an emphasis on how regulatory compliance influences these processes has been examined.
- **Lean startup methodology:** Discusses the application and limitations of the lean startup method in the context of hardware and software startups, particularly the challenges concerning regulatory and industry compliance have been covered.
- **Technology Readiness levels:** The concept of technology readiness levels (TRLs) and their applicability to startups, have been explored. Also, the hurdles with regulations have been covered.
- **Collingridge Dilemma of Control:** Analyzes this dilemma and its implications for innovation management in startups, drawing parallels to the uncertainties faced by startups in regulated industries.

Eventually, 39 articles were used for the literature review. The outlined theoretical themes were explored in-depth. Based on the insights found in the literature regarding the theme, a synthesis was made on the most relevant knowledge within the literature. This has been brief and concisely written in the theoretical framework. The synthesis combined highlights that there is still a gap in the literature, on how hardware technology startups could confront regulatory and standards compliance. This research gap is elaborated and visualised. Furthermore, a timeline is created based on three different sequential processes. These processes all have interfaces with the actual process of startup development. The synthesis of these timelines is used for guidance during the semi-structured that take place later in this study.

5.2 Explorative study on technology and product regulations and industry standards

Alongside the literature review, an exploratory study was performed to outline the regulatory framework applicable to startups. Understanding the regulatory environment, including both technology-specific and product-specific legislation, is essential for comprehending how entrepreneurs navigate compliance challenges. While the primary focus of this research is on how entrepreneurs manage regulations, gaining a foundational knowledge of the regulatory landscape is crucial for contextualizing their strategies.

The exploratory study was not based on a full academic literature review such as the first section of this research, chapter 2 Literature review. However, a more targeted review was used, to explore relevant literature combined with a focused search of legislation and industry standards published by regulatory bodies. At first, literature on responsible research and innovation was searched and reviewed, to understand the foundational principles behind technology legislation and regulations. The articles were found by utilizing Scopus. Secondly, a search was conducted for specialized knowledge on regulatory and standards compliance in the startup environment. This search was done via Google, allowing for reviewing non-academic sources such as marketplaces for legal expertise. This allowed me to learn from experts operating in the environment. Furthermore, the exploration included searches within European acts and industry-standards databases to identify relevant examples of legislation and standards applicable at each level of the hierarchy. Lastly, the researcher reached out to consultants from the Dutch standardisations organization NEN, to gain knowledge on, and validate the understanding of the regulatory and standards landscape. Primarily, two consultants were engaged: one specializing in

standardization of Environment, Climate Adaptation, and Air Quality, and the other in Construction. These sources of legislation and industry standards are synthesized to provide a comprehensive minimal understanding of the regulatory landscape. This ensured that the study accurately reflects the current regulatory environment without the exhaustive scope of a traditional academic review, which is considered sufficient for the supporting role in this thesis.

The exploratory study is focused on four levels of regulations and industry standards, companies have to, or opt to comply with. These levels are:

- Technology regulations: Regulations governing general technologies, which can be applied to a range of products in several industries.
- Product regulations: Standards and regulations specific to the industries in which the startup operates, and regulations concerning the tangible aspect of a device. Examples are, CE, medical device standards (MDR), automotive safety regulations, and consumer protection laws. These regulations ensure that products meet the necessary safety and performance standards before entering the market.
- Industry standards: These standards are not obligatory to comply with. However, these standards are often adopted by businesses as a strategic choice to enhance product quality, customer satisfaction, and market competitiveness. Compliance with industry standards can also facilitate easier market entry and increase customer trust.
- Best practices and guidelines: These are informal recommendations or guidelines, typically created by industries and certification bodies. They help companies follow efficient and effective practices and strategies.

The explorative study is performed to provide a basic understanding for the researcher and readers of the regulatory and standards landscape in which startups operate. The findings have ensured that the researcher has a comprehensive understanding of the landscape, allowing the upcoming interviews to be more in-depth. Furthermore, the research contextualizes the challenges and complexities of the regulatory landscape, offering insights into why this is such an important topic for tech-based startups. In addition, the findings help to understand why startups adopt certain approaches, and how the broader regulatory environment influences them.

5.3 Data acquisition via interviews

For the main part of this research, qualitative data is gathered via Interviews. Three types of interviewing have been considered: unstructured, semi-structured and structured interviews (DiCicco-Bloom & Crabtree, 2006). The unstructured interviews are the most open since they do not follow a script or guide. This type is frequently used to explore complex issues, adapting to participants' responses (Brinkmann, 2014). The opposite is a structured interview approach. This type prescribes a set interview guide, which typically acquires quantitative data. This method ensures consistency and comparability between participants (DiCicco-Bloom & Crabtree, 2006). The semi-structured approach lies between these two interview practices. This practice allows the interviewer to adapt and ask additional questions to the interviewee, besides his set framework of questions (DiCicco-Bloom & Crabtree, 2006).

The semi-structured approach was chosen for this study since it is still overall consistent and allows for flexibility. Using this technique allows for in-depth exploration of the processes, motivations, and decisions driving startup founders. This approach ensures a comprehensive understanding of the strategic background and operational dynamics within the startups, and how this affected compliance efforts.

The methodology to perform the interviews is outlined in this section. First, the interview structure strategy and setting are discussed. Subsequently, the sampling strategy is challenged and the participants are listed. Thereafter, the data process and analysis methodologies are

examined. Eventually, the ethical and reliability considerations have been challenged. The actual description of the coding process is elaborated in chapter 6. Subsequently, the results from the analysis are discussed in chapter 7.

5.3.1 Interview structure

As mentioned, the interviews were conducted following a semi-structured approach. All interviews were done one-on-one to have the opportunity to exclusively address the complexities of the startup in question, meaning that several topics were discussed in a natural flowing way. These topics have directly been derived from the research sub-questions. The interview questionnaire is structured following the principle as shown in figure 8. Also, the interview guideline is attached in appendix C. The interview guideline is crafted in such a way the structure adheres to the below-discussed concepts. Furthermore, the interviews were preferably held in person. In addition, the interviews were conducted in either English or Dutch, based on the participants' preferences.

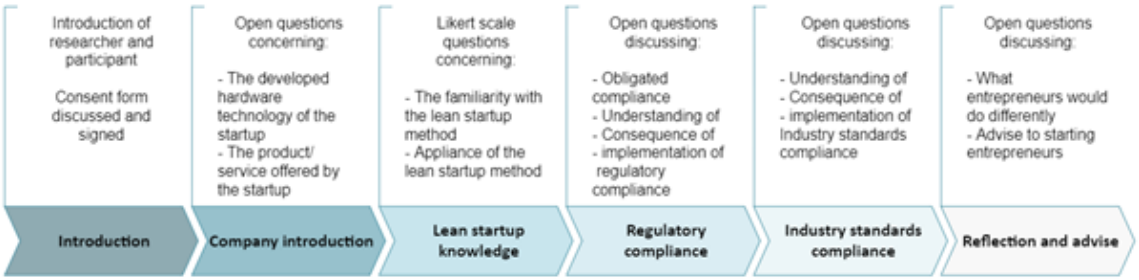


Figure 8: Structure interview questionnaire

- During the introduction section of the interview, the interviewee and participant introduce themselves, and the purpose of the interviews and thesis are discussed. The interviewee always asks if the participant still has remaining questions regarding the consent agreement. Furthermore, the synthesized framework is explained. The framework is based on existing literature, explaining how timelines of startup, technology and product development overlap. This framework is discussed beforehand to get a universal understanding of the development processes and to ensure validity in acquired data.
- Each interview starts with a few introductory questions. These questions are asked to get an understanding of the technology the company has developed, and the product they offer.
- The second set of questions are two predefined Likert scale questions. These questions test the knowledge of the participants about the lean startup method, and how actively they have applied this method during development. The Likert scale questions are asked to ensure validity in the data acquired in the interview.
- During the interview, a distinction is made between regulatory compliance and industry standards compliance. First, the discussion focuses on general regulatory compliance, which refers to the mandatory legislation that the business, technology, and products must adhere to. This section seeks to understand the interviewee's awareness and actions concerning the legal requirements. The goal here is to sketch certain compliance moments on the timeline, such as awareness and actual implementation of compliance. Also, the reasons behind compliance or non-compliance are discussed.
- Following the discussion on regulatory compliance, the interview transitions to industry standards compliance. This section explores the company's adherence to industry-specific norms and guidelines established by standardization institutions or certification bodies. Unlike regulatory compliance, which is obligatory, industry standards compliance is often

voluntary. However, compliance can be seen as required by the market. The questions in this section aim to gain insights into how a startup became aware of standards, why and when they did comply, and what the influence of outside factors was on their decision.

- The interview concludes with open-ended questions that invite the interviewees to reflect on their experiences and provide advice for future entrepreneurs. This section seeks to gather insights on what the participants might do differently if they were to start over, or had other resources at the time. In general, all advice they have for others in the field is captured. This reflective segment not only enriches the qualitative data but also allows participants to share valuable lessons learned from their journey.

The interview guide as just explained, has been pilot-tested by the internship company in question. One of the founders of this company has been the first interview participants. After this interview, the questionnaire was slightly adjusted based on feedback. Furthermore, during successive interviews minor adjustments were made to the interview guide to fully suit the participants' environment.

5.3.2 Sampling strategy

Ensuring that valuable experiences and knowledge about handling regulatory and standards compliance, an appropriate sampling strategy must be chosen. The decision was made to apply purposeful sampling, which allows for selecting individuals who are knowledgeable about and experienced with the practice of interest (Palinkas et al., 2015). In comparison to probabilistic and random sampling techniques, the generalizability of this technique is debatable. This is due to the biases that could occur in the selection of participants and in controlling potential influences of known concepts (Palinkas et al., 2015). Following the sampling technique, several criteria were set up for the selection of participants.

First of all, startups selected for this study must offer a technology-based hardware product to their customers. While these startups may also provide accompanying software extensions, the presence of a tangible hardware component is a mandatory criterion. This focus on hardware ensures that the study addresses the specific regulatory challenges associated with physical products. Secondly, the startups needed to have a minimal level of maturity, operationally defined as having found a product-market fit. Due to the variability in the development of each startup's business, and their technology, this is not strictly tied to a specific number of years. Subsequently, the interview participants were required to be either the founder or a key individual who has been closely involved with the startup since the beginning of the company. This criterion was established to ensure that participants had direct experience with, and insight into early decision-making processes, particularly regarding regulatory compliance. Only Dutch-based companies have been interviewed due to logistical and time constraints within this research. However, there was no requirement for the market region in which startups operate. This geographical focus results in a more in-depth exploration of regulatory challenges within the specific region. However, it must be acknowledged that this limits the generalizability of the study results. Furthermore, the research is intended to cover a variety of industries, and therefore startups from a range of industries were selected. Figure 9, demonstrates the funnel used to find and select startups and therefore participants for this research.

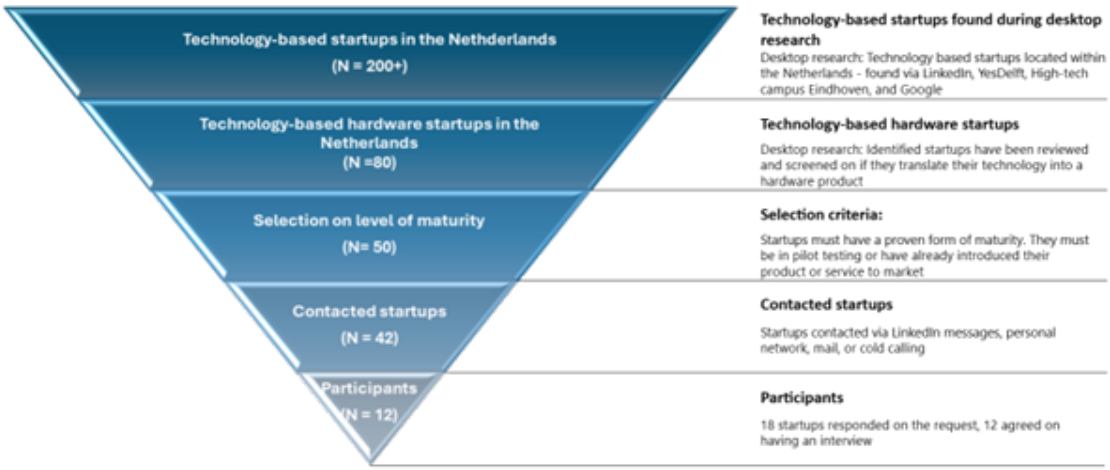


Figure 9: Process of selecting potential participants

A more in-depth overview of all participants who participated in the study is hereafter discussed.

5.3.3 Overview of participants and startups

Several entrepreneurs have been interviewed about their experiences with regulatory compliance during the development of their startups. In Table 5, an overview of all participants is given. The table includes the company's industry, founding year, current size, function of the participant, the date interviewed, and the location of the company within the Netherlands. Most of the participants were co-founders and held executive positions within their companies.

Participant number	Industry	Founding year company	Size company	Function	Interview date	Region
1	Engineering	2020	10 - 50	CEO and Founder	30-8-2024	South Holland
2	MedTech	2020	1 - 10	COO	12-9-2024	South Holland
3	Engineering	2022	1 - 10	CEO and Founder	13-9-2024	North Brabant
4	Advanced Technology	2014	10 - 50	CEO and Founder	16-9-2024	South Holland
5	Automotive	2019	1 - 10	COO and Founder	16-9-2024	Gelderland
6	Automotive	2015	1 - 10	CEO and Founder	17-9-2024	South Holland
7	HealthTech	2019	1 - 10	CEO and Founder	19-9-2024	South Holland
8	MedTech	2022	1 - 10	CEO and Founder	26-9-2024	South Holland
9	Computing	2014	10 - 50	CGO	26-9-2024	North Holland
10	MedTech	2020	10 - 50	CFO and Founder	27-9-2024	North Holland
11	Engineering	2020	10 - 50	COO	1-10-2024	South Holland
12	Engineering	2007	201-500	Former founder and angel investor	10-10-2024	South Holland

Table 5: Participants overview

- Participant 1
  Co-founder and CEO | **Civil engineering background** |
  The first participant is the co-founder and CEO of a startup in the civil and engineering industries. The company originated from PhD research at Delft University of Technology; after conducting research, the participant recognized the business opportunity and therefore

started the company almost five years ago. Currently, the company has done a market introduction and is now scaling up sales.

- Participant 2
  COO | Business and economics background |
  The second participant is the COO of a startup in the Healthcare technology industry. The company has developed an AI-powered robot for disinfection of clinical environments, the robots help reduce hospital-acquired infections and improve productivity. The idea for this company originated from a group of mechanical engineers who crafted the idea due to the COVID pandemic back in 2020. The participant joined the company after it was founded to help the team commercialize and bring the product to market. Currently, the company has just gathered the required legal compliance and is therefore ready for market introduction.

- Participant 3
  Co-founder and CEO | Business and management background |
  This participant is the CEO and co-founder of a startup in the engineering and process industry. The company has developed a photonic sensing technology to assess corrosion under isolation. The idea for this company originated from the prior experience and expertise of the participant. The company is now in a state of product and production development, while simultaneously having some pilot projects. The company was founded in 2022.

- Participant 4
  Co-founder and CEO | Chemical engineering and business administration background |
  The fourth participant is the CEO and co-founder of a startup in the advanced technologies industry. The participant founded this company already back in 2014, after completing studies at Delft University of Technology. The company is now in a phase of pilot testing and starting market introduction combined. Their technology enables researchers and other companies to prototype new materials rapidly.

- Participant 5
  Co-founder and COO | Business background |
  This participant is the co-founder and COO of a company in the automotive sector. The company develops a product that enables the legal use of an electric-powered urban vehicle in the Netherlands. The participant founded the company together with his companion over 5 years ago. The idea for the company was born by seeing the business model in other geographical locations. They are now close to introducing their development to the general market.

- Participant 6
  Co-founder and COO | Business background |
  The next participant is the co-founder and COO of a company operating in the automotive industry. The company provides smart sensor solutions for several purposes. The participant founded the company together with his companion in 2015. The idea for the company originated in the graduation thesis of the co-founder at the Delft University of Technology. After bringing their first sensors and platform to market, they expanded their solutions range.

- Participant 7
  Co-founder and CEO | Product design background |
  The seventh participant is the co-founder and CEO. This company operates in the HealthTech industry. They provide a solution to prevent stress and burn-outs. The idea for this company arose after experiences in the founder's environment. The company was founded in 2019 and just introduced the product to the market.

- Participant 8
  Co-founder and CEO | Product design background |

This participant is the CEO and co-founder of a medical technology startup. The company is developing the next-generation insufflation technology. The idea for starting the company originated from research and development at the Erasmus Medical Center and personal annoyances with current technology. Currently, the company is working on the stages of development and is preparing for market introduction.

- Participant 9
  CGO | Business strategy and management background |
  The ninth participant is the CGO of a startup operating in the Computing and CleanTech industry. The company is developing and commercializing immersion cooling technology for data centres. The company was founded because of the growing need for sustainable IT infrastructure. Currently, the company is scaling up sales as they have completed the market introduction.
- Participant 10
  Co-founder and CFO | Product design background |
  The participant is the co-founder and CFO of a startup operating in the MedTech industry. They use advanced nanotechnology, photonics, and artificial intelligence technologies to revolutionize pathogen detection. The idea for the company originated from Nobel prize-winning research. The company is currently in phases of pilot testing and redefining its product.
- Participant 11
  COO | Mechanical engineering and business administration background |
  This participant is the COO of a startup operating in the engineering industry. The participant first worked as a strategy consultant for startups and small and medium enterprises. Also, the participant lectured and guided startups within several courses at the Delft University of Technology and YesDelft startup incubator, before starting the position within this startup.
- Participant 12
  Former founder and angle investor | Civil and offshore engineering background |
  The final participant is an experienced entrepreneur who co-founded a startup in 2007, based on PhD research at TU Delft, together with a professor and three other colleagues. They recognized the opportunity to combine several existing technologies for a new application. After successfully bringing this technology to market, they sold the company. Since then, this participant has become an angel investor in various hardware tech startups. Also, this participant advises portfolio companies, particularly on engaging with regulations and standards.

5.3.4 Data collection process

Interviews are recorded and transcribed after they take place. The transcriptions were checked and then sent back to the participant for approval. Thereafter, the data is processed in the ATLAS.ti software. This software allows for qualitative analysis via coding. Using this tool provides a structured approach to allow a multiple-round coding process.

5.3.5 Reliability and validity of data acquisition

To ensure the reliability and validity of data acquisition during the interviews, several measures were employed. First, semi-structured interviews were conducted, which inherently allow for both consistency and flexibility, contributing to the reliability of the responses. To establish a baseline for participant attitudes and understanding of the lean startup methodology, the interviews began with two Likert scale questions, enhancing the validity by ensuring an initial comparable measurement across participants.

Also, a pre-synthesised timeline was used during the interviews to discuss specific moments where startups took regulatory compliance actions, providing a uniform understanding of the

startup development process, which improved both reliability and validity. The interview questions were initially crafted by the researcher, then reviewed by a company expert and discussed with the first supervisor of this thesis, ensuring content validity. Subsequently, the questionnaire was further refined after the first interview to address any emerging issues. Other reliability procedures, such as consistent interview conditions, return of participant transcripts for approval, and clear documentation, were followed throughout the data collection process. These measures ensured that participants were asked relevant questions and that participants clearly understood these questions.

5.3.6 Deductive and inductive data analysis

A substantial dataset, consisting of all interview transcripts, is generated during the interview process. This dataset is analyzed using two approaches: deductive and inductive. As for deductive content analysis, this practice involves applying a predefined theoretical framework to the data. The deductive analysis is a top-down approach, useful when the research is guided by specific hypotheses and theories the researcher aims to test or elaborate upon (P. A. Mayring, 2023; Assarroudi et al., 2018). Within this thesis, the existing literature on the lean startup method, technology development methods, technology readiness levels, and regulatory compliance in several practices has been discussed. Deductive analysis is employed to extend existing literature, ensuring that the findings are consistent with established knowledge. The deductive approach ensures that new contributions are consistent with existing literature (Assarroudi et al., 2018).

Inductive content analysis is a bottom-up approach wherein patterns, themes, and categories emerge directly from the data. This method is typically seen when there is limited prior research on the topic because researchers can develop a grounded understanding based on participants' perspectives (P. A. Mayring, 2023; Assarroudi et al., 2018). In this study, inductive analysis allows for the identification of new insights and concepts not predetermined in the existing literature. Both inductive and deductive analysis techniques are employed to balance the discovery of new insights while also validating existing theories. The analysis process starts with deductive coding, inductive coding has been applied in the second coding round.

After deductive and inductive coding rounds, thematic analysis is utilized to identify patterns in the data. Furthermore, descriptive analysis is utilized to interpret the findings per theme, based on the theoretical framework of this study. Lastly, relational analysis is executed to explore previously underdefined relations. The analysis approach allows flexibility to identify and analyze patterns within the interview data, such as the timing of regulatory awareness, decision-making processes, and strategies for compliance. This approach allows for a flexible and detailed exploration (Nowell et al., 2017).

The thematic analysis method focuses on providing answers to sub-questions (one, three and four). Simultaneously, Process analysis is integrated to examine the sequence of events and reasoning underlying these themes (Langley, 1999). This analysis maps out the steps that startups take from discovering regulations to implementing compliance measures on the synthesized timeline. This is outlined in the timeline comparison analysis. This analysis uncovers when and why specific decisions were made at different stages of the development process. This is reflected in sub-question five in this research.

5.3.7 Ethics approval

Taking interviews for research practices means that human aspects are involved in the research. This is seen as ethically critical, due to participants' privacy and data security. Therefore, Human Research and Ethics Committee (HREC) approval has been applied to the Delft University of Technology. For this application, a data management plan, consent form and HREC checklist were crafted and reviewed. The participants were informed well before the meetings about the context of the research, the goal, and how their data was collected, stored, analysed and used within the research. This has all been stated in the data management plan. Furthermore, each participant has been sent a consent form, which was signed before the interview took place. At the start of each interview, any ambiguities or uncertainties were discussed. The collected data is stored securely and ethically. The interviews were conducted via Microsoft Teams. The recordings and transcripts of the interviews were saved on TU Delft's OneDrive, under the authority of the researcher and the first and second supervisors. After the research is finalised, interview recordings will be deleted immediately, the transcripts will be stored for a maximum duration of two years. The data management plan and informed consent form were approved by TU Delft's HREC committee on 09-09-2024.

