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Lean Production Scale-up. How a startup can scale the manufacturing of physical product innovation

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This constructive research focuses on the business environment of a startup company with physical product innovation. More specifically, the focus is on the scaling of manufacturing in this context. The research aims to identify the critical challenges the startups face and what are the best practices for overcoming them. For the research, multiple entrepreneurs, employees, investors, and other stakeholders in the field were interviewed and invited to focus group discussions. The constructive output of this study is a guidebook written for startups in the named context at the beginning of their entrepreneurial journey.

Startups associated with manufacturing face a wide range of challenges unfamiliar to startups that operate solely in the digital world. When physical manufacturing is required, the need for heavy machinery, factory buildings, a wide range of human operators and robots, and the entire complex world of supply chain management are involved. Moreover, when manufacturing is associated with innovation, it means it is being done for the first time, increasing the level of uncertainty around the internal processes. To match the challenges, the startup must adjust its approach to risk management, innovation management, and business model design. The listed business topics translate into concrete challenges for the startup: Significant upfront investments are needed to development projects that take months or even years to complete. Committing to these decisions for a young developing company with limited data, experience, and unproven innovation is risky and very challenging. Additionally, the reliance on the supply chain means that external stakeholders largely impact the startup's fate, a clear difference to software development, where success in operation scaling is mainly dependent on internal factors. Lastly, the requirements related to manufacturing lead to extended time-to-market, a key metric for all startups.

The results of this thesis research and the strategic guidebook created based on it do not offer direct yes or no instructions to questions like should a PPI startup use a contract manufacturer or not to address the business challenges. Instead, a set of strategic key questions are presented that the startup management must evaluate and answer based on their unique business environment. Using the guidebook to assess its unique position in its business environment, a startup with physical product innovation can address the named challenges of limited flexibility, high-risk exposure, and extended time-to-market.

Keywords
Startup, scaling, innovation, business model design, growth, manufacturing.

Contents

Terms and Abbreviations

AI	Artificial Intelligence
Bits and Atoms	Bits companies earn profits by writing algorithms to provide a service or using them to outsmart financial markets. What they do not do is a physical product. Atom companies are the ones that manipulate physical objects.
Capex	Capital Expenditure
CDR	Carbon Dioxide Removal
CM	Contract Manufacturer
CTO	Chief Technology Officer
Design and Manufacturing Startup	A startup company that must address manufacturing processes and raw materials challenges.
Design-Only startup	A startup company that has no manufacturing processes.
GICS	Global Industry Classification Standard
ICB	Industry Classification Benchmark
IoT	Internet of Things
IP	Intellectual Property
LPS	Lean Production Scale-Up. LPS is the name of the business strategy model developed by the author.
LTSE	Long-Term Stock Exchange company
MVP	Minimum Viable Product
OEM	Original Equipment Manufacturer
Opex	Operational expenditure

PPI Startup	Physical Product Innovation Startup. PPI Startup is the term used for the companies in the scope of this thesis.
R&D	Research and Development
S&P	Standard and Poor’s company
Startup company	A human institution designed to bring something new under conditions of extreme uncertainty and aim for high growth.
Startup unicorns	A startup company with a valuation of one billion dollars or more
TPS	Toyota Production System

1 Introduction

Today the market entry for new ideas and entrepreneurs is easier than ever as the digital age is reshaping how business is done (Rindfleisch & al. 2017). Through digitalization, the business environment has become highly open (Chesbrough & Appleyard 2007) and widely connected (Priem & al., 2018; Kotler, Kartajaya & Setiawan 2016, chapter 2). The combinations of digital technologies like edge computing and artificial intelligence, AI, enable new business model opportunities (Teece 2018). In this fast-changing environment, the most important thing is to learn as fast as possible what to do next and what is worth doing at all (Ries 2011). Multiple non