6 Data collection and analysis

Within this paragraph, the qualitative content analysis practices are discussed in more detail. The qualitative analysis methodology has already been elaborated in section 5.3. This section delves deeper into the deductive and inductive coding techniques that have been applied. Also, the analysis techniques to extract results are discussed. Furthermore, an assessment of the validity of the results is made.

6.1 Qualitative coding analysis

This section elaborates on the coding and analysis process of the interviews, which is done deductively and inductively. The coding process is executed to ensure a comprehensive foundation for the analysis results.

6.1.1 Deductive coding and analysis

The deductive content analysis is done following the prescribed process of P. A. Mayring (2023), which elaborates on five sequential steps to ensure rigour and trustworthiness via a systematised approach allowing for traceability and verification of the analysis. This process is shown in figure 10. The full deductive codebook including themes, and groups of codes regarding the same phenomena, is given in appendix D. The sequential steps involved in the process are elaborated below.

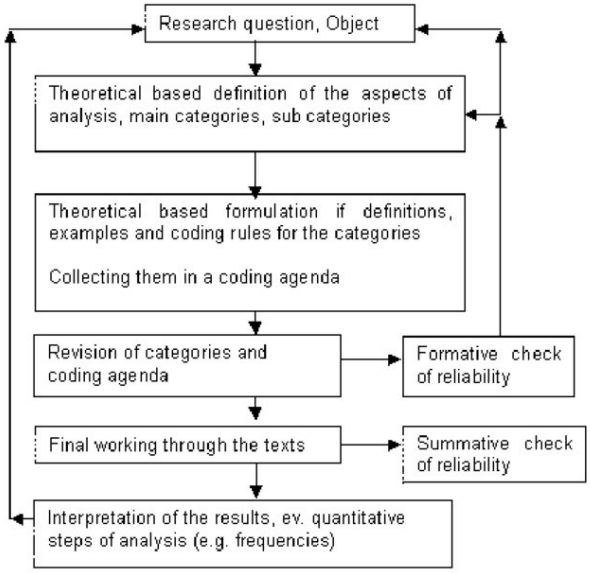


Figure 10: Step model of deductive category application (P. Mayring, 2000)

1. **Preparation phase: familiarization with the data**. Initial engagement with the data involved conducting the interviews, developing the transcriptions and familiarization by reading the transcriptions several times. This step ensured the data was well understood before the actual coding started.
2. **Generating initial themes and codes**. A predefined codebook was created based on the existing literature and research questions. To ensure clarity and consistency in understanding the codes and themes, the codebook was reviewed and discussed with others. Its development followed a thorough familiarization with the data. Within the first coding round, codes were applied deductively, while focusing on the predetermined themes. The data segments that corresponded to the codes were systematically categorized,

using Atlas.ti. Beneath, an overview of the initial list of themes is given, which indicates the sub-question to which the theme belongs.

Sub-question	Corresponding deductive theme(s)
Influence lean startup methodology on technology-based hardware startups (SQ1)	1. Validated learning 2. Lean startup methodology
Influence of obligated regulatory and industry standards compliance on hardware tech startups (SQ2)	1. Regulatory compliance 2. Industry standards compliance
The influence of startups knowledge and expertise on regulations and industry standards (SQ3)	3. Knowledge on compliance
Impact of regulatory and industry compliance on hypothesis-driven entrepreneurship (SQ4)	4. Steps on compliance 5. Missteps on compliance
Interference moments by startups on compliance during development process (SQ5)	3. Timing compliance

Table 6: Deductive themes derived from theoretical framework and literature

3. **Pilot coding**: The first three out of the eleven interviews have been used as a pilot- or test-run. These were used as a formative check to asses whether the predefined codes and themes were stated correctly. Some codes were redundant and others were added. After the first three transcripts were coded, the following changes were made to the codebook, see figure 11

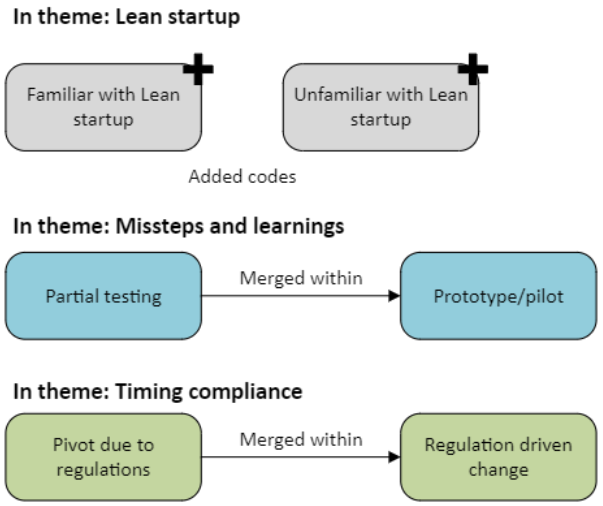


Figure 11: Added and merged codes during coding process

The changes were made to ensure clarity and suitability for the overall data. After the changes were made, the first round of coding was continued for the other remaining interview transcription.

4. **Systematic coding in the remaining dataset** The coding process is continued to finalize the first round of coding. After this completed round, the full dataset is re-coded completely in a second round, to ensure all insights are gathered. To finalise the coding process, a summative check is done to ensure consistency and check if all codes align with the original framework and research questions.
5. **Summarizing and interpreting** After the coding process was finalized, the data was summarized. To accurately interpret the relationships between different concepts, four analysis methods were employed: interview comparison, descriptive analysis, timeline comparison, and co-occurrence analysis. These methods are elaborated on in section 6.2.

6.1.2 Inductive coding analysis

While the deductive framework was informed by a pre-defined list of codes and themes derived from the theoretical framework, the data revealed additional relationships and insights that were not initially anticipated. These emerging insights were identified and categorized through an inductive coding process. This process took place during the first coding round.

The inductive codes provided new perspectives, revealing relationships and substantiations that the predefined codes could not fully capture. Once identified, these inductive codes were reviewed and compared against the deductive framework to ensure cohesion between new and pre-established themes. This process resulted in the integration of inductive codes into existing themes. Furthermore, the analysis led to the emergence of a new theme, not anticipated in the initial deductive structure, but directly driven by the inductive insights. This theme is named "Startup Roadmap". A full overview of these inductively emerged codes, and their integration into the deductive framework is presented in Appendix E.

6.2 Analysis

The identification of themes within the qualitative content analysis enables a framework that is suited for analysis. Furthermore, during each interview, participants were given a timeline of moments they interfered with regulatory and industry standards compliance during the development of their product and company. This synthesised timeline is based on existing literature, as discussed in section 2.2. The themes, timelines, and underlying quotes are analysed via the multiple techniques discussed below.

- **Interview comparison**
  A comparative analysis of the interviews was conducted, focusing on participant demographics such as company size, company age, industry, and perceived level of compliance strictness. In addition, participants' knowledge and engagement with the lean startup methodology were assessed using a scale. This scale highlighted differences in how participants described the impact of regulatory compliance on their development processes, such as how early they engaged with or gathered knowledge about regulations. The analysis also examined whether participants sought external consultants for help, designated specific personnel for compliance tasks, or experienced active delays due to compliance requirements. These factors were evaluated to identify patterns across industries, knowledge or experience levels, and other similarities among the entrepreneurs.
- **Descriptive analysis**
  The descriptive analysis provides insights into the key elements: Validated learning and Lean startup, regulatory and industry standards compliance, the knowledge of compliance, the process of compliance, Timing of compliance, and the Startup roadmap. During this phase, the most insightful and unique quotes from participants were identified and stated. This allows for a good understanding of how the participants experienced the themes, and how they impacted their development processes. This gives the researcher the possibility to learn and derive insights from the participants' knowledge and experiences.
- **Timeline comparison**
  Each participant was assigned a timeline synthesis, based on established literature discussed in section 2.2, to map out the ideal steps they would take in addressing regulatory and industry standards while developing their technology. Participants were asked how they integrated these challenges alongside bringing a product or service to market. The timelines were categorized by industry and then compared, revealing industry-specific differences in regulatory and standardization practices.
- **Relational analysis**
  Using the coding and co-occurrence tools in ATLAS.ti, the interview comparisons were further examined to uncover relationships between individual codes and themes. The

analysis is first focussed on the co-occurrences explaining the research sub-questions, stated in chapter 1. The relational analysis helped to identify the strength relations between codes. Such as, how the market requiring additional industry certifications, is an incentive for startups to comply with certification. Furthermore, the co-occurrence helps to uncover relations between codes or themes, not anticipated at the forefront of this research.

6.3 Results validation

The theoretical framework was derived and validated by the insights and empirical findings in the academic literature. In addition, the results from the qualitative content analysis have been validated in several ways. First, the company supervisor and first supervisor of this thesis, peer-reviewed the interview guidelines, delivering feedback, based on their knowledge and experience. All steps taken during the qualitative content analysis, including the sampling strategy, data collection procedure, coding procedure, and analysis, ensure the traceability and justification of decisions made. Furthermore, the results of this study were presented to a senior startup investment manager and a consultant from a regulatory body. This was done to consider their incentives for this research and to validate whether they recognised the findings.

Additionally, a reflection on the results of the theoretical framework was included in the discussion section to validate the consistency of the findings. Finally, the author examines his own influence on the research and presents the limitations of the study.

7 Results

Chapter 7 presents the results found in the qualitative content analysis. The chapter starts with a comparison of the conducted interviews. Thereafter follows a discussion on the deductively emerged themes. Different perspectives and incentives per theme are given and discussed. After that, the chapter represents the results from the inductively emerged codes and themes. Also, the timeline indications on steps taken to achieve compliance are challenged. Finally, the relational analysis results are discussed. As mentioned in section 5.3.1. The interviews were conducted in either English or Dutch. Quotes from Dutch interviews have been translated into English.

7.1 Interview comparison

During the qualitative data collection, twelve startups were interviewed. All participants shared their knowledge and experience. This analysis examined the similarities and differences between participants, focusing on factors such as industry, size, and length of existence. In addition, it was assessed whether participants were familiar with the lean startup method and whether they actively applied it during their development. In addition, participants were asked how they perceived the regulatory strictness within their market and industry. This refers back to the levels of legal and voluntary compliance, explored in chapter 4. Participants were asked how they perceived the regulatory strictness in their market, instead of the assessment provided by the researcher.

With this comparison, similarities between participants can be found, which gives the ability to discover underlying relationships. Following the first topic, the overall impact of complying with regulations and industry standards. The following themes were evaluated:

- **Impact of compliance in overall development:** This theme seeks to evaluate the overall impact of regulations and standards compliance on the process of bringing the product to market. Some indicated this as extremely impactful during development, others didn't.
- **Limited in pilot testing:** This theme evaluates whether startups were hindered in conducting pilot tests due to non-compliance with mandatory regulations or industry standards.
- **Delays due to compliance:** This theme evaluates if a startup got a direct delay within their way-to-market, due to compliance efforts acquiring longer time than initially planned.
- **Experienced oversight:** Participants who experienced oversights in the context of compliance with regulations and/or industry standards, during the process of bringing their product to market.

Within the second section, the way startups developed an understanding of, and how they then approach compliance, is compared. The following themes have been compared:

- **Prior knowledge of regulations and standards:** The first theme evaluates if participants indicated if they, or others within their organisation, already had prior knowledge or experience with regulatory and standards compliance within their market.
- **Use of external consultant for advise:** Several participants indicated the use of consultants to get advice on regulation and standards compliance, while others did not.
- **Had others perform compliance efforts:** Besides asking for advice, some participants indicated they would ask external (freelancers) to perform compliance efforts.
- **Dedicated internal person or team:** This last theme evaluates if participants discussed if they actively dedicated internal employees to figure out all the requirements and perform the compliance process.

Furthermore, all participants were asked to provide advice for future entrepreneurs, based on their experiences and knowledge. The recurring key themes in these pieces of advice have also been compared:

- **Create early awareness on applicable standards:** This scale indicates whether participants advised other startups to gain awareness about existing regulations and standards within their market, as early as possible.
- **Get a thorough understanding of requirements:** This second theme indicates if the advice also included that the compliance requirements should be clarified early on.
- **Perform all compliance efforts internally:** The following theme compares if the participants advised on the importance of performing all efforts in ensuring compliance with regulatory and standards internally.
- **Embed compliance process into the startup roadmap:** This last theme indicates whether participants advised actively integrating the compliance process and effort needed in the startup roadmap.

To validate the reasons why the respective colour scales were assigned, an overview is provided in appendix H, which includes quotes from the individual interviews. These quotes explain why the colour scale was allocated. In figure 12, the results of this analysis are shown. Thereafter, the results have been analysed. The insights should be interpreted as exploratory, shedding light on individual experiences and knowledge.

Participants	1	2	3	4	5	6	7	8	9	10	11	12
Interview job role	CEO and Founder	COO	CEO and Founder	CEO and Founder	COO and Founder	CEO and Founder	CEO and Founder	CEO and Founder	CGO	CFO and Founder	COO	Former founder and angel investor
Industry	Engineering	MedTech	Engineering	Advanced Technology	Automotive	Automotive	HealthTech	MedTech	Computing	MedTech	Engineering	Engineering
Participants perceived their market as strictly regulated	No	Yes	No	No	Yes	No	Yes	Yes	Yes	Yes	No	No
Current size of company	10 - 50	1 - 10	1 - 10	10 - 50	1 - 10	1 - 10	1 - 10	1 - 10	10 - 50	10 - 50	10 - 50	201-500
Year of founding	2020	2020	2022	2014	2019	2015	2019	2022	2014	2020	2020	2007
Familiarity with lean startup scale: 1 = Very unfamiliar, 5 = Very familiar	5	3	1	5	5	5	4	5	4	4	5	2
Actively used lean method scale: 1 = Not at all, 5 = Very often	4	3	2	4	3	5	4	4	3	3	5	2
1. Attitude towards compliance												
Impact of compliance in overall development												
Limited in pilot testing												
Delays due to compliance												
Experienced oversights												
2. Developing an understanding and their approach to compliance												
Prior knowledge of regulations and standards within the startup												
Used an external consultant for regulatory and standards advice												
Had others perform their compliancy efforts												
Internal person or team dedicated to compliance												
3. Advise given by participants towards other hardware tech. Startups												
Create early awareness on regulatory and standards applicable to the market to be targeted												
Get thorough understanding on requirements as early as possible												
Outsource regulatory efforts to consultants												
Perform compliance efforts internally												
Proactively embed compliance process into the startup's roadmap												

1. Colour scale attitude towards compliance	
High influence	
Moderate influence	
Lowinfluence	
Not discussed in interview	

. Colour sc. understanding and approach compliance	
Very applicable	
Applicable	
Not applicable	
Not discussed in interview	

3. Colour sc. advise given to others	
Highly recommended	
Recommended	
Not recommended	
Not discussed in interview	

Figure 12: Results interview comparison

Theme one, the impact of compliance on development, participants 2, 5, 6, 7, 8, and 10, all operating in the automotive and life science industries, perceived their market as strictly regulated, which affected their development processes. This pattern suggests that industries with higher regulatory scrutiny, face significant challenges in aligning their product development with strict regulatory requirements and compliance processes. Furthermore, almost all of these participants indicated that they could not conduct pilot tests as much as desired and experienced compliance oversights, meaning that they were unable to fully understand the impact and resources the compliance process would have on their development. This also regularly resulted in delays in development.

The second theme explored participants' prior knowledge of regulations and industry standards, assessing whether their startups had a baseline understanding of necessary compliance requirements. The findings reveal a varied level of prior knowledge. Notably, participants who reported little to no understanding of regulations and standards also noted that they experienced compliance oversights and delays during their development processes. This suggests that a lack of prior knowledge can lead to oversights and delays in development. Furthermore, participants receiving their industries as strictly regulated all indicated to seek external expertise, such as consultants, to navigate the regulatory and standards compliance. Indicating that in more regulated industries, it is common to seek outside help due to the complexity of regulations.

The third and final theme addresses the advice provided by participants to fellow entrepreneurs. Across various industries, it is consistently recommended to develop an early awareness of regulatory requirements and standards as a strategic priority. This collective agreement underscores the need to understand the regulatory environment specific to the market in which a startup operates. This is particularly emphasized in sectors such as MedTech and HealthTech, where it is advised to clearly define and understand all regulatory and compliance requirements at the beginning. Furthermore, integrating compliance efforts and accounting for the time required to meet these obligations within the startup roadmap is strongly advised, especially by participants operating in strictly regulated industries. While some participants in less regulated markets noted that a basic understanding of compliance is beneficial, they did not consider it a top priority.

Overall, Startups within industries which are strictly regulated, tend to have more internal dedication and external consulting needs, to comply with regulations and standards. Less regulated industries may not experience compliance as such a major hurdle.

7.2 Descriptive analysis

As earlier discussed in chapter 6.1 Qualitative content analysis, the themes were directly distracted from the sub-questions discussed in the theoretical framework, chapter 3. This theoretical framework is in turn derived from the existing literature. The themes have underlying codes which are related to one another. A complete overview of all themes and codes that have been drafted for deductive qualitative analysis are attached in appendix D. Furthermore, inductive codes emerged, which have been allocated to existing themes, and even a new theme emerged. The entire inductive codebook can be found in Appendix E. Within this descriptive analysis, all deductively derived themes, as well as the inductively emerged themes have been analysed.

7.2.1 Validated learning

The theme of validated learning, as highlighted in the literature on lean and agile development methods, see Section 2.1.1, centres on the continuous process of testing assumptions through data-driven feedback and iterative product development i.e. hypothesis-driven development. This theme is crucial in understanding how entrepreneurs employ validated learning during various stages of product and business development. Iterative learning is distinguished by business hypotheses, technical hypotheses, and customer feedback. These distinctions guide how startups test their hypotheses to gain insights into their technology, products, or business goals. Several interesting quotes on hypothesis testing are given to understand real-life practices of the methodology.

"What we did at the beginning was essentially a product we had still held together with tape, something you're actually ashamed of. It is enough to test and it generates revenue, but also a lot of hassle. You do learn an awful lot from it." [Participant 6]

"But yes, we're always busy with the question: what are we going to develop? Not what do we want to develop, but what does the market want?" [Participant 6]

"Also, that it is desirable, that people actually want to buy and own it. Feasibility, viability, and desirability are like a diagram. Where it's feasible, viable, and desirable, that's where you have your proof of concept. Proof of concept means proof that it's feasible, proof that it's viable, and also proof that it's desired." [Participant 8]

"It also turned out that the technology works. Now it's very much about industrializing it and then commercializing it." [Participant 3]

"When a customer starts speaking negatively about you. In our case, there are many things to improve, a lot of things to improve, and sometimes they are things that people find very strange that we never tested. But yes, we didn't have time for that, or they lacked the knowledge, so the products are just good enough in terms of quality and what they can do for the customer to really start working with the technology." [Participant 4]

"In the beginning, you find it hard to make choices about these kinds of things. You also believe in your product. You want to go as broad as possible into the market, you don't want to make a decision yet, and you haven't received any feedback. That's the real challenge. You have a new technology, and a new market, and you need to make a directional choice as quickly as possible. Making this decision would benefit you greatly, but in practice, it's very difficult." [Participant 9]

The participants indicated that they all in some way, used validated learning techniques to see if their business ideas and products are working in the market. The differences in how the practice has been applied in these methodologies differ per participant and have been in-depth discussed in section 7.1. Participants expressed validated learning as a suitable way to develop everything needed to bring their product or service to market. The practices ensure that assumptions and expectations made, are either validated or rejected based on real-time feedback. In addition, the data revealed that some participants also acknowledged the limitations. Development cycles are complex and take a long time. Therefore continued iteration and validated learning were limited, due to reduced market interaction.

7.2.2 Lean startup methodology

The earlier validated learning practices are part of the lean Startup methodology, as discussed in section 2.1.2. This methodology has been incorporated as a central theme within the deductive analysis, reflecting a systematic approach that enables startups to efficiently develop products through validated learning and continuous iteration. The underlying codes highlight various aspects of this methodology, such as participants' familiarity with Lean Startup principles, the progress monitored by the startup, resource limitations they encounter, and their strategies for reaching the market. The methodology is seen as a separate theme due to the overall effect of this methodology that is captured within this theme. In contrast, the previous theme 'validated learning' specifically focused on how the hypothesis-driven practices were implemented.

One of the research sub-questions specifically focuses on how startups implement validated learning practices outlined in the lean Startup method. While the previous section 7.2.1, examined the application of these practices by startups, this theme is aimed to delineate the implications of employing these methodologies for the startups themselves. Employing validated learning practices allows startups to adapt quickly to market feedback, minimizing the risk of failure by ensuring that their product development aligns closely with customer needs. It is important to understand how participants used this, and how this influenced their way-to-market. Quotations

from participants regarding their progress and way-to-market further explain their perceptions:

> ”Perhaps naturally. It’s not that we clearly set specific goals beforehand and then tracked how far we were from those goals. You don’t really know what goals to set, especially not at the beginning.” [Participant 7]
>
> ”So yes, we have been keeping track of traction, but you never really know what you can compare it to or how good it really is. What you’re doing is, of course, new” [Participant 7]
>
> ”You try to accomplish the minimum amount of work as quickly as possible to bring your product to market.” [Participant 5]
>
> ”This is also the challenge with the Lean Startup method: how do you determine the point at which you stop? This makes it difficult to measure progress. This may well be the biggest point of criticism and the reason many hardware projects tend to falter.” [Participant 8]
>
> ”This relates to your route to market, as well as time to market. It also fundamentally pertains to your cash h position. Therefore, you need to consider all these factors. These aspects must be aligned; if you know that the certification process takes 1.5 years, then you should also focus your marketing efforts accordingly to ensure you are prepared.” [Participant 3]
>
> ”I think that if you want to do it properly, you need various frameworks, spreadsheets, and tools. [Name of a colleague] was not around at that time, so it all went smoothly in my head.” [Participant 1]

A recurring theme was the uncertainty inherent in setting specific goals early in the process. As one participant noted, ”Perhaps naturally. It’s not that we clearly set specific goals beforehand and then tracked how far we were from those goals. You don’t really know what goals to set, especially not at the beginning.” This sentiment reflects the flexibility of startups that prioritize speed over concrete long-term planning during the initial stages, resulting from the uncertainty on practically everything in the beginning.

In practice, many startups emphasized the importance of rapid development. One participant described their approach: ”You try to accomplish the minimum amount of work as quickly as possible to bring your product to market.” This strategy aligns with the principles of the Lean Startup method, where minimizing waste and achieving market feedback as early as possible are critical to iterating efficiently and avoiding resource drain.

However, participants also expressed challenges with this approach, particularly in hardware development. One common issue raised was the difficulty in aligning various operational aspects, such as certification timelines, development times, and cash flow management. The participants themselves indicated the difficulties of validated learning in hardware development, also discussed in the literature that was reviewed in section 2.1.2. Participants indicated the difficulties of hardware development and how they were hindered by iterative development. Some interesting quotes made about the challenges are listed beneath:

"Especially in this world, particularly with hardware, it costs an incredible amount of money. Startups often have to rely mainly on subsidies and equity. Well, it just takes time; salaries need to be paid, and you also have to invest in your components, and so on. A lot of money goes through it relatively quickly." [Participant 2]

"The difficult thing is, we are really struggling with it now. Struggling to figure it out. We already know that we want to change and improve various things about that product, and if we get it certified externally now if we change a single bolt, do we need to get it certified again?" [Participant 4]

"You will always have to do simulations. Either with mock environments, animal testing or by building an investigational medical device dossier and testing prototypes in humans. That still leaves some residual uncertainty, because the ultimate certainty comes from people buying your product." [Participant 8]

"Lean is more for software." [Participant 9]

"They actually only use a hybrid form of Lean or Agile. We do the same." [Participant 9]

"So you spend a few years developing, and then you have to bring it to market. Yeah, that's not possible. You can't just throw a kind of prototype into the market, because that doesn't work. So, a lean startup... in biotech and healthcare, you can't really start Lean." [Participant 10]

"As quickly as possible, because everything you do later, you have to fix afterwards. Especially in hardware, it is just very difficult to fix once it is there." [Participant 12]

7.2.3 Regulatory compliance

The theme of regulatory compliance explains the concept of legal legislation that imposes regulations for technology, and products or services in specific markets. Legislation, as discussed in 4, can be made on several levels and impose regulations for general technology, or specifically for products. Legislation is established to ensure safety, reliability, and security. All participants discussed the specific legal regulations to which their product or service must adhere. Furthermore, some explained how different markets require different legal compliance. Furthermore, similar markets in other regions can also result in changing legal requirements. To begin with, startups are required to understand these different requirements per market. Thereafter they have to decide how to act on this and what the best strategy would be.

This specific theme is employed to reveal these different legal requirements per market, and how the impact this has on the startups. Some interesting quotations within this theme are as follows:

"You are not allowed to simply sell a product in the European Union that runs on batteries or is electrically powered, whether it has a plug or runs on batteries. Anything that uses electricity cannot be sold without CE certification" [Participant 1]

"For the hardware, only CE marking is required in principle. If we enter another market, such as the United States, UL certification becomes mandatory. Additionally, the company is subject to other legal obligations, but these are in the form of Terms and Conditions." [Participant 11]

"Especially costs versus opportunity. For example, we have sometimes made the decision not to supply to America for a long time, saying no to projects. This was because the UL certification process was so complex." [Participant 9]

"Yes, I would say that for us, the regulatory process and the QMS report are so important. You simply cannot enter the market without them" [Participant 10]

"Yes, you are only allowed to commercialize once you have both CE and FDA approval. So, that's at the time of introduction." [Participant 10]

"So one, your customer finds many things important, especially if you have large customers, such as [Name of Multinational]. Something that is not a go or no go, but ultimately it is important, not if you are a startup, but in the adult world. It starts with CE certification and ISO9001 certificate, so a quality management system." [Participant 12]

Participants indicate that regulatory compliance can be complex, time-consuming, costly and most likely difficult to understand. Furthermore, they withhold startups from targeting specific markets or scaling up internationally. The data revealed that each startup at least has to adhere to some legal regulations to sell their products in markets. However, the level of impact of compliance differed significantly between the participants. Especially, participants that indicated they have to adhere to medical regulations such as MDR, had to highly prioritize compliance and needed to dedicate significant resources to it. Others had less extensive and impactful compliance processes, changing the level of priority that has been given to legal compliance. In addition, the data revealed that within medical-, and healthtech, compliance is an absolute must and certification must be in place before any product introduction to the market. Other markets, which for example only required CE certification, are considered more accessible, since a form of self-certification is permissible.

7.2.4 Industry standards compliance

Industry standards are a distinct phenomenon, they are not obligated to comply with; but are seen as necessary to enter a market. The theme industry standards capture the phenomenon of meeting industry-specific standards to ensure the product or service is compliant with certain quality or safety thresholds. Underneath this theme, codes on specific explanations of industry standards and reasons to comply with standards are listed. Furthermore, the code 'Industry networks' focuses on how participants learned from other startups or others in the same industry.

"At the start, we thought, why should we even do this? But later we were very happy with it because it standardized many things and also forced us to maintain order during growth. Engaging with ISO may feel like it slows your growth, and it does. But it ensures that everything is well-organized, which helps when you grow later on. It is better to do it early on." [Participant 6]

"This has more to do with market demand than our own intention. We encountered a customer who said, 'I believe in your technology, but I want to use it preventively, (...) I can't explain to my boss if a crane collapses, that I bought this from a group of students from Delft.'" [Participant 1]

"This is about DNV certification; it is not required by law but purely to gain more credibility. This heavily depends on your business. In the heavy industrial B2B sector, people like stamps and checkmarks. Also, certifications like ISO9001 and ISO27001 for cybersecurity help. You are not required to have them, but it makes it easier for a customer to buy from you." [Participant 1]

"There aren't always standards or regulations for what you are developing. We experienced that as well. You have to choose which available standards to use." [Participant 9]

"Our consideration for hardware is that if something goes wrong, there is almost no way back. If you're one of the first and it goes wrong, that technology will likely get no chance in the business-to-business sector. So you must aim for high standards compliance. We wanted to make that a key point." [Participant 9]

"If you have an opportunity in Japan and change your entire approach to make your technology earthquake-proof, you are probably already too late if you are only thinking about it at that point. You can't just turn back, and you may find yourself on a project that you cannot handle because you don't meet compliance. So you invest in it, but in doing so, you miss out on other opportunities." [Participant 9]

"Especially as a startup, you're already dealing with it, often competing with the established players. That takes quite a lot of effort to filter out what is really a credible industry standard, and what is just a stick to beat you with." [Participant 9]

The data reveals that industry standards can play a critical role as a barrier to market entry, sometimes even drafted by concurrent companies to establish competitive advantages, following the participant's experiences. While not legally obligatory, these standards can be perceived as essential for gaining market access, and failure to meet them can hinder a startup's growth. The data showed that compliance with these standards can be financially challenging. Also, the vague nature and amount of standards complicates the decision-making process, regarding which regulations to adhere to. Insights from the analysis indicate that startups often learn from their peers in the industry, emphasizing the importance of industry networks. Also, they actively engage with consultants or attract people with experience to their team, to gather a more thoughtful understanding. Participant reflections underscore a common sentiment: although engaging with standards such as ISO may initially seem to slow growth, it ultimately standardizes processes and fosters the maturity of the startup. This approach not only meets customer expectations but also enhances credibility in the market.

Overall the findings highlight the challenges of navigating all existing standards, and the ambiguity or vagueness of the standards, while simultaneously leveraging them as a strategic opportunity to establish trust and provide business value for customers.

7.2.5 Knowledge on compliance

For startups to address regulatory compliance and industry standards, they must possess prior knowledge or actively gather an understanding of the purpose, requirements, and implications of

compliance. This includes evaluating what compliance means for the organization, the time and resources it will consume, and how it integrates with other business priorities. Acquiring this understanding can be challenging, as startups often prioritize developing their core technology and products, interacting with customers, and building their business infrastructure. As a result, compliance is frequently overlooked in the early stages. However, failing to comply with industry standards or legal regulations can incur substantial costs, both financially and in terms of delayed growth. This theme captures the diverse ways in which startups become aware of legal requirements and industry standards, the steps they take to achieve compliance, and the associated costs.

This theme offers essential insights into how startups navigate the process of identifying relevant regulations and industry standards. Key findings shared by participants are highlighted in the quotations section below.

"Again, that's one of the thirty problems you can think of, but it's very low on your priority list. Certification is not really something you think about in the beginning, at least not in our market. Look, if you're making a MedTech device, it's probably a different story." [Participant 1]

"Honestly, if we had known how difficult the compliance process would be, we probably wouldn't have done it. We weren't aware of how long this process would take." [Participant 5]

"Well, I have a background in this industry, so I know that a lot of regulations apply. That doesn't mean I know exactly which regulations are applicable, but I know there are a lot of them, and that means I ensure we bring people into our development processes who take that into account." [Participant 3]

"But we make sure that we bring that knowledge in-house, so that we don't end up developing something and then saying, 'it works, but we're not allowed to use it." [Participant 3]

"So, we didn't have to bring this expertise in-house. At least, by hiring our CTO with experience, we didn't have to engage a consultancy firm. The only thing we did, was to have a consultant from (Notified body company) look at our products. Just to get a sense of where we stand, how far we are, what we still expect, and how much time we need. That was the external input, which was also very valuable." [Participant 2]

"It is really hard for an engineer starting a startup, or a doctor starting a startup, to do the work needed for compliance, because you have not done it many times before." [Participant 8]

"It was so complex with the UL certification. It simply wasn't feasible. Just the research alone took so many resources away from development. That's why we had to decide not to do it." [Participant 9]

"At that time, we spoke to a lot of other companies via YesDelft (Startup incubator), companies that were already a bit further along. They helped guide us on which consultants we needed, what kind of quality management system we should purchase, things like what kind of certification we actually need." [Participant 10]

"We thought, oh, we can just bring something like this to the market very quickly. But yeah, that's not possible at all. So then, we built the entire QMS to comply with the standard. I think around 250,000 euros went into setting up the whole QMS" [Participant 10]
"Look, what we are also seeing, this has to do with AI and everything related to the internet, and it is also entering the quality domain. Legislation is really extremely behind on AI. It's impossible." [Participant 10]

The data revealed startups often face significant challenges when it comes to understanding and complying with regulatory and industry standards compliance. Most participants in this study highlighted the complexities of identifying the correct regulations for their products and the significant costs involved in obtaining certification. The data revealed that startups are often unaware of the resources, such as time, costs, and external consulting, required to navigate compliance processes. Participants stressed the importance of acquiring both internal and external knowledge to navigate these challenges. External knowledge is gathered via consultants or notified bodies, that can provide a clearer explanation of the requirements. Several participants explicitly stated that they hired knowledge in-house by hiring a specialist, to avoid the need for ongoing consultancy costs.

The participants also underscored the financial and time burden compliance can impose on startups. Participant 6 shared that obtaining a basic CE certification for a product can cost between €10,000 and €15,000, while Participant 7 explained that a more structured process like MDR 2A compliance could reach up to €250,000. These costs, coupled with the time required for compliance, present significant challenges for startups, which should be beneficial to be known upfront. Participant 2 described the delays they faced when seeking certification: "Initially, it was estimated to take 8 to 10 weeks from testing to certification. In the end, it took 7 months." This delay essentially halted their operations for seven months.

Overall, the findings demonstrate that while regulatory compliance is often not highly prioritized in startups, it becomes a crucial factor in ensuring long-term success. Failure to comply can lead to costly delays, while proactive engagement with industry standards can provide startups with added business value. These results show that it could be beneficial for startups to prioritize compliance early on, to avoid delays and costly processes.

7.2.6 Steps on compliance

Gathering knowledge and understanding about regulatory and industry compliance can be seen as the first step of interference. However, to be eventually completely certified, startups have to take sequential steps. These steps potentially affect other processes such as technology or product development, since compliance imposes iterative design processes to stop. The theme 'Steps on compliance' captures the steps taken by a startup to become fully compliant. These steps include initial awareness, an in-depth understanding of, actively working on and implementing requirements, the time of being compliant, and the moment certification is acquired.

This theme also touches upon how startups decide on regulatory and standards compliances. What goes into making decisions on why and when to comply? Several participants even noted that it was steps were driven out of an necessity, while others saw compliance as a strategic decision. The most insightful quotations within this theme are mentioned hereafter.

"We actually quickly built a quality team and a regulatory team, internally. After we had all the templates, we hired dedicated people. Also, that consultant, he contributed for a while, but at some point, he was better off pointing out someone who could take over full-time." [Participant 10]

"We had that too. Then you have to make choices about which available standards you are going to use. We noticed that different stakeholders ask about this early on. Potential investors, you're already pitching your story early, and then those kinds of questions come up. You need to have a clear idea early on; What should it be? When are you compliant? When your design technically meets requirements, or when you are certified?" [Participant 9]

"A basic medical certification. You can obtain that. Okay, so they went back, raised money, and then returned to that party, saying, 'Okay, now we're going to start.' But yeah, the audit of your entire quality control process, that happens in 3 days, but building your whole quality control process to meet that certification takes almost a year. That's what I mean, you shouldn't think you're done in 3 days. You really need to understand what goes into it." [Participant 4]

"We then made some choices about what we would really keep as it is and whether there are still things we need to adjust. We considered that at the time. Then we sent the sensor with the note that maybe there's a sensor somewhere with a different component. If that's on a small level somewhere else, it doesn't make much difference." [Participant 1]

"Part of those user requirements are, for example, regulations. You try to include that as broadly as possible. But that's not always feasible. It's also impossible to map out everything in advance, especially if you're operating globally" [Participant 9]

"We have reached a certain scale that we can continue to rely on for a few more years. So I think for the next three years, two years, we won't make a new version of the product. Therefore, it makes sense to apply for CE certification." [Participant 7]

The findings within this theme reveal that the process for compliance involves a set of critical steps that are both strategic and necessary-driven. The data shows that once startups recognize the importance of compliance, they dedicate resources to building internal teams to approach the process. This reflects again the specific expertise needed to get compliance. Furthermore, the data shows startup investors also require startups to have an understanding of the process and what resources it will cost them.

The complexity of the whole process is emphasized by Participant 4, who highlights that even though the final certification audit may only take a few days, the preparation and establishment of a compliant quality control system is a time-intensive task that can span nearly a year. This underscores the need for startups to concisely decide on what to comply with, and when.

Furthermore, the data revealed that there are two significant challenges imposed due to compliance. First of all the requirements for compliance; after understanding which requirements to meet, they must be implemented into the product or service. Secondly, the moment that a notified body is approached to get final compliance and therefore certification, means that the design is set. These constraints limit the further development of the product. The iterative learning principles following the lean startup method are hindered by these imposed restrictions However, Participant 1's reflection on minor adjustments to components indicates that compliance can be flexible on small details, but the broader standards must still be met. This emphasizes that while startups may need to adapt their designs, the overall regulatory framework cannot be overlooked.

7.2.7 Missteps and learnings

Somewhat relational to the previous theme, the 'Missteps and learnings' theme covers all instances where startups missed regulations or industry standards, and had to take actions to rectify mistakes. Most participants experienced missteps along the way, resulting in delays, restrictions, or unforeseen setbacks. The theme explores instances where participants took missteps and the actions they had to take to address these oversights. This is especially useful in understanding the impact, or the missteps had on the other processes that take place in these emerging companies. The theme highlighted the moments where startups focussed on the validation of their technology and business, either overlooked or underestimated the importance of compliance.

The codes under this theme reflect the broader impact of these missteps. The code 'Compliance oversight' captures the missed regulations, while 'cause correction' details the corrective actions taken to rectify these mistakes. Additionally, the theme sheds light on how iteration restrictions and delays due to compliance limited startups' ability to iterate their products freely and slowed their time-to-market. The code prototypes and pilots focussed on the compromises made when full testing wasn't feasible due to compliance barriers. Most insightful quotes made by participants are mentioned below.

"Yes, so you have a two-year delay, due to compliance oversight, in delivering to manufacturers (B2B) sales. What is now about 70% of our revenue, so yes. It has cost money" [Participant 5]

"Well, we actually try to have the certification ready by the launch, but usually, as I said, it comes a few months later, and officially every iteration you make to your product requires re-certification. I must confess that we don't do that." [Participant 5]

"No, we are really looking for pilots where we say, listen, we are still in a testing phase, so there is no certification yet. We really need to find pilots with parties that say, well okay, go ahead and test it, we find it interesting enough to test, but we will do it in a relatively low-risk environment." [Participant 3]

"Yes, when you have a relatively advanced product, it still has some impact. You actually have to go back; you need to redesign certain parts. That costs a lot of time, and it also costs a lot of money. You are actually going a few months back in time to adjust a choice you made at the beginning to ultimately get that certification." [Participant 2]

"It's very important because it makes no sense if you are building a product, iterating on it, and you want to adhere to the rules while at the same time selling, redesigning every six months, and then spending 30,000 euros every six months." [Participant 1]

"The Lean Startup approach assumes that you will go to the market with an initial shot. You will see how the market reacts, and then you will adapt. You will adjust the product. This doesn't quite work in Medical devices, as the regulators do not allow you to go to the market with an unsafe or ineffective product." [Participant 8]

"That is also a common mistake. I speak to many other startups as well. I spoke to one yesterday, a Swedish party, who are on the software side. They said, what we have also seen is that you are so focused on your technology roadmap that you forget about the other two: compliance and funding." [Participant 9]

"So you are definitely busy developing for a few years, and then you have to bring it to market. Yes, that doesn't work. You can't just throw a sort of prototype onto the market because that doesn't work, so a lean startup approach, yes, in biotech and healthcare, you can't really start lean." [Participant 10]

Analysing this theme revealed that navigating regulations and standards is complex, and almost all participants experienced challenges in doing this. As highlighted, many startups encountered significant compliance oversights that necessitated corrective actions, thereby underlining the importance of regulatory awareness in the startup environment.

Furthermore, the mentioned cause corrections illustrate the measures taken by startups to address these compliance mistakes. Participants described the extensive time and resources required to rectify mistakes, often leading to iterative design processes that halted product development. This was particularly evident in scenarios where redesigning products for certification delayed market entry. This is especially crucial since the lean startup method prescribes the most efficient way to market.

The results also point to how iteration restrictions create bottlenecks in the product development lifecycle. Participants mentioned that the necessity for compliance often conflicted with their ability to pivot or iterate on their Minimum Viable Products (MVPs), as certification processes were lengthy and unpredictable. Furthermore, the processes were costly, so startups couldn't further iterate after application for compliance, because they wouldn't want to spend the costs again.

Finally, the data showed the compromises that were made when compliance barriers limited testing. Several startups mentioned they could not deploy their MVP in a real setting, due to these constraints, so they had to pilot test in low-risk environments. This also does not align with the lean method, which prescribes startups to test their product in the beachhead market they want to approach.

7.2.8 Timing compliance

The last theme derived from the deductive analysis focused on the timing of steps taken related to compliance, startups took during their development. This practice is crucial in understanding when certain steps are taken at a moment during development. By understanding this knowledge, certain practices can be explored and patterns can be derived.

In line with this theme, participants were asked to indicate steps taken on regulatory and industry standards compliance, on a given timeline. The in-depth analysis of these timelines is discussed in 7.3. This theme further focuses on the incentives behind the timings. Several interesting quotes were recognised in the data. These are listed below.

"I would consider it a waste of time and money if you develop a product only to find out later that it doesn't comply with all kinds of standards. Then you're finished, so we absolutely do it at the earliest possible stage and try to get a clear picture of what you need to comply with."
"Yes, that's correct, so when we actually do a rollout, meaning when we want to introduce it on a broader scale, we have to ensure those certificates are in place." [Participant 3]

"That's a bit of a chicken and egg story of okay, how do you get through this? How do you make something new if you have to do everything by the book? Well, what are you going to do first? Are you going to make something new first and then that booklet will follow; or so that dilemma." [Participant 12]

"Based on what he observed, he made recommendations. He indicated what was important for certification. With that information, we got to work and eventually implemented those adjustments in the product development." [Participant 2]

"At the beginning of the opportunity phase, you want to demonstrate feasibility, viability, and desirability in a multidisciplinary way. By the end of that phase, you want to show that your technology is feasible, complies with regulations, and is viable. You want to ensure that you can build a good business and that people actually want to buy and own the product." [Participant 8]

"When you're still working on your core technology, you're really dealing with the entire available market, which makes it much more difficult. For example, with the product, you choose a specific region, and different standards and regulations are required."
"There are many regulations. We tackled the legal aspects primarily during the first R&D phase for the core technology. We had to deal with electronics legislation, but fire safety was also a big issue, especially with fluid storage and use. So all already on the technology level." [Participant 9]

"I sometimes advise new startup entrepreneurs on how to approach this. I see two approaches. The first is the one we followed: getting all your regulatory aspects in order from day one. I can tell you, it's a long process."
"Ideally, you'd build first and then test in the market, so you'd need to have your documentation fully prepared in advance. But practically speaking, that's just not feasible for a small company." [Participant 10]

The results derived from this theme revealed distinct patterns in how hardware tech startups approach regulatory and industry standards compliance. The key finding is that most startups prioritize early awareness and compliance, which is in contrast with the compliance oversights, found and discussed earlier in section 7.2.7 on missteps and learnings. The data extensively cover the upsides of early compliance and awareness, such as clear specifications in what you have to develop, ensuring an expert attitude towards the market, and foreseeing costly iterations and delays. Also, the data showed that the startups recognize the potential financial and operational risks of delaying the steps.

Despite the early awareness, participants highlight the complexity of deciding on compliance. For example, Participant 9, indicated multiple layers of compliance across different global regions, which creates significant challenges. This emphasizes that weighing regulatory and standards compliance in concept generation is crucial, to developing the product to meet requirements within the targeted market.

Furthermore, the data revealed a balancing done by startups on feasibility and practicality. While some startups aimed to finalize compliance documentation early, others found this impractical due to resource constraints. They first wanted to interact with the market to understand what legal and industry standards requirements are expected. These contradictory approaches result from the differences in industries. Some participants knew upfront, that the industry they would be

targeting requires compliance before introduction could happen. Others targeted markets that less prioritized these legal needs. Therefore, they could already interact and introduce the product before full compliance.

Lastly, the startups that delayed compliance until the rollout phase often found themselves struggling to meet necessary certifications before product launch. This approach, while sometimes unavoidable, often led to delays and additional costs.

Overall, the results indicate that early awareness, before product, production, and marketing development, is advantageous, because compliance requirements can be implemented early on. However, startups must balance the timing of compliance with resource availability and strategic goals.

7.2.9 Startup roadmap

This theme emerged from inductive coding and encapsulates the insights provided by participants regarding the development of the roadmap of their startup and the integration of compliance within this framework. Unlike the previous section 7.2.8, on the timing of compliance, this theme highlights comprehensive strategies for implementing compliance measures. In addition, The theme also includes advice given by these experienced participants for future entrepreneurs, aiming to bring a hardware technology to market.

The findings underscore the critical importance of legal compliance and adherence to industry standards as prerequisites for market entry. Regardless of the participants' backgrounds, legal requirements played a significant role in the development of the startup. This necessitated that everyone incorporate these requirements into their respective roadmaps. The data revealed a variance among startups: some had proactively integrated compliance processes as concretely as possible into their roadmaps, while others lacked this knowledge and awareness, which forced them to adjust their roadmaps accordingly. Interesting quotes captured within this theme are listed beneath.

"Yes, definitely. It relates to your route to market, but also to time to market. And it also purely has to do with your cash and your cash position. So you need to consider all those things. These elements need to be aligned. If you know that the certification process takes 1.5 years, then you need to target your marketing accordingly so that you're ready" [Participant 3]

"But I definitely wouldn't invest actively until you are sure there are customers for your product. That's just pointless. You are essentially burning investment money for nothing." [Participant 4]

"Yes, medical is multidisciplinary. There are many different streams, as I call them. You're not just working on the technical development of your product as a developer; you're also focused on quality management development. You're working on your regulatory plan, clinical evaluation plan, usability engineering, risk management, and manufacturing. Essentially, you want to create a good overview of all those streams regarding what the uncertainties are and how big they are. You want to reduce those uncertainties as quickly as possible." [Participant 8]

"Yes, they also ask, what are the risks? You might say one risk is that we lack this expertise, and they would say, okay, good that you're aware of that. That is already the first step: an awareness that you are not competent. Then you move to being consciously incompetent. After that, to being consciously competent by bringing someone in-house, undergoing training, or seeking coaching; it can be done in various ways." [Participant 8]

"You are so focused on your technology roadmap that you forget about the other two: compliance and funding. Everyone always wants to see the latest and greatest of your technology. (...) They need to be balanced with each other. If you don't have that, you'll run into problems. That has been my biggest lesson, and I would always do it differently now." [Participant 9]

"First, make sure you solve a problem. That problem exists within a certain regulatory area. You have to deal with that. You need to have a problem and ensure there's enough margin so that people will pay for it. You need to have both a problem and a business model before another thing becomes important." [Participant 7]

The analysis of this theme highlights the indispensable role that compliance with legal and industry requirements plays in the roadmap development of startups. Participants emphasized the necessity of integrating legal requirements into their planning processes, underscoring that proactive compliance not only facilitates smoother market entry but also aligns with financial and strategic objectives. The findings indicate a clear divergence among startups regarding their approach to compliance, with some demonstrating a forward-thinking strategy by embedding compliance measures from the outset, while others had more difficulty with the process due to a lack of awareness or expertise.

Moreover, the insights shared by experienced participants serve as valuable guidance for future entrepreneurs. They illustrate that a balanced approach, which includes compliance alongside technological innovation, business development and funding, is essential to mitigate risks and avoid pitfalls. However, as also noted, it shouldn't be the main priority when you don't have a problem to solve or a valid business model. Especially, it is important as a startup to understand your competence and incompetence on regulations and standards. The lessons learned emphasize the importance of problem-solving within a regulatory framework and the need for a comprehensive understanding of the industry and market.

7.3 Timeline comparison

During the conducted interviews, participants were asked to indicate certain interference moments with regulatory compliance over a synthesized timeline. This timeline was specifically designed for this thesis and is based on the synthesis of existing academic literature discussed in section 2.2. The timeline provided a universal understanding throughout the interviews.

The indicated moments at which startups have taken steps regarding legal regulations and industry standards showed some variation. The key moments identified by startups include when they became aware of existing laws and regulations, the point at which they began actively exploring what these regulations entailed, the phase when they implemented the necessary requirements to comply with the regulations, and finally when they certified their product components. Furthermore, regarding industry standards, they indicated or explained when and why they became aware of the industry standards. Thereafter, they discussed how the industry standards were incorporated into the product or service, and when they were certified.

The differences in timeline indications are related to several factors. First, there is variation in the starting point of each startup, as some technologies are more regulated than others. This is closely tied to the most important factor: the industry in which the startup operates, or the initial market they intend to target, which can predetermine the extent of regulatory obligations. Industries such as automotive, medtech, healthtech, and other stricter regulated sectors require an earlier awareness of the requirements of regulations. Startups in these compliance-critical industries are often more aware of regulations and incorporate this awareness into their roadmap during the research and opportunity phases. In addition, prior knowledge of regulations among startup founders is another key factor in determining their awareness of the necessity of legal compliance. Furthermore, awareness of industry standards varies. As discussed in the previous section 7.2.4, this often arises from market demands. The awareness and subsequent actions to address these standards tend to occur at a later stage when startups begin to interact more actively with the market.

Based on the data from participants, two timelines have been derived. The first represents interference points noted by participants from less regulated industries, while the second reflects a synthesis from startups operating in compliance-critical i.e. strictly regulated industries. Both complete timelines are introduced hereafter. Subsequently, they have been set parallel to each other to clarify the differences.

7.3.1 Interference timeline several industries

The type of market seems to be the most important factor in why startups start to work on compliance with regulations. Some markets and corresponding industries seem to have a lower prioritization on the need for regulatory and industry standards compliance. Several participants noted that the need for compliance is largely shaped by the type of customer, business-to-business, and the specific market and industry they operate. For participants who indicated that their solution was introduced into a market where at least regulatory compliance is not a primary concern, a synthesis of their identified interference points has been developed. This is represented in the following analysis.

The term, markets where compliance is not a primary concern, does not imply the absence of compliance requirements. As outlined in section 4, nearly all products sold within the European Union must adhere to CE compliance. Similarly, other regions, such as the American market, require specific certifications like UL compliance. However, these regulatory requirements are so widely recognized that they tend to have a lesser impact on startup development compared to more complex regulatory processes. In addition, while legal compliance is less critical, participants have more often highlighted the importance of industry standards. The proposed interference timeline for hardware startups in less stringent industries is shown in figure 13.

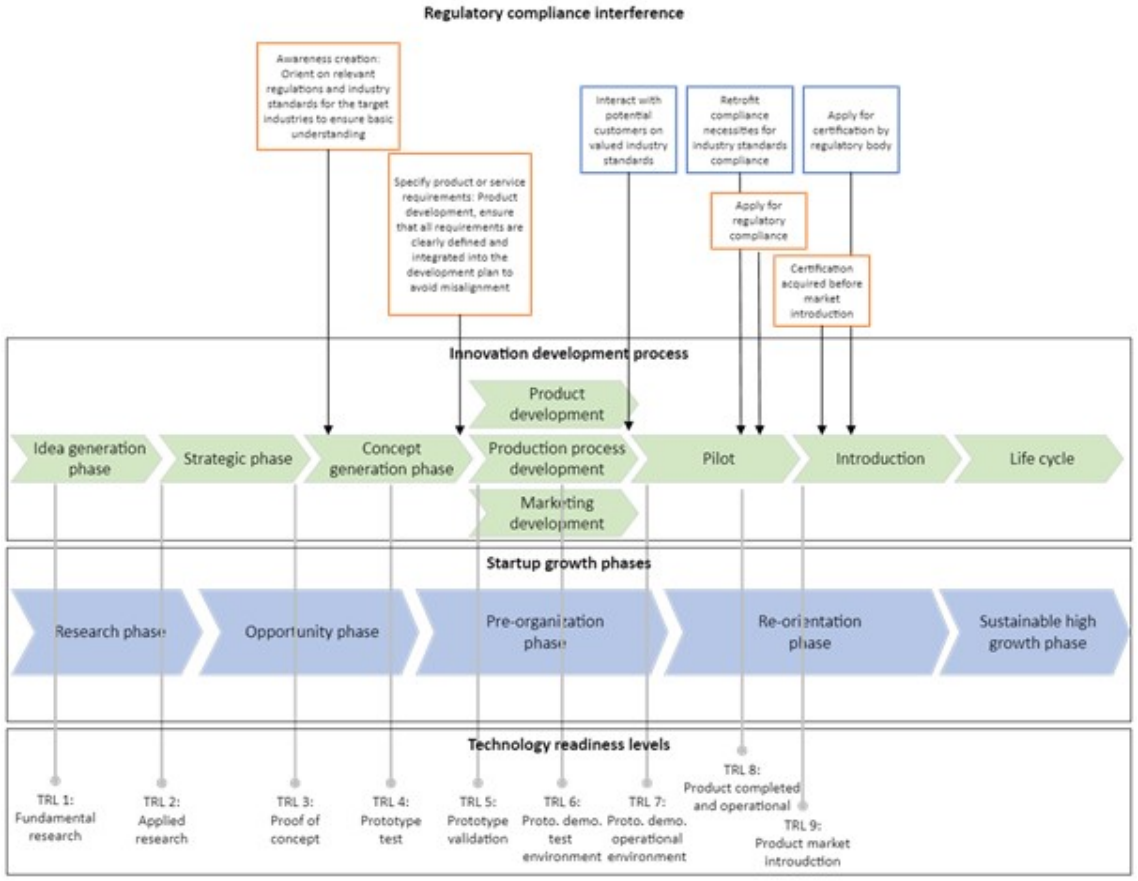


Figure 13: Timeline regulatory and standards interference moments during development in less stringently regulated markets (Created by researcher)

7.3.2 Interference timeline in compliance-critical i.e. strictly regulated industries

The second derived timeline is the indicated timeline by participants which underlined they operate in a strictly regulated market. This distribution is purely based on the answers from participants. Following the results, startups that operate in such industries, are earlier aware of the importance and understanding of regulatory compliance. Especially regulatory compliance is important within this field, as startups are obligated to be certified before market introduction. Also, this distribution requires participants to confirm that full pilot testing was not feasible in a real-world setting, where such testing would necessitate a minimal standard of compliance or ethical approval. The timeline indications are therefore distinct from the earlier discussed timeline. The timeline proposed for startups operating in higher regulated i.e. compliance-critical industries is visualised in figure 14.

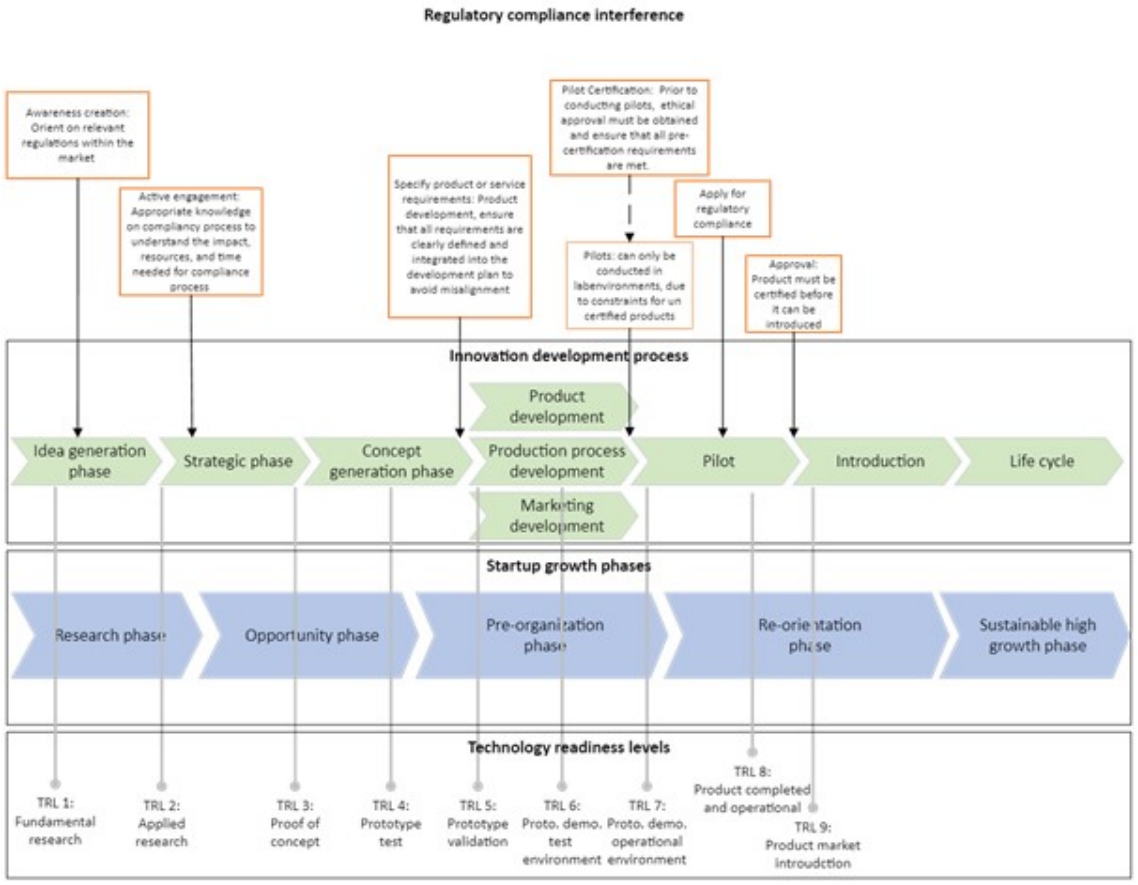
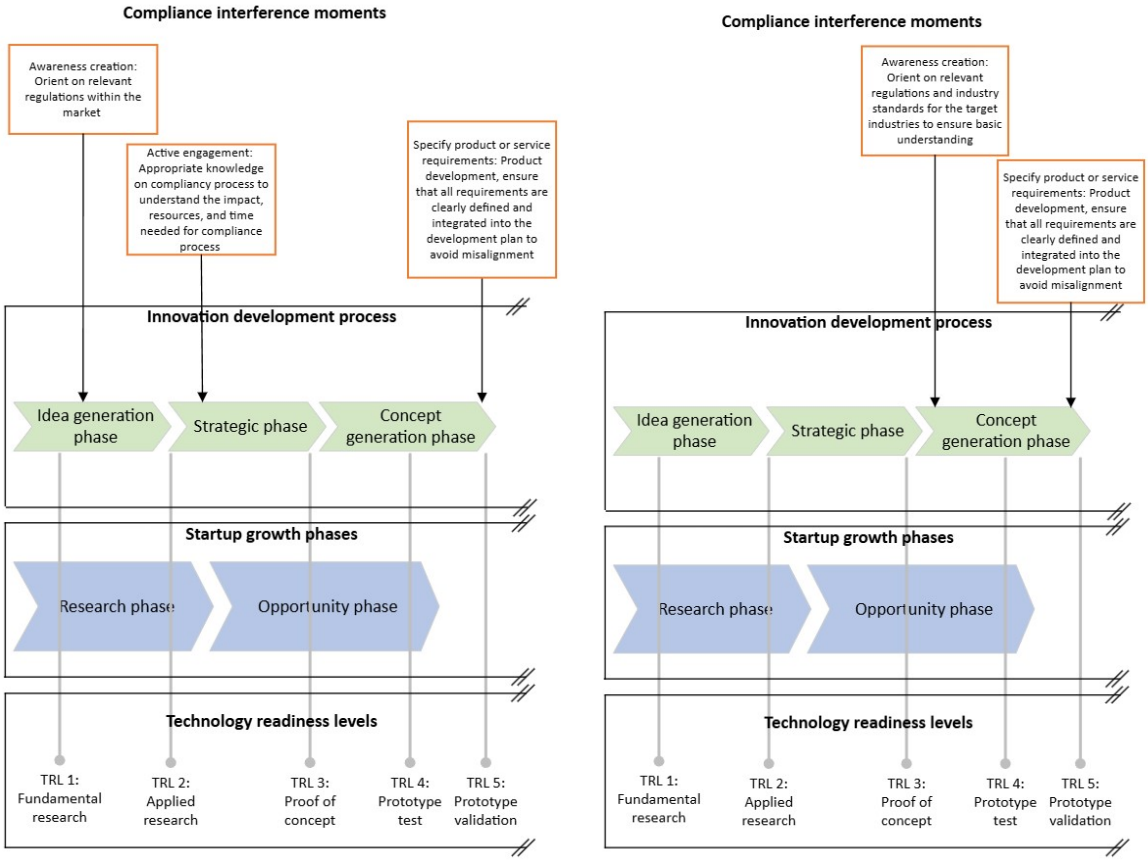


Figure 14: Timeline regulatory and standards interference moments during development in stricter regulated markets (Created by researcher)

7.3.3 Comparison compliance-critical and less critical industry timelines

Following the introduction of both timelines, the differences are compared hereafter. Below, the timelines are divided into two sections: the first covers the phases from idea generation up to the start of development, while the second illustrates the time from development through to sustainable high growth. On the left, the timeline for the compliance-critical industries is shown, on the right the less critical timeline is given.

Comparison phases of idea generation until development
The first section compares and examines the steps starting from initial idea generation through to the stage where concepts are well-defined and ready for further development. This period includes Technology Readiness Levels (TRLs) 1 to 5, which cover phases from basic principles and concept formulation to technology validation in a relevant environment. Also, the research and opportunity phase of startup development is passed during these stages. The steps ensure that foundational ideas are solid enough to proceed to development.



(a) First section compliance critical industries

(b) First section several industries

Figure 15: Interference timelines during phases of idea generation until development

The following notes summarize key moments of compliance interference as derived from interview results, distinguishing between compliance-critical and less critical industries.

In **Compliance-critical industries** i.e. strictly regulated industries, startups are typically aware of compliance requirements from the very beginning. The intensive prioritization needed to manage these regulatory demands means that startups must consistently have to pay attention to compliance requirements and processes.

- **Awareness creation:** Already from the beginning onwards, where technology is recognised to become a marketable product, startups recognize the importance of legal certification to eventually sell a product to the market.
- **Active engagement:** During applied research, the participants explained they were actively acquiring knowledge and understanding of the regulatory requirements that will likely apply to them. They mentioned it as an aspect of the applied research phase.
- **Specify requirements:** The results showed that before development started, the startups aimed to have all the physical and quality management requirements clearly defined.

For **less regulated industries**, the moments of interference allow for more flexibility and are less intensive to include. The moments seen in this timeline include:

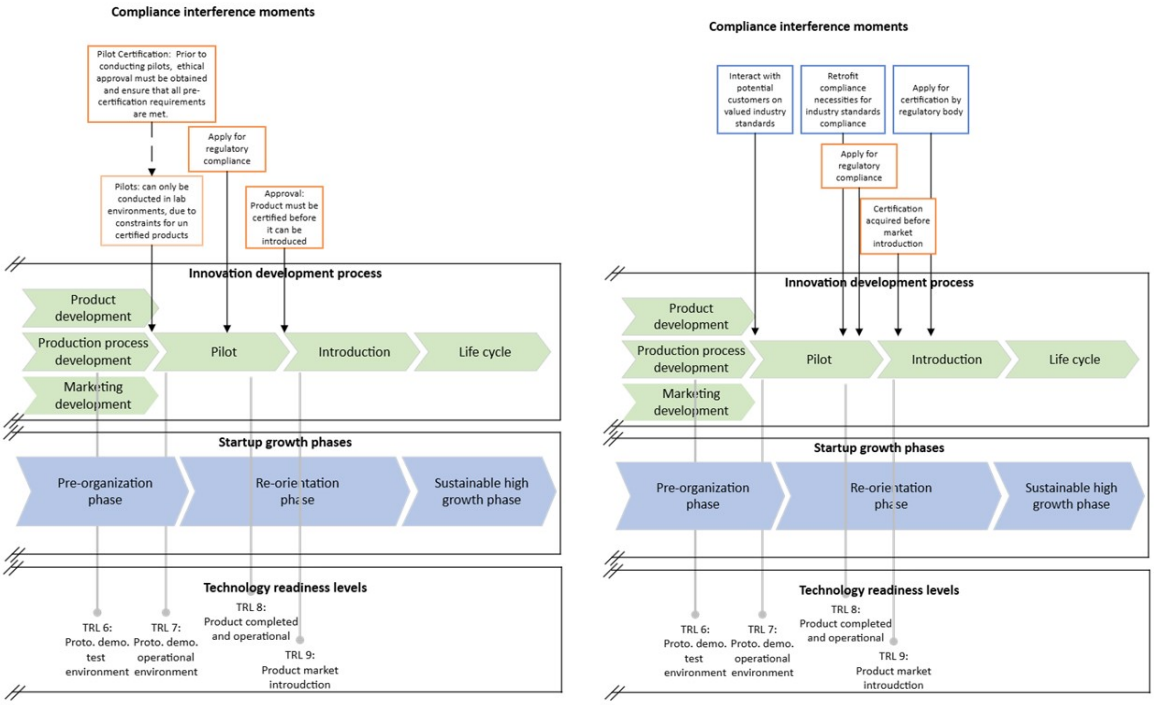
- **Awareness creation:** Participants indicated that awareness of regulations and standards should arise after the idea for the company, or a general solution to the market has been

formed, but before the actual concept is derived. Startups often explore relevant legislation for their solution and assess regulations in the markets they aim to enter

- **Specify requirements:** While TRL 4 prototype test, is reached, startups explained they would delve deeper into the requirements needed to comply with regulations that have earlier been identified. As Participant 3 noted, "It is very important to take this into account and to keep it in your mind from the beginning of your development. Consider it as one of the design requirements that you need to think about." By early on being aware of requirements startups can avoid retrofitting requirements afterwards.

The key difference between compliance-critical and less-regulated industries lies in the timing and intensity of compliance engagement. In compliance-critical industries, startups prioritize regulatory awareness from the outset, integrating compliance knowledge as early as the idea-generation stage and actively specifying detailed requirements before product development begins. In contrast, less-regulated industries allow startups more flexibility, with regulatory awareness emerging after the initial concept is formed and intensifying at later stages.

Comparison phases from development onwards to mass market adoption
The second section examines the steps from product development through to the life cycle. During this phase, Technology Readiness Levels (TRLs) 6 to 9 are checked, covering stages from prototype demonstration in relevant environments to fully operational systems ready for market entry. For startups, this progression involves moving from pre-organizational phases to a structure capable of sustaining high growth, to scale effectively.



(a) Second section compliance critical industries

(b) Second section several industries

Figure 16: Interference timelines during phases of development until mass adoption

Below notes have been made on the moments of interference as derived from interview results, distinguishing between compliance-critical and less critical industries.

In **Compliance-critical industries** i.e. strictly regulated industries, startups are typically bounded from easily accessible pilot testing in markets. Furthermore, they have a hard requirement to be

certified before products can be introduced to the market. In addition, these certification processes at notified bodies are typically long-lasting, and self-certification is not an option.

- **Pilot certification:** Several participants emphasized the importance of obtaining initial certification and/or ethics approval before starting pilot testing in an operational environment. As Participant 8 explained: "You need to have an IMDD (Investigational Medical Device Dossier). Also, you must have Ethics approval to conduct that study. Actually, it's already a product that is either in alpha design, which you can't manufacture yet, but you learn from it during your pilot." This statement highlights the complexities involved in testing a single development iteration and underscores the inherent limitations of iterative development in these industries.
- **Apply for regulatory approval:** Since notified bodies can have a long processing time, startups are advised to apply timely for approval. As Participant 10 explained: "The FDA has very clear rules: Pre-submission takes 9 weeks, submission takes 12 weeks. These are just standard timelines. They can request some extensions, so there's some flexibility, but it's fairly predictable. In Europe, however, there were only about 15 notified bodies, and they were completely overloaded. So, in the past few years, it was just a real struggle."
- **Approval before introduction:** The results show that in these industries, compliance with regulatory requirements is crucial; without it, customers simply won't purchase the product Participants within this category all highlighted the importance of this.

For **less regulated industries**, industry standards are challenged during the later phases of development. Also, for these industries, it is still important to have a legally certified product before market introduction.

- **Interact with potential customers on industry standards:** In comparison to regulatory requirements, industry standards are not obligatory to comply with. Therefore, the need to implement these differs. To understand which standards are valued by potential customers, the startups can interact with the market while conducting pilots. As Participant 9 mentioned: "Especially as a startup, you're already dealing with it, often competing with the established players. That takes quite a lot of effort to filter out what is really a standard, and what is just a stick to beat you with.", indicating that the impact of industry standards can differ within the same market.
- **Retrofit standards compliance:** During the pilot phase, it is essential to address industry standards that may be requested by the market. Implementing these standards prior to achieving TRL 8 is most sufficient, following the participants. Consequently, it is important to prioritize compliance with these specific standards and to integrate the associated requirements effectively into the overall development process.
- **Apply for compliance:** Reaching the end of the pilot phase, when Technology Readiness Level (TRL) 8 is attained, it marks an optimal time to implement compliance with regulatory requirements. Before reaching this stage, the findings from the pilot phase have been iteratively incorporated into the product. By TRL 8, the product is fully developed and operational. This timing is particularly significant, as opportunities for iterative development diminish following the application of regulations, as discussed by Participant 6: "You should only apply when you have a pilot that you are 99% confident will resemble your final product. Otherwise, it is pointless if you are going to make changes afterwards."
- **Apply for industry standards certification:** Once the requirements of the standard have been implemented, the product can be submitted for compliance assessment. It is advantageous to undertake this process early in the introduction phase since it can facilitate a smoother market entry. Also discussed by Participant 1: "But ultimately, it all comes down to business value. You certify something so that people buy more, allowing you to secure longer contracts and enabling faster purchases. In the end, it's just an investment of money. So, it costs money and

time, but it will also generate revenue. You should view standards certification as a business opportunity"

In comparing the timelines for compliance-critical versus less regulated industries, the distinction lies in the depth and timing of required compliance steps. Compliance-critical industries face stringent requirements, including the need for adjusted pilot testing, lengthy regulatory approval processes, and mandatory certifications before market introduction. This imposes a more rigid development path where iterative adjustments are limited due to the complexity of compliance. By contrast, less regulated industries can afford more flexibility, engaging with industry standards and customer preferences later in development, particularly around the pilot phase. Here, startups have the opportunity to align with industry standards iteratively, applying for regulatory compliance closer to full product readiness.

7.3.4 Timeline limitations acknowledged by participants

The participants agreed on the overall structure of the timeline and expressed that it provided a clear representation of the steps involved. However, several participants noted that the processes, while visualized as linear, are not linear in practice. Instead, they follow a more iterative path. Furthermore, the participants noted that the respectively shown stages occur in a more parallel way to each other. There is no fixed point at which one moves from one stage to the next, as the processes tend to flow naturally into each other. Furthermore, the indicated duration of each step, currently indicated all the same duration, is in practice not equal to the actual duration. Some stages take considerably more time than others. However, some of the participants explicitly noted the clarity and uniqueness of the timeline, with a few even requesting to share the timeline with their startup teams for further discussion.

7.4 Relational analysis

The last analysis utilizes the co-occurrence table, generated based on the codes produced in Atlas.ti. This analysis focuses on seeking direct answers for the sub-questions stated in chapter 1. Furthermore, it focuses on uncovering and exploring relationships between codes that were not earlier found. These relationships are not statistically ground, they serve as insight into patterns and connections. Within the analysis, all codes as derived from the deductive coding process and the inductive coding process, described in section D and E, have been analysed. The results of the analysis can be found in appendix F.

Validated learning during development The first research subquestion is about how startups apply validated learning practices i.e. hypotheses testing and iterative learning. The co-occurrence results showed that participants actively used business and technical hypothesis testing, and even tested both simultaneously, also discussed in the quotes section below. The results also show that business hypotheses are regularly validated via customer feedback since these codes regularly occur together. Lastly, the occurrence also proved the limitations of testing technical hypotheses, as prescribed by validated learning principles, of which an example is seen in the quotes below.

"This allowed us to show that the system did work. This gives you your technical validation, but also a customer who had a bridge [Name customer]. He says: hey, this is very interesting. We are willing to pay for a follow-up project with wireless sensors." [Participant 1]

The tricky part was that we couldn't test that much, because it is, of course, a medical product. So you spend a few years developing it anyway and then you have to bring it to the market. Yes, that's not possible. You can't just throw some kind of prototype into the market. [Participant 10]

Regulatory and industry standards landscape: Codes within the themes corresponding to the regulatory and industry standards occur regularly with the importance of compliance. The results show that participants use industry standards to demonstrate the safety and reliability of their products. Additionally, it is more often discussed that regulations and industry standards often overlap, indicating that regulatory bodies incorporate these standards within their regulations, as seen in the quote by Participant 10 below, wherein the ISO standard is required for regulatory approval.

> "There are often gradations. Do you go for a basic level within a standard, or do you go for a high level? We decided to immediately go for the higher standard and then set a benchmark. That is also a strategic, logical choice. Even with new technology, our reasoning is for hardware, if something goes wrong there is almost no way back." [Participant 9]
>
> So we must comply with ISO13485 to bring a product to the market. And then in Europe, we have CE-IVD and in America with FDA approval, where the emphasis in recent years has increasingly been on cyber and AI. [Participant 10]

Identification of regulations and standards: Within the research scope there is a specific interest in how regulations and industry standards are identified by startup teams. Within the co-occurrence, it is seen that participants highlight the upside of early awareness and early adoption. In all probability, they can integrate necessary requirements early on during development to overcome costly mistakes. Furthermore, to create early awareness, the results show that participants consult with external consultants, market representatives, and others within their network. This relationship was indicated by the co-occurrence of 'Early awareness' and 'Consult on'. Lastly, the high co-occurrence between personal experience and expertise, and early awareness was identified. Indicating that based on someone's own experience and prior knowledge, the urgency and requirements of compliance are earlier identified.

> "You must do this at the earliest possible stage. I would consider it a waste of time and money if you have developed a product and it later turns out that you do not meet all kinds of standards because then you are done immediately." [Participant 3]
>
> "You can also simply ensure that you find that expertise. At a consultancy or at a regulatory expert who comes into your employ or goes Freelance. Those (...), and write a regulatory plan." [Participant 7]
>
> "Regulatory and quality, these are the two super underexposed areas in Delft, but they play an enormous role. We then spoke to many other companies via YesDelft that were already further along in this regard." [Participant1 10]

Compliance effect on startup development: Also of interest are the relationships on how compliance affects the startup's development process. The results indicate there are limitations to iterative development. The co-occurrence showed two relations that impose these limitations. Firstly, participants indicated that hardware development is inherently constrained in iterations due to the costs and processing time of iterations. Secondly, the process of acquiring compliance constraints the participants in further iteration. The cost of acquiring certification at notified bodies is significant, just like the lead times. Within the quotes section below, these relationships are illustrated.

Besides restrictions to iteration, the findings also suggest that the effect of internally implementing the compliance requirements is costly and can cost significant time to implement. Both show high co-occurrence with the development process. This implies compliance efforts do affect iterative development and the development of the startup.

"Especially in this world, especially with hardware, it costs an incredible amount of money. Well, it just takes time, salaries have to be paid, you also have to invest in your components, you name it all. A lot of money passes through it relatively quickly." [Participant 2]

"Every time you change a component you have to officially recertify CE. That makes it difficult." [Participant 1]

"So that automotive certification ultimately took two years to complete. Of course, that deal was postponed during those two years. Well, of course, that also costs your organization turnover" [Participant1 6]

Actions to achieve compliance: Within the analysis is further focussed on the underlying relationships between action or decision-moments startups had in regards to regulatory and standards compliance. The results revealed that key decision points were in some cases influenced by market demands, particularly when certified products were necessary for introduction. This finding was evident in the high co-occurrence between the codes "before market introduction" and the "reason to comply." Furthermore, it is identified that startups see adherence to standards and regulations as a way to show maturity. This was illustrated by the co-occurrence of compliance motivations, both in terms of adhering to industry standards and legislative requirements.

Furthermore, the high co-occurrence between roadmap and advice for others showed an interesting relationship. Participants advised others to see regulatory and standards compliance as a major importance from the beginning onwards, or even as a separate roadmap next to your technology development and funding roadmap. This insight is identified from the co-occurrence between the codes. The quotes below illustrate these relationships.

"When the financial transaction actually takes place, then it must also be proven that it is certified. Otherwise, you are also quite liable in Europe" [Participant 4]

"Compliance is also an enabler for sales. By being certified you indicate that you have a certain level of maturity. It simply makes it easy for your customers to buy your product." [Participant 11]

"In my opinion you always have two roadmaps. One has to do with funding and one has to do with the market approach, compliance is part of that. So you have two roadmaps and they need to be somewhat balanced relative to each other." [Participant1 9]

Emerged relationship Several other interesting relationships were discovered during the analysis. These were labelled as not directly linked to one of the sub-questions, dictated in the research outline. Nevertheless, these relationships explore important relationships. The first relation between the co-occurring codes 'Customer feedback' and 'Early awareness' is recognised. This relationship explores the influences of potential customers on the early awareness of required regulations and industry standards. As Participant 9 specifically described: "In our case, it makes quite a difference whether the end user is a telecommunications company or a bank. It's a completely different regulatory world compared to each other, with the same product.", indicating the importance of early customer interaction to evaluate regulatory and standards needs.

Furthermore, the analysis revealed the relationship between the codes describing keeping progress in startup development and validating of business hypothesis. This indicates participants were able to in some form track their progress with regards to business validation. A relation not found in regards to technological validation. As Participant 1 explained: "After a while you see, okay, it's not one or two, but it's not a hundred either. That's kind of what we were doing in the beginning. Which, by the way, was a really good way to validate your business. We used a quite clear methodology there to keep progress."

Lastly, the co-occurrence of the codes describing acquiring an understanding of compliance

requirements and actively working on implementing requirements showed an interesting relationship. Participants explained that these processes often interact, in a way that if the requirements are clarified, they will be directly implemented. This is illustrated in the development process of Participant 9, which explained: "What we then do is map out all the requirements. Then apply as much as possible. In any case, they enter the development process that is Lean and Agile. Within this development, you work with user requirements. Part of those user requirements are regulations requirements." This again indicates the importance of considering regulatory and standards requirements before development.

7.5 Results validation by notified body and startup investment manager

Validating research findings is critical for ensuring the reliability and applicability of the research findings, in a broader context. Within this research, there has been a specific focus on hardware technology startups, which have their incentives regarding this topic. A startup investor and a standardization consultant from the NEN (Netherlands Standardization Institution) have been interviewed to generalise the research findings. They were asked their point of view on this topic, and if they recognised themselves in the research findings. Furthermore, they were challenged if they could adapt certain practices to help hardware tech startups.

As a standards institution, the standardisation consultant from NEN has validated that innovations commonly don't fit existing norms and that these are hard for them to implement: *"Well, they do not fit in our standards and it is actually very difficult for us to do anything with that."*. Furthermore, was explained that each NEN standard consultant must consider innovations in his or her own group of standards. *"At the moment it is the case that for all individual consultants, i.e. the people who work on all individual standardization topics, it is up to them to take that into account and keep an eye on it."* This aligns with earlier results, where startups described that standards do not always align with what they are developing. Also, it aligns with notified bodies having long processing times, which do not align with their fast-paced environment.

Startups describe that it is difficult to get clarity from all industry standards, financially challenging, hard to understand, and generally inaccessible. This incentive is also recognised at NEN; *"Knowing what is that spider web of standards that you move in and how much do I comply with that? Yes, I completely agree with you there. I think that's where we are as NEN we still have a task to improve accessibility, especially because standards are not cheap."*. The advice from NEN is given to startups to apply for a standardisation commission in the topics related to the startup. When a startup is below ten employees, the company can access a commission for 500 euros per year. Which also gives them the right to access all related standards to that commission.

Furthermore, startups even explained industry standards as market barriers, created by incumbents to prohibit innovations from entering a market. This incentive was partly recognised, however the NEN underlined that standards are made on consensus. If startups don't agree with the consensus they should join a standards commission to safeguard their interests. As explained in the following statement: *"But if you cooperate, then it requires others to think along with your idea. So think of it as a tool instead of a barrier."*

Besides the NEN, a senior investment manager from a venture capital fund was interviewed to discuss the research findings and their point of view. This person was challenged by experiences seen by startups in their portfolio. Several key findings from this research were validated. Firstly, the investment manager highlighted the inherent differences between hardware and software-developing startups, confirming that *"With software, you can quickly see whether it takes off or not. It's easier to get funding, but the competition is much higher because it's easier to create"*. Furthermore was noted: *"On the hardware side, there's more of a challenge between product and commercial development, depending on the founders, but the potential impact is greater because hardware can inherently differentiate itself, which is harder to do with software."*. This distinction aligns with the findings from literature and qualitative analysis, regarding the differences in development pathways for hardware startups.

Regarding the prioritization of regulations and standards, the investors acknowledged that *"For most startup founders, it's generally not top of mind."* From the investor's perspective was noted *"As long as the customer is happy, we as investors are usually happy."* They also emphasized how regulatory changes could present opportunities, stating that *"When a random rule is introduced, it can actually create a market opportunity if you stay ahead of changing regulations, which is very commercially driven."* This aligns with the research findings, wherein is seen that besides challenges related to compliance, it can also bring strategic benefits when compliance is accomplished.

Furthermore, the investment manager validated the importance of early awareness of compliance, especially in strictly regulated industries like Life Sciences and Health (LSH), noting that: *"Awareness on regulations and standards should begin from TRL3, and even earlier if you're in LSH, where compliance is crucial."*. This emphasizes the findings on the timing and strategic steps required for compliance during development. Also, they noted that: *"You need to start considering compliance requirements around TRL 3 and plan for them as you approach pilot stages, but not necessarily aim to have everything certified by the pilot stage because it can be very costly to change."*, which validates the research findings regarding the compliance efforts' timelines.

Together, these validations offer both regulatory and market-oriented perspectives, enhancing the robustness of the findings.

8 Discussion

Within this chapter, the research sub-questions are addressed and explored in detail. Additionally, the theoretical framework is revisited to evaluate how the anticipated relationships align with the insights gathered from the interviews. Lastly, the social and scientific contribution are discussed.

8.1 Research insights

8.1.1 SQ1: Hardware startups applying validated learning principles

The first research sub-question is seeking to explore the way hardware tech startups use validated learning principles to bring their product to market. The question which is answered is: *"How do technology-based hardware startups use validated learning to test and refine their business and technical hypotheses during development stages?"*

Validated learning principles, also referred to as iterative development, are the practices of continuously testing and refining hypotheses such as business and technology ideas, through cycles of experimentation using minimal valuable products (MVPs), feedback and adaption until product-market fit is achieved. **For hardware startups, this practice is seen as complex and challenging, due to inherent constraints by hardware.** Herein a range is seen: Some are unable to conduct any testing due to hardware constraints, others can test in simulated environments, and others can build MVPs to validate in real market conditions. **However, all startups seem to use market interaction as a way to validate hypotheses and assumptions on business-related topics,** such as, what is the actual problem of my targeted customer, what they require, and what are they willing to pay.

Furthermore, there seems to be a general consensus that early on interaction with a customer is needed for a successful way to market. This interaction with customers is multifaceted, since product requirements, services, prices, and compliance requirements are challenged. Continuously challenging potential customers on their expectations, helps the startups find a market fit. In addition, early feedback helps startups to make directional decisions, which helps to create clarity regarding market requirements.

Startups that do apply validated learning principles while developing their product, **seem to test technical hypotheses and business-related hypotheses at the same time.** By testing and demonstrating their technological feasibility, they also test the enthusiasm of potential customers based on the results. This practice shows technological feasibility, and viability, as well as market desirability.

Overall, technology-based hardware startups using validated learning, encounter inherent challenges due to inherent hardware constraints. The impact of these constraints differs, as some use MVPs due gather technological validity, product market fit and customer interest simultaneously.

8.1.2 SQ2: Regulatory and industry standards landscape for startups

Secondly, the landscape of different levels of regulation, and industry standards, is explored to gather a universal, minimum understanding for researchers and readers on this topic. This is done by answering the question: *"How is the regulatory and industry standards landscape for technology-based hardware startups shaped?"*

Regulations are established by governmental bodies and provide specific guidelines on how laws should be implemented and adhered to. These regulations are based on general legislation issued by these bodies. **Regulations apply at both the technology level and the product level, meaning that to legally introduce a new product to the market, the technologies applied in those products**

must meet regulatory requirements. In addition, general product regulation requirements should also be adhered to in the development.

Besides legally required regulations, industries can have additional standards and certifications created for their use. Industry standards are technical specifications for the design, dimensions, interoperability or performance of products and processes. In a sense, they specify how something should operate or interact to create a universal language between producers, suppliers, and consumers. These standards are drafted by notified bodies and can differ based on industry, and region. As said, **these standards are not legally required but can be expected by customers within specific industries.**

Within the startup context, **it is essential to understand the legally required regulations that your product must comply with. These regulations can be seen as design requirements for both the technology and the product. To sell legally, certification is necessary. Pilot testing in real-world environments can be conducted with customer consent.** However, some startups argue that existing regulatory frameworks are outdated; they believe that because they have developed innovations, these regulations should also be updated. On the other hand, it may also be the case that startups develop an innovation for which regulations have not yet been created or are not complete.

When it comes to industry standards, startups often have more flexibility. Industry standards are typically drafted by established incumbents (competitors) who reach a consensus on current best practices. Introducing an innovation to the market may mean that existing industry standards do not incorporate this innovation. **Startups can decide whether to adapt themselves to the current standards, not adhere to standards, or take on the task of developing new ones.** Furthermore, while compliance with these standards is not mandatory, it can facilitate sales by demonstrating maturity and professionalism.

In conclusion, understanding the regulatory and industry standards landscape is important for hardware startups, as it shapes their approach to compliance and innovation. While adhering to established regulations is crucial for legal market entry, startups have the flexibility to adhere to or challenge industry standards that reflect their innovative solution.

8.1.3 SQ3: Awareness of relevant regulations and standards

The third research sub-question explores how startups identify regulations and standards potentially important for their products or services. Do they have external help, prior knowledge or other manners to gather understanding on regulations and standards? The following question explores this phenomenon: *"How do technology-based hardware startups identify relevant regulations and industry standards, applicable to their product and accessory industry?"*

There is a noticeable variation in how startups become aware of existing regulations and standards. While some startups have prior knowledge of the regulations and standards relevant to their industry, others may initially be unfamiliar with these requirements. According to findings, startups operating in compliance-critical markets often become aware of the applicable regulations and standards at an early stage. However, for those startups that do not perceive themselves as operating within such strictly regulated environments, this awareness is not always immediate. Some acknowledge having considered the issue, but only begin to take action when customers start inquiring about regulatory compliance. Generally, **all startups indicate that they receive inquiries from the market regarding regulations and standards.** It must be noted that this is the context of business-to-business (B2B) industries.

In addition to awareness, startups employ various approaches to identify relevant regulations, standards, and their associated requirements. **Some report consulting external experts, while others firmly believe that this process should be managed internally.** This difference is especially pronounced in stricter regulated industries, where external consultants are frequently engaged. Nevertheless, across all startups, it is common to rely on market feedback to identify

necessary regulations and standards. Consulting suppliers is also a typical practice to gain an understanding of regulatory frameworks and standards.

To conclude, technology-based hardware startups identify relevant regulations and industry standards by either prior knowledge, engaging external consultants, market interactions on requirements, and consulting suppliers, especially in strictly regulated industries like Automotive, Medtech, and Healthtech, consultants are a typical way. This approach helps ensure compliance and market readiness early in the development process.

8.1.4 SQ4: Effect of standards and regulatory compliance on development

After awareness and understanding of compliance requirements are achieved. Startups will decide on how they will work with, or around them. Which potentially affects the overall development of the company itself, technology and product. The fourth sub-question explores the impact adherence to regulations and standards can have. *"How do compliance processes affect iterative development and validation cycles in hardware startups during their development phases?"*

The impact of regulations and industry standards varies across startups and is influenced by several factors. **The industry dictates mandatory regulations, seen in the compliance pyramid, and the startup's knowledge and the anticipated impact also play a significant role.** Some startups reported encountering oversights, leading to necessary product modifications, delayed business deals, or incomplete certification processes—all contributing to high costs and delays.

Even for startups aware of regulatory impacts, **accurately estimating the real impact remains challenging.** Some even noted that if they had known beforehand the required effort, expenses, time, and other resources, they might not have undertaken the process at all.

In addition, the role of the notified body can be significant. Several **start-ups mentioned that long lead times for certification approvals, often managed by the notified body, can hinder rapid iterative development.** In general, compliance with regulations and standards often impedes iterative development, ranging from markets where testing cannot even begin without regulations to cases where certification requests force start-ups to halt their development due to the high costs involved.

Lastly, is seen that compliance processes involve a set of critical steps that are both strategic and necessary-driven. The interview results showed that **once startups recognize the importance of compliance, they dedicate resources to building internal teams to approach the compliance process.** This reflects again the specific expertise needed to obtain compliance.

8.1.5 SQ5: Timing of steps

The last sub-question tries to understand and map the steps taken to achieve compliance. Compliance processes often follow general sequential steps to obtain certification. The way startups incorporate these, is discovered in the sub-question: *"When do startups initiate actions to achieve regulatory and industry standards compliance?"*

The timing of compliance efforts varies for each startup, as they must navigate unique and complex environments, with differing resources, available time, and shifting priorities. However, startups were asked to outline their compliance efforts, specifically identifying key steps in the compliance process along a synthesized timeline. These results are discussed in section 7.3, where several patterns and similarities emerged.

For startups operating in less regulated markets compared to fields like Medical-, and HealthTech, a series of sequential steps are typically followed within the same development phases. **Startups emphasize the importance of initial awareness during the early stages of concept generation**, specifically after passing TRL 3, proof of concept. This initial awareness refers to understanding the relevant regulations and standards in their target market and region. Soon after, startups seek

to identify the specific requirements necessary to achieve regulatory compliance, which they aim to clarify before the development phase begins. Following development and initial pilot testing, industry standards are more deeply examined, and if relevant, implemented. **Upon reaching TRL 8 and completing several re-evaluations, startups submit their product to a notified body to ensure regulatory compliance before its full market launch.** They commonly express that if minor changes are made to the product after compliance is acquired, due to orientation after introduction. The product is not re-evaluated for certification.

Startups operating in the more strictly regulated industries, such as the earlier discussed medical-related industries, follow a similar compliance path as other sectors but with different timelines. These startups emphasize the need for immediate regulatory awareness as soon as they consider bringing an innovation to market. During the strategic phase, companies must understand the substantial effort and resources required, which are also influenced by investor expectations. **Before development begins, all regulatory requirements must be clearly defined. Unlike other industries, pilot testing in these sectors requires initial certification or ethical approval, before testing can occur in the market.** Otherwise, pilot testing must take place in a controlled, experimental environment. Since the notified body process can be lengthy, startups must apply well in advance of market introduction. A product must be fully certified before general market release.

In conclusion, the timing of compliance efforts differs, but common steps and patterns are seen in similar startups. Early awareness and clarification of requirements are prioritized to overcome compliance oversights and retrofitting requirements. By aligning their compliance actions with product and production development phases, they ensure to meet all necessary certifications before launching their products into the market.

8.2 Reflection theoretical framework

Based on the existing literature, a theoretical framework was developed, including the main concepts within the study environment, see chapter 4. Between these concepts, research sub-questions were stated to explore the relationships. In the following section, the relations described above have been evaluated based on the results of the study. Thereafter a revised version of the theoretical model is given.

The first sub-question relation is seen between the technology-based hardware startups and the lean startup methodology. Literature highlights that hardware startups face specific challenges due to factors such as their unique knowledge base, limited time, venture capital resources, and reliance on networks and human capital (Sevilla-Bernardo et al., 2022). This relationship is bidirectional: while startups can choose if and how to implement lean startup principles, the methodology itself imposes practices of iterative learning and adaptation (Ries, 2014; Eisenmann et al., 2011). The analysis confirms this relationship, revealing that although startups attempt to apply the lean methodology, they often encounter the inherent difficulties of hardware development. Furthermore, the results reveal that technical feasibility and market validation are done simultaneously. Also, the resource constraints in this model could be expanded. The results showed that the type of industry significantly influenced startups' ability to prototype in the market or not. This can contribute to existing literature and is further discussed in 8.3.1

The second sub-question relationship is about the constraints of regulatory and industry standards compliance on technology development. The study results underlined the requirements imposed by legal constraints and the difficulties of finding the desirable industry standards within a specific market. In addition to this, the direction can be seen as bi-directional, since the results showed that industry standards compliance can be seen as a strategic advantage. By choosing to adopt or challenge these standards, startups can position themselves as innovative while still aiming for a mature appearance, customer trust and market fit. This aligns with earlier studies covering the upsides of aligning with industry standards (Ortt & Egyedi, 2014).

Next, the sub-question covers the interaction of how startups gain awareness and understanding of regulations and standards. This sub-question was identified as unidirectional. However, this relationship appears to be more complex due to several influencing factors, including the specific industry, the involvement of external consultants or experts, supplier involvement, and the priority given to regulatory matters within the startup team. While these influencing factors were not clearly identified in the existing literature, they emerged during the qualitative analysis. As such, these factors should be incorporated into the theoretical framework, and future research could further delve into these factors. Existing academic literature does not yet cover awareness and understanding of regulatory and industry standards compliance within startups.

Furthermore, the fourth relationship indicated between regulatory and standards compliance and the lean startup methodology. This relationship concerns how regulatory and standards requirements constrain or impact iterative development. This relationship is validated in the results, since regulatory requirements impose design requirements, require long lead times not aligning with fast-paced startup development, and can hinder the ability to pilot test products in operational environments. Regarding this sub-question must be recognised that startups are not passive in confronting compliance; they develop internal resources and even dedicated teams to integrate regulatory requirements into their development. These findings can contribute to existing literature describing agile i.e. iterative development and compliance processes, such as (Nguyen-Duc et al., 2018; Fitzgerald et al., 2013b).

For the final sub-question relation, the framework determined a one-way influence where startups can decide when to engage in compliance efforts. This relationship was not based on existing literature, since neither any academic literature covers how startups should confront compliance. The indicated relationship aligns well with the findings, which show that although the timing of compliance actions varies, start-ups generally take a phased approach, adjusting efforts based on their market's regulatory strictness and development phase. The final explorative sub-question was not explicitly addressed in the existing literature but was anticipated by the researcher, underlining the scientific contribution of these findings.

All results found have been incorporated into the revised theoretical framework, represented in figure 17.

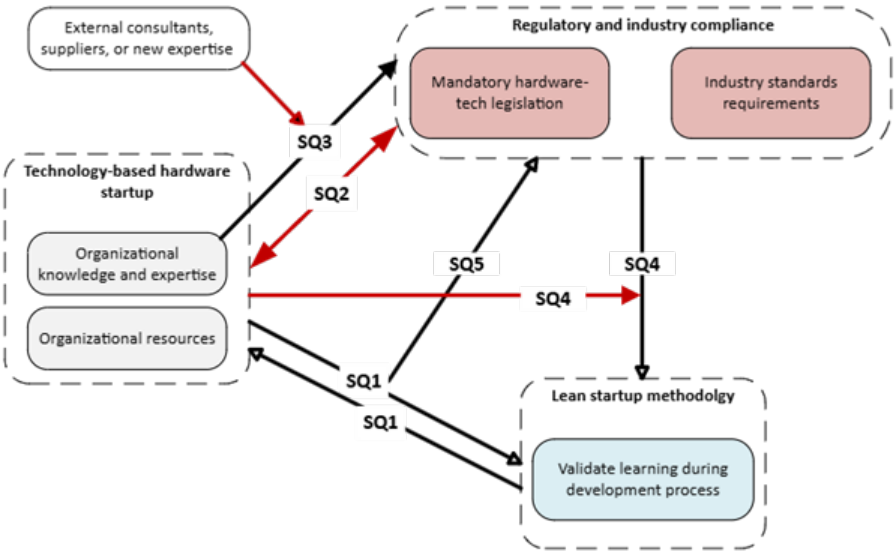


Figure 17: Revised theoretical framework based on qualitative analysis results (Created by researcher)

8.3 Social and scientific contribution

This research aimed to contribute to the existing scientific literature, but also to provide valuable knowledge to future entrepreneurs. In this section, the scientific contribution is first challenged. Thereafter, the social implications are discussed, providing advice for future hardware tech startups.

8.3.1 Scientific contribution

This section introduces the scientific contribution of this research, addressing a clear gap in the existing literature on this topic. No explicit studies were found to cover this area, making the insights presented here foundational for academic literature concerning technology startups. This exploratory study offers a new understanding, exploring how technology startups confront compliance processes.

This research makes contributions to four key academic areas. Starting, it raises awareness within the ecosystem about the regulatory and standards challenges faced by startups. Second, it presents a framework for understanding the landscape of legal regulations and industry standards. Third, it expands knowledge of the interaction between compliance processes and agile development methods. Finally, it provides in-depth insights into the inherent limitations faced by hardware startups. A more detailed discussion of these contributions to the core concepts is provided below.

- **Awareness on regulatory and standards challenges in startups**

First of all the gap in lack of awareness of the challenges, is pronounced within this study. The results show that startups are facing significant challenges in complying with industry standards and regulatory requirements, depending on the industry they are in. It was regularly mentioned that in advance no one noted the startups on the possible impact. In general, the challenge of regulatory and standards compliance is not discussed at all, or to a limited extent, in the existing literature on startup development. While multiple studies address startup development and barriers to growth in subsequent phases (Unterkalmsteiner et al., 2016), (Nguyen-Duc et al., 2018), and (Vohora et al., 2002), the specific challenge of regulatory and industry standards compliance is overlooked.

Entrepreneurs frequently describe this as a significant challenge, which, despite its importance, typically lacks priority or interest in a startup environment. This lack of priority contributes to the ignorance of wrong prioritization by startups when bringing their new technology to market. As discussed, not meeting legal requirements blocks a product from being sold in a market and, in some cases, being pilot-tested. Furthermore, compliance with industry standards can be used as a strategic advantage for startups to add business value and can be seen as an enabler for sales. The study of (Ortt & Egyedi, 2014), also partially substantiates these findings, since they found that pre-existing standards can significantly shorten the adoption phase of innovations.

Moreover, entrepreneurs often highlighted that industry standards and regulations lagged behind contemporary innovations, meaning their advancements frequently fall outside the scope of existing frameworks. This observation is consistent with the literature addressing the Collingridge dilemma of control (Collingridge, 1980; Genus & Stirling, 2018). This research reinforces these findings, offering additional substantiation from a startup perspective.

- **Understanding of the regulations and standards landscape**

There is a lack of a comprehensive overview of the regulations and industry standards relevant to hardware technology development in both academic literature and legal sources. To address this gap, this research combines multiple sources and consults experts to create a pyramid framework that outlines the practical implications of the various compliance levels a product or service must meet. This framework can be applied to the existing literature on hardware technology development, such as (Fitzgerald et al., 2013b) and (Atzberger & Paetzold, 2019), as well as

literature focusing on technology startups in the hardware sector, including (Nguyen-Duc et al., 2018) and (Eisenmann et al., 2011).

– **Interference of regulatory and standards requirements with agile development methods**

In the literature, it was seen that handling regulations and industry standards during development processes require the need for specialized knowledge and experience (Fitzgerald et al., 2013b), (Berg et al., 2020) and (Cawley et al., 2010). This study reinforces these findings and provides additional explanatory knowledge. as all participating startups reported that regulatory and compliance requirements created significant barriers to iterative development. This challenge was multifaceted since on the one hand requirements knowledge was missing within the team, resulting in the need for outside expertise. Secondly, regulatory constraints limited their ability to test and refine products in short cycles, a key principle of Agile methodology. Some even indicated that they were not at all able to iterative test and refine their developments, due to regulatory constraints. This highlights the challenge for Agile teams (such as a startup team) operating in regulated environments, suggesting a need for new strategies to integrate compliance into the development process without sacrificing agility. In addition, this study revealed that the impact of interference varies depending on the industry and the operational scale of the startup. Further complicating the relationship between agile practices and regulatory demands.

– **Inherent limitations in hardware startups**

The findings emphasize the distinct challenges faced by hardware-based startups aiming to follow a lean startup approach, in comparison to their software counterparts. While the existing literature explains both types of startups must navigate limited resources and short timeframes While developing MVPs to test and refine their product before bringing it to the market (Ries, 2014), (Berg et al., 2020), and (Nguyen-Duc et al., 2018). However, hardware development introduces unique complexities. The iterative nature of hardware production demands physical prototyping, which is both cost-intensive and time-consuming, significantly hindering the agility of lean startup methodology. Unlike software, where iterations can be implemented swiftly through code changes, hardware iterations require high resources, longer durations, and compliance with strict regulatory standards. Furthermore, the study shows that companies developing more complex products are not at all able to iterate in hardware. Meanwhile, startups do use customer feedback to validate business hypotheses and choose strategic directions. In conclusion, hardware startups do make use of lean startup practices, but mainly to validate business hypotheses.

8.3.2 Implications for hardware technology entrepreuners

This research aims to help future hardware technology entrepreneurs by clarifying regulatory and standards compliance processes. By exploring the experiences of startups that have already (partially) overcome compliance practices, future startups can learn from these and foresee them for themselves. The research does not guide entrepreneurs through specific compliance processes. Instead, it aims to create awareness and prioritization by entrepreneurs so they can help their startups address and smoothly navigate regulatory and industry standards processes.

Starting this contribution section with common oversights experienced by hardware technology entrepreneurs, underlining the importance of this research.

- **Delayed prioritization of compliance:** Most startups fail to prioritize regulatory and standards compliance, especially in the early stages when they are managing numerous priorities. In addition, startups were not fully aware of the legal requirements necessary for market entry until they were far along in the product's development.

  This lack of early awareness brings about several specific challenges:

  – **Inadequate understanding of compliance requirements:** The first challenge involved startups underestimating the complexity of the compliance landscape they were facing. Participants indicated that compliance often involved more steps, more specific

knowledge, more time, and greater costs than initially expected or consulted on, especially when entering strictly regulated markets.

  - **Unanticipated processing times of notified bodies:** Participants shared experiences where their timelines for obtaining certification were not in line with the evaluation process times needed by notified bodies, leading to significant delays. For example, the certification process of Participant 2 took 7 months instead of the estimated 8-10 weeks, stalling their market entry.
  - **(Overlooked) financial burden of compliance:** Participants commonly expressed the significant costs they had to pay notified bodies for the compliance processes, ranging from 10.000 euros up to 250.000 euros, depending on the type of compliance process i.e. certification. In addition, several underestimated the financial impact of this process, at least hindering agility during development.
  - **Complexities of international compliance:** Startups targeting multiple markets often encounter additional complexities in managing different layers of compliance across various international regions. This complexity hindered their ability to scale efficiently and caused delays in international market expansion.

- **Misalignment between iterative development and linear certification processes:** Hardware startups struggled to align their iterative product development approach with certification requirements, particularly since certification often required design freezes that conflicted with continuous iteration i.e. build-test-revise cycles as discussed in the literature.
- **Industry standards as market barriers:** Lastly, participants explained that industry standards, although not legally required, were sometimes seen as essential for market access. Furthermore, other incumbent competitors even used them to prohibit innovations within the market.

All participants mentioned that regulatory and industry standards compliance can at least be challenging to effectively navigate the compliance processes, required for the startups. The following practical advice could be taken into consideration.

Practical recommendations for future hardware technology startups

- **Understand your compliance landscape from the beginning:** Despite the industry you are in, begin your development process with a solid understanding of regulatory and standards compliance, applicable to you. Early awareness of these requirements helps avoid costly redesigns and delays by ensuring that compliance requirements are embedded in the product design from the beginning. In addition, finalising your designs or ensuring minimal adjustments are needed after certification, prevents halting product development during certification reviews.
- **Engage with external expertise:** Don't navigate compliance alone. Reach out to peers, industry experts, consultants, or notified bodies to get a comprehensive view of what's required in your industry. Depending on the complexity of your compliance needs, choose the right support that best aligns with your needs.
- **Allocate adequate resources:** Budget your expected costs, time, and other resources required to prepare documentation and undergo audits to avoid financial setbacks or time delays. In addition, revise this budget when more knowledge is available.
- **Adapt iteration cycles to meet compliance needs:** While the lean startup method encourages continuous iteration, you must tweak this approach to work within regulatory constraints. Consider using pilot testing in mock environments when full deployment in the intended market is not yet feasible due to compliance limitations (especially relevant in strictly regulated industries).

- **Anticipate international compliance early:** Startups with global ambitions are advised to thoroughly research and embrace compliance requirements across different regions early on. Developing a region-specific strategy for certification will contribute to easier international market entry.
- **Compliance as a strategic opportunity:** Compliance processes are regularly expressed as a hurdle. However, recognise the business value they add to your company. As underlined by participants, especially industry standards can enhance customer trust, and maturity, and establish market credibility, setting you apart from your competitors.

The practical implications derived from this study highlight the need for early, engagement with regulatory and industry standards in hardware technology startups. Furthermore, they emphasize the challenges related to lean startup development. By learning from the experiences of others, future entrepreneurs can avoid common oversights, better allocate their resources, and navigate the processes more effectively.

The practical advice has also been implemented in the infographic seen in appendix G. Visualizing the research implications in a satirical way.

8.3.3 Implications for startup investors, incubators and academia

Besides entrepreneurs, startup investors, incubators, and academia could also benefit from this research. First of all, startup investors can understand the complexity of compliance processes and therefore account for the long certification processes and associated financial needs. Furthermore, if investors encourage startups early on to prioritize compliance requirements, this can minimize delays and increase long-term value. This is also of importance for startup incubators since they can provide comprehensive support for hardware-related regulatory and standards advice. This could involve partnerships with legal advisors or certification experts. In addition, they could offer programs specifically focussed on accounting compliance restrictions in iterative development. Also, academic institutions could better identify the significant impact of regulatory and standards compliance. In addition, they could create programs that teach future entrepreneurs the knowledge to address compliance early on. Collaborative research between academia and industry can help define best practices for balancing innovation and regulatory constraints.

9 Conclusion

9.1 Key findings

The main goal of this research is to explore the impact and way technology-based hardware startups align lean startup methodology and compliance with regulatory and industry standards. This is due to the overall surge seen in entrepreneurial activity, and the recent attention this topic has received at the European Commission level. During the systematic literature review, a gap was found regarding this. While several barriers to startup growth are identified and widely covered, regulatory and standards compliance were not (extensively) covered. Furthermore, the literature highlighted that hardware startups inherently face challenges not seen by their software counterparts. In addition, an explorative study on the regulatory and industry standards environment was performed to get a comprehensive understanding of the landscape that awaits startups. Eventually, via semi-structured interviews, a qualitative study was performed to further explore the coherence between iterative development and regulatory and standards compliance within startups. The study showed startups use validated learning principles to iteratively test and refine their business and some technical hypotheses, despite the complexities introduced by hardware development. Due to the physical nature of the hardware, startups face constraints in testing prototypes, ranging from the high costs of building MVPs to difficulties with pilot testing in regulated environments. Nonetheless, early customer interaction proves crucial in validating both technological and business assumptions, helping startups find product-market fit and build customer-driven solutions.

In addition, the regulatory and industry standards landscape, visualized in Chapter 4, plays a central role in shaping hardware startup development. Startups must comply with legally mandated regulations on the technology and product levels, often treating these as design constraints. While industry standards offer flexibility, adhering to them can signal maturity and responsibility, easing market entry. However, some startups push for innovation by challenging or updating outdated standards, especially when their technology does not fit within existing frameworks.

The regulatory and standards landscape can, as explored, significantly influence startup development. This is also reflected in the main research question of this study, which is stated as:

"How can technology-based hardware startups include regulatory and industry standards compliance during the development process of their technology and products?"

A startup must be aware of the regulations and standards relevant to its market. Depending on the industry and with it the market requirements, the priority is thereafter determined. However, early on awareness is at all times desired. To be more specific, regulations and industry standards are market requirements and should be challenged during the research and opportunity phases. Experienced startups also advised on asking potential customers what regulations and industry standards they require the product to meet.

After awareness of regulations is acquired, startups can choose to decide to actively invest in time and resources themselves, to figure out specific requirements, and to work on compliance processes. Or, they can seek external help, via consultants or other experienced. Although startups in compliance-critical industries such as Automotive, MedTech, and HealthTech often engage external consultants, others rely on internal efforts and market feedback to identify requirements. Consulting suppliers and responding to customer inquiries further helped to understand compliance requirements.

The impact of regulatory and industry standards on iterative development is in all cases substantial and increases by the regulatory strictness in certain industries. Compliance can delay development cycles, introduce unexpected costs, and create challenges, due to startup oversights or long processing times at notified bodies. In addition, the study found that once startups

recognize the importance of compliance, they dedicate resources to building internal teams to approach the process, underlining the significant impact. Also, some startups even suggested that if they had fully understood the complexity and resource demands of regulatory compliance, they may have reconsidered their development path.

Finally, the timing of compliance efforts is critical. Startups operating in less-regulated industries tend to follow sequential steps after initial pilot testing, while those in strictly regulated sectors initiate compliance actions earlier, often before development begins. Early regulatory awareness, combined with proactive steps to meet certification requirements, ensures that startups avoid costly retrofits and market delays. Regulatory compliance must be acquired before products can legally enter the market, while industry standards can be acquired later during the introduction or growth phases.

In conclusion, hardware startups face significant challenges in complying with industry and regulatory standards while aligning lean principles in development. Early awareness, market validation, and strategic alignment of compliance requirements with product development phases are essential to overcome these hurdles and efficiently launch hardware innovations into regulated markets.

9.2 Limitations

All research has limitations that should be clearly acknowledged. For this research, the qualitative nature gives a subjective bias from the author (Nowell et al., 2017). Although a systematic methodology is used to perform this qualitative study, the author's personal experiences, environment, skills, and perspective unconsciously shaped the research, including literature review, regulatory landscape study, participant selection, data collection, coding, analysis, and interpretation. In addition, subjectivity can occur in establishing sequential steps during the timeline analysis. By using the systematic sequential steps described in the methodology section, this limitation has been minimized and could also be further reduced through peer reviewing. Additionally, it is important to recognize the subjectivity of the participants. Their decision to participate in this research suggests a likely alignment with the challenges regarding standards and regulations outlined in the invitation, which may involve a form of subjectivity within their responses. However, this is partly mitigated due to the validation of found results by a startup investment manager, and NEN standards consultant.

Beyond the limitations of the qualitative content analysis, it is essential to acknowledge the constraints of the literature review and exploratory study on the regulations and industry standards landscape. The literature review is not without its flaws, partly due to the scarcity of directly related research, which necessitated the use of broader search terms. However, broader search terms lead to lots of articles being rejected. After the first systematic search, a snowball method has been applied for further exploration of the literature. By employing this review approach, a selection bias has to be recognised. The process of selecting is inherently subjective, potentially excluding relevant studies that offer alternative perspectives (Kitsiou & Paré, 2017). Furthermore, the sampling size could result in a non-diversified representation of articles, only discussing concepts from one perspective. Additionally, the limited sample size could result in a non-diversified representation of perspectives, while synthesizing findings from various studies results in overgeneralizing conclusions and overlooking individual methodological shortcomings. The exploratory study provides a broad overview of the regulatory landscape. However, due to the limitations of this thesis, it does not cover every possible regulation in detail. Also, it only prescribes the basic landscape of legislation and standards, lacking in-depth insights. Furthermore, the approach lacks the reliability and rigour of a full systematic review, as it now only involves selective academic articles and legislation, and industry standards of regulatory bodies. Also, the selective approach may lead to potential biases in the interpretation of the regulatory environment.

Furthermore, the sample size for the interviews is limited. In addition, two-thirds of the startups

are linked to the Delft University of Technology. Because of this, the results may not be representative of a broader population, making it difficult to generalize the research findings. However, because startups from several industries and with varying personal experiences were interviewed, the impact of this limitation is minimized. In addition to this, the decision to interview participants from a range of industries also resulted in the inability to generalise within one industry.

Also, because this study is performed as a master thesis project, there are time and resource limitations. The qualitative approach provides for rich data collection. However, this demands significant time and resources to handle, resulting in less available time for more in-depth analysis or further validation. Lastly, the reliability and applicability of this study must be noted. Given the flexible nature of the methodology for this study, replicating the same conditions or responses in future studies may be challenging. In addition, this limitation is minimized by following a clear step-by-step methodology, prescribed earlier.

9.3 Future research

The explorative nature of this study resulted in perhaps even more questions than it started with. First of all, it would be interesting to study whether hardware technology startups in other global regions, for example, the US, have the same experiences and attitudes towards regulatory and standards compliance, as the results found in this study. In addition, industry-specific research regarding the challenges associated with regulatory and industry standards would allow for more focused insights into the effects and specific challenges faced by the startups in that industry.

Secondly, future research could explore how the challenges identified in this study differ and relatively impact the barriers to growth discussed in the academic literature reviewed at the outset of this research. The premise of this research is that there is a gap in the literature regarding hardware startups and their interaction with regulations and industry standards. However, it would be valuable to conduct a quantitative study to explore how challenges related to compliance, compare to other growth barriers, such as finding venture capital, business models, product development, etc.

In addition, it would be valuable for future research to explore how entrepreneurs' prior competencies, such as their educational background and work experience, influence their understanding and approaches to regulatory and standards compliance. This study highlighted that participants with specific prior experiences were often more aware of the importance and impacts of compliance processes. Future research could investigate whether inexperienced young entrepreneurs, especially those from academic spin-offs, may lack the same depth of understanding and prioritization for compliance requirements as those with previous industry experience. Understanding these differences could provide insights into the support needs of early-stage entrepreneurs.

Also, this research provided several key insights on oversights, mistakes and retrofits startups had to make to acquire compliance. Future research could explore how startups should be guided to prevent others from making the same mistake. A part of this could also be how academia can support academic spin-off companies in navigating industry standards and regulations. In addition, it would be interesting for future research to seek methods on how to make startups aware of the importance of regulations and standards compliance.

Furthermore, the results of this study also revealed the costs associated with compliance were challenging for startups who typically lack financial resources. Due to this, a standardization body was challenged on the following question: "Does the business model, which requires the purchase of standards and certifications, inherently inhibit innovation?". This is contrary to governments that want to stimulate startups and more mature companies, to innovate. Future research could challenge this and potentially seek methods to make standardization and regulatory compliance easily accessible for companies.

Lastly, inconsistencies in regulations emerged as an unexpected finding in this research, revealing their impact on startup development and performance. While this was not the primary focus of the study, the results indicate that varying and inconsistent regulatory frameworks can create challenges for startups, affecting their ability to scale and implement compliance requirements effectively. These inconsistencies may force startups to navigate differing legal environments or pivot their initial developments, slowing their progress and diverting resources away from core activities. This finding opens up a potential field for future research. Examining how startups adapt to or are constrained by regulatory inconsistencies could offer valuable insights into their flexibility and long-term success.

All mentioned possibilities for future research would contribute to the broader understanding of how regulatory and industry standards frameworks influence startup ecosystems, potentially finding recommendations for policymakers, standardization bodies, academia, and startup investors and incubators, that could better support startup growth.

9.4 Reflection

I experienced this master's thesis as a challenging yet highly interesting journey. I was especially intrigued by the opportunity to conduct qualitative foundational research at a startup in collaboration with the Delft Centre of Entrepreneurship, an experience that matched my enthusiasm for practical and impactful research. Although the thesis presented significant challenges, consistent work and well-structured planning, which I refined several times each week, made it manageable. This process contributed to my professional and academic growth. Being in an office environment surrounded by ambitious professionals inspired and motivated me, while engaging with entrepreneurs working hard to bring their technologies to market, reinforced my commitment and drive to extract the maximum value from this research.

Academically, I deepened my understanding of qualitative research methodologies, enhancing my ability to critically understand and engage in research conducted by others. The skills I gained in the Management of Technology (MOT) program at Delft University of Technology aligned seamlessly with the knowledge required for this thesis. Courses focused on emerging breakthrough technologies, my specialization in entrepreneurship, and the comprehensive insights from the Technology, Strategy, and Entrepreneurship course provided a strong foundation for this thesis.

Moreover, the findings from this research have the potential to provide a meaningful contribution to the existing MOT and DCE programs. Specifically, there is a gap in awareness of legal and industry standards within these curricula. The knowledge gathered throughout this research could help future entrepreneurs develop initial awareness and improve their ability to navigate compliance challenges, thereby enhancing the relevance and applicability of their education.

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Appendix A Elaboration of technology readiness levels

Technology Readiness Levels (TRLs) are a standardized framework used to assess the maturity of a technology throughout its development. The TRL levels are divided into nine stages, ranging from basic research, to fully market-ready. This helps organisations, researchers, and others to evaluate the progression of technologies, ensuring a consistent understanding of the development. The different levels, as stated by (Rijkdienst Ondernemend Nederland, 2022) are listed below.

1. TRL 1 Fundamental research: Initial research is conducted on the innovative idea and the basic principles of the innovation.
2. TRL 2 Applied research: The technological concept and its practical application are formulated. There is a main engagement in experimental and/or analytical research.
3. TRL 3 Proof of principle: The feasibility of the concept on an experimental basis is investigated. Various components of the concept are tested and validated.
4. TRL 4 Prototype implementation and testing: The proof of concept is tested on a lab scale. A prototype is developed at this stage, which is relatively inexpensive and quick to produce and is still far from a final product, process, or service.
5. TRL 5 Prototype validation: The operation of the technological concept is tested in a relevant environment. Which is seen as the first step in demonstrating the technology. A prototype developed at this stage takes more time and money and is close to the final product or system.
6. TRL 6: Prototype demonstration in a test environment: The concept is extensively tested and demonstrated in a relevant test environment. Testing takes place after technical validation in a relevant environment, such as a testing ground. The concept provides insights into the operation of all components together.
7. TRL 7 Prototype demonstration in an operational environment: The concept is tested and demonstrated in a user environment to prove its operation in this setting. The demonstration of the concept in a real-world environment provides new insights for the final market application of the innovation.
8. TRL 8: Product/service is completed and operational: in this phase the innovation gets its final form. The technological operation is tested and proven to meet set standards, qualifications and expectations.
9. TRL 9 Market introduction of technology: The innovation is technically and commercially ready. The entire development process is completed, and the knowledge to introduce the innovation to the desired audience is known.

Appendix B Consent form interview participants

Consent form – interview master thesis "The influence of regulatory and industry standards compliance on hardware technology development in lean-startups"

You are being invited to participate in a research study titled "The influence of regulatory and industry standards compliance on hardware technology development in lean-startups". This study is being done by Alex Dekkers from the TU Delft and Villari.

The purpose of this research study is to gain knowledge about how startups should deal with product regulatory and industry standards compliance, during the development process of their technology and product, and will take you approximately 30-45 minutes to complete. The data will be used for analysis to provide findings for the master thesis. We will be asking you to provide your experiences and knowledge about lean/agile product development and having to deal with regulatory and industry standards compliance within development. We will ask questions about when regulations and standards became important in your company's development process, and how you found out about the importance of compliance.

As with any online activity the risk of a data breach is always possible. To the best of our ability your answers in this study will remain confidential. We will minimize any risks by only using your name and companies name for administrative tasks. Within the thesis itself only analysis results and anonymised claims will be used to make arguments. It is not the intention to reveal business-sensitive information. Only descriptions of experiences and choices are desired knowledge. De interview transcriptions will be stored on the TU Delft OneDrive, which is accessible for the master student, first and second supervisor. After conducting the interview, the transcription will be sent to you (participant) for approval.

The audio recording of the conversation will be deleted at the latest one month after the completion of the thesis. The transcript will be preserved up to 2 years at TU Delft, under the responsibility of the Victor Scholten and Geerten van de Kaa. The transcript may be reused for future scientific or educational activities by TU Delft on the topic of [regulatory compliance and adoption by startups]. If the transcripts are used, you will be anonymous in any and all outputs created based on your inputs.

The thesis is being conducted in collaboration with Villari, as they have encountered regulatory challenges during their entrepreneurial journey. However, Villari does not have access to or possession of the interview transcripts. They only have access to the general knowledge gained in the thesis.

Your participation in this study is entirely voluntary and you can withdraw at any time. You are free to omit any questions.

The responsible researcher and first supervisor for this thesis is: Victor Scholten, v.e.scholten@tudelft.nl
The corresponding researcher is student: Alex Dekkers, a.j.a.dekkers@student.tudelft.nl

Additional consent	Yes	No
I give permission for anonymized quotes to be used in the thesis to substantiate arguments. Anonymized quotes are statements made by participants that have been anonymized and are therefore no longer traceable to the participant.	☐	☐

Signatures:

Name of participant [printed] Signature Date

I as a researcher have accurately read out the information sheet to the potential participant to the best of my ability, ensured that the participant understands to what they are freely consenting

Researcher name [printed] Signature Date

Figure 18: Consent form signed by each interview participant

Appendix C Semi-structured interview questionnaire

Interview - Influence of regulatory and industry compliance on hardware technology development

Definitions list – to discuss before interview starts

To ensure clarity, the following meanings are used during the interview.

- **Technology**: Technology refers to the fundamental innovation developed to solve a specific problem or perform a particular function. It is often the underlying mechanism or scientific principle that makes a solution possible, such as microprocessors, sensors, and robotics, as well as advanced systems like AI, IoT, or big data analytics.
- **Product**: A product is the specific application of a technology that is designed, packaged, and offered to the market to meet customer needs. It's the tangible or intangible item that consumers can purchase or use, often subject to regulatory standards to ensure safety, quality, and compliance. Examples include electronic devices that must meet CE, UL, or CSA regulations.
- **Regulatory compliance**: Refers to the adherence to laws, regulations, and government-issued guidelines that are mandatory. These can vary in different regions. Examples are GDPR, NIS2, DSA, the AI act, Blockchain act, etc.
- **Industry compliance**: Refers to adherence to standards, and guidelines that are typically established by standards organizations like ISO. This is done to align with the expectations of the industry, customers, and partners, even though these standards are not legally required.

Introduction questions

- Could you please introduce yourself and describe your role within the company?
- What kind of technology has your company developed?
- What is the product that your company offers to its customers?

Lean startup practices

- How familiar are you with the Lean startup methodology?

Very unfamiliar	Unfamiliar	Neutral	Familiar	Very familiar
☐	☐	☐	☐	☐

- Did you actively apply the Lean startup method during the development of your startup?

Not at all	Rarely	Sometimes	Often	Very often
☐	☐	☐	☐	☐

- How has the Lean startup approach influenced the development of your business and technology?
- What methods did you use to validate business or technological hypotheses?
- How did you measure progress through validated learning in your development process?

Figure 19: First page of the interview questionnaire

Regulatory compliance

- What specific obligated regulatory compliance did your technology have to meet?
- And was their extra regulatory compliance your product had to meet?
- How did you/your company first become aware of the regulatory requirements?
- How did you implement these regulations
- Were you able to validating business and technology hypotheses in the market in parallel?
    - Moreover, did compliance requirements limit your iterative development process?
- When did you take steps on regulatory compliance?
    - Goal is to indicate this on the given timeline
- What factors influenced the timing of your compliance efforts (e.g., market pressure, resource availability)?
- Towards entrepreneurs starting their new businesses. When would you advise them to start looking into regulatory compliance / acting on it?
- Optional: Who was involved in the decision-making process regarding regulatory compliance?
- Optional: Did someone advise you on regulatory compliance?
- Optional Did the need to comply with regulations lead to any significant changes in your product?

Industry standards compliance

- Besides regulatory compliance, what industry standards or certifications were necessary for your technology?
    - Where their other additional industry standards required for your product?
- How did you find out about these industry standards or certifications?
- When did you find out about industry standards during the development process?
    - Why did you choose to comply at the particular stage you did?
- How did you implement these industry standards while validating hypotheses in the market?
    - Moreover, did compliance requirements limit your iterative development process?
- What factors influenced the timing of your compliance efforts (e.g., market pressure, resource availability)?
- Optional: Did you collaborate with industry experts or consultants to achieve compliance?
- Optional: Did the need to comply with industry standards lead to any significant changes in your product?

Follow up questions

- What would you do differently in the context of the compliance process, if you would have had more resources or more time to develop your technology?
- Where their individuals or organizations who advised you on regulatory compliance?

Figure 20: Second page of the interview questionnaire

Appendix D Deductive codebook

Core concepts	Definition	First order Themes	Definition codes
Validated learning	Process of continuously testing assumptions through data-driven feedback and iterating product development	Technical hypothesis	Testing technology and product performance and functionality
		Business hypothesis	Testing market demand, customer needs or business model viability
		Customer feedback	Feedback from customers is used to inform within development
		Iterative learning	Cycles of testing and refining based on results from hypothesis validation
Lean startup methodology	Systematic approach for startups to efficiently develop products by using validated learning and continuous iteration	Familiar with Lean startup	A participant is familiar with the principle of the Lean startup methodology, and has potentially applied these in their companies development
		Unfamiliar with Lean startup	A participant is unfamiliar with the principle of the Lean startup methodology
		Resource limitations	Budget, knowledge, time, or personnel constraints during startup development
		Hardware- specific difficulties	Unique challenges to hardware development in rapid iteration and product development
		Progress	Keeping progress of learned principles and startup development
		Way-to-market	Refers to the way that startups bring their product to market via minimal viable products (MVPs)
Regulatory compliance	Ensuring that technologies, products and processes meet legal standards at various geographic levels	National compliance	Compliance with Dutch laws
		EU compliance	Compliance with laws stated by the European Union
		International compliance	Compliance with other international laws
Industry standards compliance	Meeting industry-specific standards to ensure the product meets certain quality or safety thresholds, for accessory industries	Industry standards	Compliance with unique standards set by standardization bodies, for the associated industry
		Reason to comply with standards	(Strategic) decision to comply with additional industry standards
		Industry networks	Specific learning or knowledge from other startups in the same industry
Knowledge on compliance	The depth understanding about regulatory and certification processes in relation to the startup development	Decisions on obtaining certification	The actions and considerations for an organization or product to achieve formal certification
		Cost implications	Discussion around money invested to achieve compliance and certification
		Duration compliance	Discussion around the time taken to achieve compliance and certification
		Experience with regulations	Prior experience of the participant or others involved in the startup, on the impact of compliance processes
		Prior knowledge on regulations	Prior knowledge of the participant or others involved in the startup, on regulations and industry standards required for the startup
		Consult on regulations	Seeking legal expertise or consulting on regulations and industry standards
		Effect compliance	Major impact due to industry standards or regulations compliance on the startup development
Steps on compliance	Sequential steps taken by the startup from getting awareness on regulations and standards compliance, until the step that they are fully compliant	Awareness creation	First awareness or contact on regulations or industry standards by the startup team
		Understanding regulations	Consciously understand industry standards and regulations and also know what must be met to comply
		Actively working on compliance	Actively adapting products or processes to meet the required requirements in regulations and standards
		Being fully compliant	Have implemented all product and process requirements, but have not yet applied for compliance
		Certification acquired	Technology, product or process is fully complaint with regulation and standards, and is positively assessed by a regulatory body
Missteps and learnings	Instances where startups missed regulations or industry standards, and their actions to rectify mistakes	Compliance oversight	Instances where startups missed regulations or industry standards, and therefore had to adjust
		Cause correction	Actions taken to rectify compliance mistakes
		Iteration restriction	How regulations and standards limit the ability to pivot during MVP iterations
		Delays due to compliance	Extended timelines due to certification or legal approval processes, which were not foreseen
		Partial testing	Strategies for validating some aspects while waiting for compliance, or not fully testing due to compliance restrictions
		Prototype/pilot	Pilot testing due to restraints for market entry, while not being compliant
Timing compliance	The point in the development timeline when startups begin addressing and adopting compliant measures	Regulation driven changes	When design or functional pivots occur specifically due to new compliance knowledge
		Design freeze point	When the startup locks design to ensure compliance
		Early awareness	Startups that have knowledge on regulations and industry standards from the beginning
		Early adoption	Startups that plan compliance from the beginning
		Retrofitting compliance	Adjusting an existing design to meet regulations

Table 7: Deductive codebook

Appendix E Inductive codebook

First order Themes	Definition codes	Core concepts	Definition
Roadmap	The strategic plan or steps tat a startup follows to achieve technology and product development and market entry, also include regulatory and industry standards compliance	Startup roadmap	Highlights the progression from ideation to product-market fit as the company evolves from a simple idea to a stable, mature business.
Startup Development	The stages and growth milestones a startup experiences, from concept to market-ready product		
Advice for others	Insight or guidance shared by entrepreneurs to help future startups navigate similar challenges		
Multinational vs. startup	Contrasts how large multinational corporations versus lean startups handle product development, particularly in terms of multidisciplinary involvement in the developmen	Lean startup methodology	Systematic approach for startups to efficiently develop products by using validated learning and continuous iteration
Technology vs. product	The distinction between developing the technology itself and creating a market desired product. Highlighting the differences in needs and priorities		
Iterative development	The process of continuous product development and improvement, often involving repeated cycles of testing, feedback, and iteration		
Reason to comply with legislation	The motivations behind startups ensuring their products meet geographically required regulations	Regulatory compliance	Ensuring that technologies, products and processes meet legal standards at various geographic levels
Market requires legislation	The principle certain markets are only accessible if a product adheres to regulatory standards, expressed by the market		
Market requires certification	The necessity for products to have industry specific certification, to enter and compete in accessory markets	Industry standards compliance	Meeting industry-specific standards to ensure the product meets certain quality or safety thresholds, for accessory industries
Entrepreneurial behaviour	The action and decision-making process of entrepreneurs when dealing with regulatory and industry standards compliance matters	Knowledge on compliance	The depth understanding about regulatory and certification processes in relation to the startup development
Uncertianty / unclarity of regulations	Regulations and industry standards are vague or hard to interpret and understand for startups teams, making compliance challenging		
Unclear regulations or standards	Industry standards or regulations governing a product are not in place, ambiguous, causing confusion for startups		
Decide on regulations and certification	The decision-making process startups undergo to take certain steps in their development		
Lack of attention on importance regulation	Instances where startups overlook or underestimate the role or impact of regulations, leading to delays, mistakes or other effects	Missteps and learnings	Instances where startups missed regulations or industry standards, and their actions to rectify mistakes
After market introduction	ompliance steps that are addressed after the product is introduced to the market	Timing compliance	The point in the development timeline when startups begin addressing and adopting compliant measures
Before market introduction	Compliance steps that must be completed before a product is introduced to the market		
Pilot phase	The initial stage of testing products, often to identify areas for improvement before full market introduction		

Table 8: Inductive codebook

Appendix F Relational Analysis

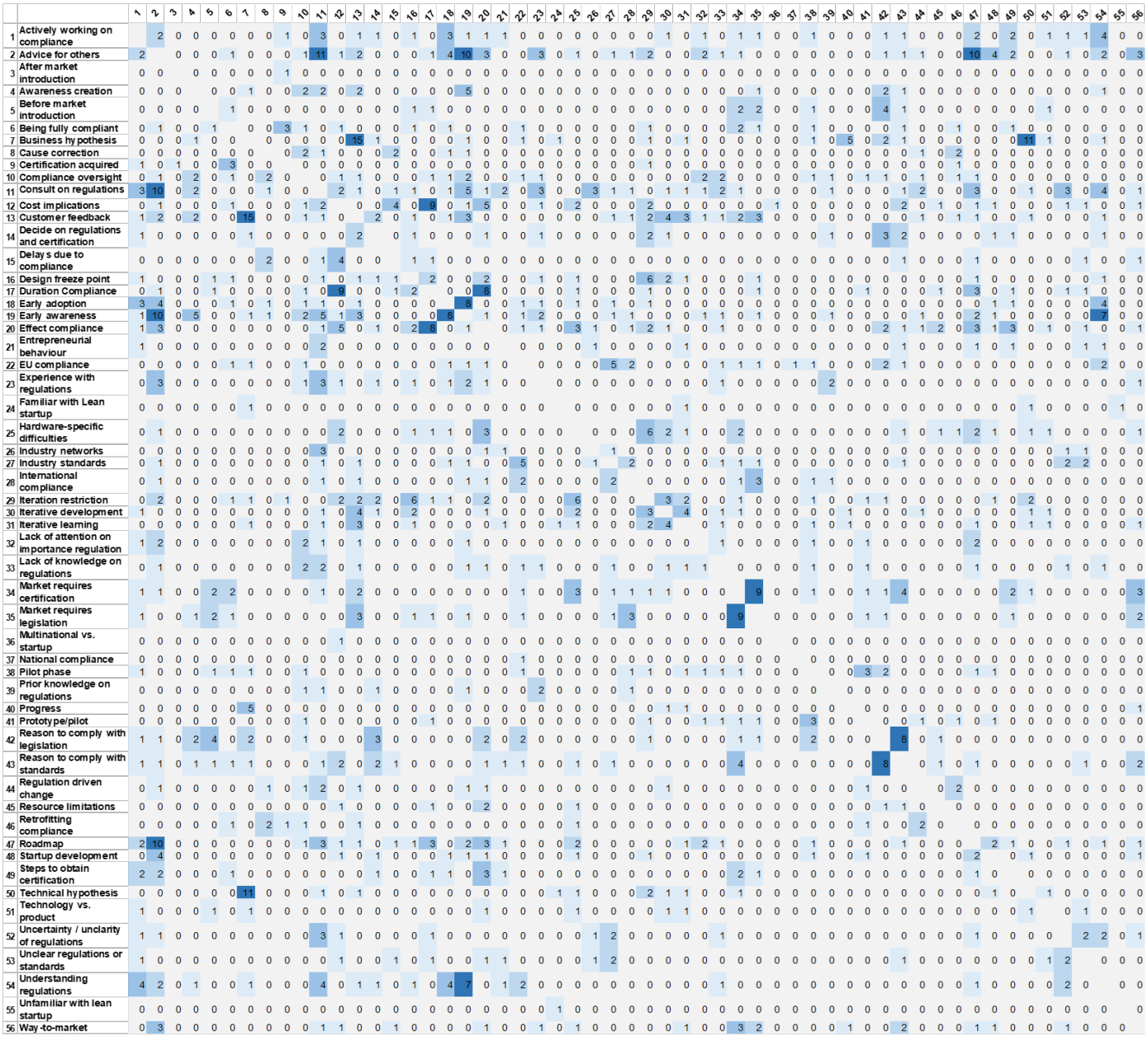

Table 9: Results relational analysis - co-occurrence results

Appendix G Infographic: Practical implications

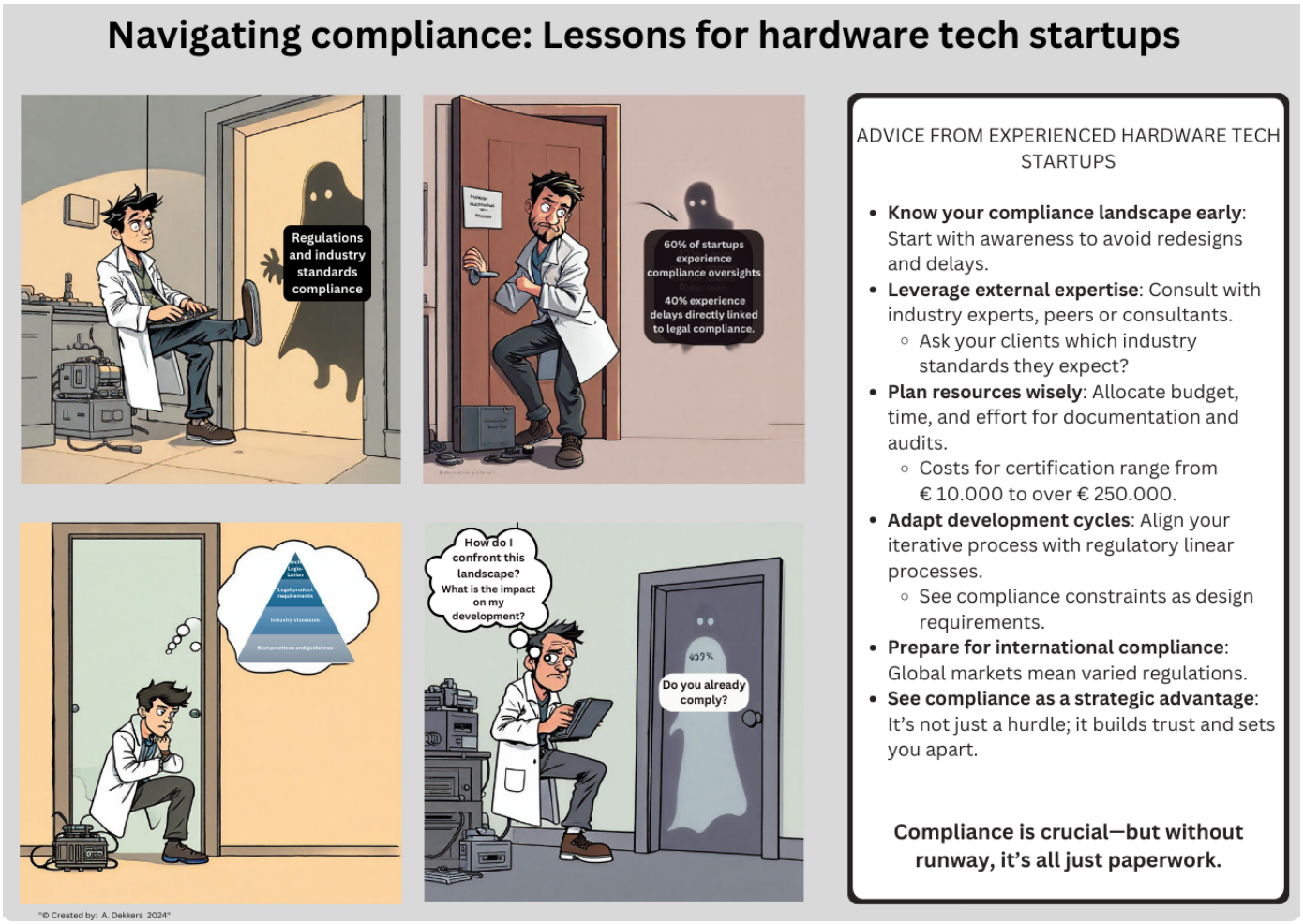

Figure 21: Infographic: Recommendation to hardware tech entrepreneurs

Appendix H Results interview comparison analysis

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Participants	1	2	3	4	5	6	7	8	9	10	11	12
Interview job role	CEO and Founder	COO	CEO and Founder	CEO and Founder	COO and Founder	CEO and Founder	CEO and Founder	CEO and Founder	CGO	CFO and Founder	COO	Former founder and angel investor
Industry	Engineering	MedTech	Engineering	Advanced Technology	Automotive	Automotive	HealthTech	MedTech	Computing	MedTech	Engineering	Engineering
Participants perceived their market as strictly regulated	No	Yes	No	No	Yes	No	Yes	Yes	Yes	Yes	No	
Size of startup	10 - 50	1 - 10	1 - 10	10 - 50	1 - 10	1 - 10	1 - 10	1 - 10	10 - 50	10 - 50	10 - 50	201-500
Year of founding	2020	2020	2022	2014	2019	2015	2019	2022	2014	2020	2020	2007
Familiarity with lean startup scale: 1 = Very unfamiliar, 5 = Very familiar	5	3	1	5	5	5	4	5	4	4	5	2
Actively used lean method scale: 1 = Not at all, 5 = Very often	4	3	2	4	3	5	4	4	3	3	5	2
Attitude towards compliance												
Impact of compliance in overall development	CE is the only really mandatory certification, we must have it.	Yes, when you have a relative product that is already nearing the final phase, it has some impact. You actually go back, redesign certain parts. That takes a lot of time, and money.	N/A	So I think we're quite familiar and comfortable with CE. We also supply a lot to America these days, so the demand for UL certification is increasing. (...) Struggling is trying to clarify everything.	Massive, super big part of the whole company development.	So our production line, you're going to see it soon when we get down there. fully complies with automotive standards. These are also inspected every year by the RDW, for example	For example, applying for such an MDR 2A will cost 250,000 euros. We also had that calculated in that report. That's just an amount, not realistic for us to spend now	So you'll first need to provide evidence that your product is safe and effective. That is such a costly exercise and time-consuming.	We are dealing with electronics legislation, but fire safety was also a major theme, in combination with liquid storage and use.	This means that we have quite strict regulatory and quality requirements. So we must comply with ISO13485, and in Europe we have to deal with CE-IVD and in America with FDA approval	In principle, only CE is mandatory for the hardware. If we go to another market, for example America, UL will become mandatory.	If you, as a bunch of brats, start working with a device, then the first thing is. First we came from the offshore branch, so we had a professor who was really on top of that.
Limited in pilot testing	You are also in a pilot and demonstration phase of course. Customers also understand (...). The chance that you will have trouble (...)does not comply with CE regulations is therefore smaller.	If you're talking about a customer pilot, we haven't really been able to do that yet. We only piloted to get test results for ourselves	No, we are really looking for pilots, where we say, listen, we are still in a test phase, so there is no certificate yet. We really need to find pilots with parties that say, okay, fine	say, certification, we dare to plant a prototype system for a period of time, but that is not the same as when we actually sell it to a customer	Due to the legislation we weren't allowed to sell them for road use	You can only apply if you have a pilot that you 99% expect to be your end product. Otherwise there is no point in changing it again	In the meantime, we can operate by, for example, conducting pilot experiments. Then we can work without MDR.	You want to be able to iterate within those five, six, seven years. You cannot, as Mr Ries says, go to the market and collect feedback	we didn't have an agile development process yet. It was purely traditional waterfall process. We really had an end goal. It was very directive. We also didn't have much contact with the end users yet	We always have to be in a lab environment. No one wants to burn themselves with something that has not yet been certified.	For a commercial pilot, your customer must actually use your product. If you are already certified, the threshold for the customer to enter into a pilot project is much lower	Yes, the pilots, but with our own people on them. We never transferred anyone without a stamp. First the proof of concept, then the demonstrator in operational environment.
Delays due to compliance	N/A	initially approximately 8 to 10 weeks from testing to certification and final reporting. In the end it took 7 months. This means that for 7 months you can't actually do anything.	N/A	When we really get to that point where we are really going to introduce the product to the market. That you know how long it will take.	We were not aware of the time this process would take	Yes, so you have a two-year delay in delivering (B2B) sales to manufacturers. Which I think is now 70% of our turnover	N/A	N/A	You open one door and it turns out that there is a lot behind it. That has also sometimes caused delays	Well, we were two years old when we finished the QMS	That has a nice impact. The lead time for a notified body is simply very long.	N/A
Experienced oversights	The customer then said how is that possible, then you can't sell it. At that time we were completely at a loss for the meeting and that is still possible.	Then you think you've come a long way, but in the end we had to go back to the drawing board to make a number of significant changes to prepare the product for certification	And is that complete? Yes, that will be difficult, especially if you are in a new market or one with which you have little familiarity. Yes, then it is difficult,	N/A	We had to redevelop quite a lot of things over again. In general, just a huge amount of effort for being able to get started. A difficult hurdle we had to do.	At some point we had our first deal with a major German manufacturer. (...) I got back, please send me your ECR10 documentation. So we okay ECR10 what the fuck is that	Yes, we are now on burnout prevention, which is not medical, so we have completely drifted away from that title.	It's actually really weird startups experience oversights because it's just very well known that it's one of the streams. One of the disciplines in your multidisciplinary team in your core functional team.	You open one door and it turns out that there is a lot behind it. That has also sometimes caused delays	We thought, oh, we can just get something like this to market really quickly. But yes, that is not possible at all. So well, we built that entire QMS . I think about 250,000 euros went into the entire QMS	This was actually because a customer pointed this out to us. The customer gave feedback: Do you have this certification? We had to figure out what exactly this meant in terms of specific requirements	N/A
Developing an understanding and their approach to compliance												
Prior knowledge and understanding of compliance within the startup	In the beginning I didn't know anything and I just started building something and also started selling.	The experience that a product must meet, (...), to successfully pass such an audit. That was still missing from these young men	I of course have a background in that industry, so I know that a lot of regulations apply. This does not mean that I know which regulations apply,	But yes, we didn't have time for that or they had no knowledge in it,	Honestly if we would have known how difficult it would be we most likely not have done it.	Then you think CE quality mark, how should we get that	You just have to mess around a bit and at some point you'll run into a door somewhere.	Yes, my expertise is development in an ISO13485 certified environment. Dealing with standards that you have to meet and regulations.	Well, in that phase we used a very broad network. This worked with us on the technology. There were also experts who were actually deeply involved in this	The only reason we did that is that we knew someone who had his own diagnostics company and who said, yes, you have to do your regulatory piece	No, a customer pointed it out to us	First we came from the offshore branch, so we had a professor who was really on top of that;(...) not responsible for this?
Used an external consultant for regulatory and standards advice	You have to do that yourself, of course. You're not going to hire a consultant	That we did have an advisor from (notified body) look at our products	We ask a professional third parties collaborate to develop those sensors. Well, you can also acquire knowledge in this way	Interviewer: ... by hiring employees with knowledge of this or by consultants? Participant: No consultants.	There we met up with someone who knows the regulations and discussed what had to be modified	Do as much of it yourself as possible, because otherwise it will quickly become very expensive.	We had research done into it once. By someone who understands medical certificates,	That was the case with us too. But be aware that you are taking on a task that you are not an expert in. So you will have to call in expertise.	Namely people from the market	They then helped us a bit with which consultants you need	No, not consultants. We have started sparring with notified bodies	I really hate the word consultant. You're not going to call McKinsey. You are going to investigate that yourself and not pay a bunch of idiots a premium to find out something that you can do much better yourself.

Table 10: Section 1: Evidence to interview comparison analysis

Had others perform their compliancy efforts	After the investment round we decided To CE certify that sensor , deliberately externally at KiWa.	is that we did have an advisor from (Notified body) look at our products. To get a sense of where we are at the moment	What we are doing now is setting up a development process with 1 to 3 parties, (…) they specialize in the development of these types of sensors and also have specific and relevant regulatory knowledge in the industry.	Especially not parties that can do that certification, but yes. In other words, experience is how you deal with this pragmatically, that is the experience you need.	We started in the production facilities mostly. It wasn't even online back than. We drafted a document together with them.	We then had everything tested by external test houses. They generally have a lot of knowledge, and you can ask them a lot.	The product only have a CE certificate. So that is also self-certification	N/A	One of our shareholders is [Company Name}. They supply liquids. They have a lot of know-how in that area. We also use that. We also use those standards	We'll just work with a consultant and they'll know it all. Then we don't have to do anything and we will be told which documents we have to provide, what we have to do and when we are registered.	We asked the hardware supplier what regulations apply and how we should deal with them. This supplier indicated that we did not have to worry about that	Don't pay a bunch of idiots a premium to figure out something you can do much better yourself. So no, that is not an issue.
Internal person or team dedicated to compliance	N/A	At least, by bringing him in-house we did not have to engage a consultancy branch.	N/A	by hiring employees with knowledge of this or by consultants, for example? Participant No consultants.	We now have a main engineer that understands how the regulations work, and he has the knowledge on RDW. So that really helps us, and it is good to have him on board.	Do as much of it yourself as possible, because otherwise it will quickly become very expensive.	N/A	you just have to ensure that you get regulatory expertise in your team and that can be done by hiring someone.	There you also have to deal with packaging regulations. Then you take everything with you. Another team is then involved	The consultant also played a part, but at some point he could have done better by appointing someone to take over full-time. We have had a three-man Quality Regulatory team for a long time	N/A	I then went to London. Met a very good guy. (…). Then we had an open conversation about we are making something new. We want you to look at it, how can we fix this?
Advise given by participants towards other hardware tech. Startups												
Create early awareness on regulatory and standards applicable to the market to be targeted	If it is important, you must quickly include it in your development direction. In any case, you have to agree that it is an important part	If you are going to sell it, should it be certified or not? The moment the answer is yes, you can take that with you from day one	You need to know what rules apply to that market, (…) at the earliest possible stage	I think it is important if you are in a certain sector that you talk about requirements with parties at an early stage	It would be good if you could analyse the full situation and check how long this will take and how much it would cost	Think of regulations and check with potential customers and suppliers and from the market.	You want to know about it soon, but I wouldn't invest my time in it sooner	You want to demonstrate (…) at the beginning of the opportunity face. (…) technology is feasible and that it is feasible in terms of regulations	I would certainly look at the legislation and regulations with a consultant, early on. I would look at the standards with an end user	I think you should always gain knowledge first, because if you don't know then you're really going to go wrong	My advice would be to know what your laws and regulations can mean. So what is required for your product, what does it mean if I go to a different geographic market	You are very aware of what you have to do and then you can really do your best. Yes, you're a loser if you don't deal with this from the very beginning. Make every effort to know which hoops you have to jump through
Get thorough understanding on requirements as early as possible	N/A	This has an effect and influence on all choices that are made. The sooner you think about this, the better (…) design into account	You need to know what rules apply to that market, (…) at the earliest possible stage	N/A	It would be good if you could analyse the full situation and check how long this will take and how much it would cost	Then you at least know which list you have to comply with. The fact that you do not yet meet the requirements in that phase is not that interesting	There is still so much to manage, yes it is not the most important thing.	you have reached the end of an opportunity phase, (…), and that it can be certified in the countries you want.	N/A	Ideally, you would build first and then go on the water, so then you actually have to get all your documentation right in advance.	Do identify the requirements for your product. This ensures that you can immediately develop your product with these requirements taken into account	It needs to be on the radar. It should be taken seriously, but it doesn't have to be complete. There just has to be a plan. It has to be on the roadmap.
Outsource regulatory efforts to consultants	You have to do that yourself. You're not going to hire a consultant. Paying for this is absolute nonsense, especially in the early phase.	By bringing him in-house, we did not have to engage a consultancy arm.	they know If we want to develop this, we must take these standards into account	find people who already have experience with this and who have knowledge about this. especially parties that know how to deal with this pragmatically	N/A	you always want to do as much as possible yourself, because a little consultant costs easily 150 per hour.	N/A	You can also simply ensure that you find that expertise at a consultancy or at a regulatory expert, who becomes your employee or goes freelance	Yes you for the first section a consultant would be sufficient	N/A	No you shouldn't ask consultants.	N/A
Perform compliance efforts internally	You have to do it yourself, because you learn all kinds of things during that process	The team you gather around you, the sooner you can gain experience at the front end, (…), the better it is.	let's collaborate with professional third parties (..) .to bring the knowledge to your home	You want to find those self-employed people who also do this in the field and who simply have a lot of experience	it would be good to have from the beginning some experts on building quality systems. People who have dealt with it	Do as much of it yourself as possible, because otherwise it will quickly become very expensive	N/A	You can also simply ensure that you find that expertise at a consultancy or at a regulatory expert, who becomes your employee or goes freelance	You have to work them out in advance with your end goal insight, and then work backwards. (…). If you don't have that, you're just going to get into trouble	N/A	N/A	Someone has to be accountable for it and you have to set it in motion.
Proactively embed compliance process into the startup's roadmap	That is part of your path as an entrepreneur.	Startups that have the ambition to go to the market and whose product needs to be certified, build in sufficient runway	You have to take that into account business wise (…) that is a long and intensive process	I don't think it should be a top priority. Well, you have to be aware of it and you have to have a plan (…). That you know how long it will take.	It is keen to understand how much you need to do and how important it is for you. Try to get the minimum done as fast as possible	Then you at least know which list you have to comply with. (…), but you can take this into account in your planning	I would approach it more like, first make sure you solve a problem. That problem is in a certain control area. You have to deal with that.	In the early stages you have to realize it is multidisciplinary (…). So you need multiple expertise and that also required regulatory knowledge	You always have two roadmaps. One has to do with funding and one has to do with the market approach, compliance is part of that.	Well, you prefer to have someone who can help you, who you can hire to actually guide you in drawing up a plan for your startup.	When you embark on such a process, (…) at a much slower pace. You must take this into account and adjust your own development	Just by putting it into your planning. (…). You have to reserve people and budget for it and plan when you want it finished.

Colour scale attitude towards compliance	
High influence	
Moderate influence	
Low influence	
Not discussed in interview	

Colour scale understanding and approach compliance	
Very applicable	
Applicable	
Not applicable	
Not discussed in interview	

Colour scale advise given to others	
Highly recommended	
Recommended	
Not recommended	
Not discussed in interview	

Table 11: Section 2: Evidence to interview comparison analysis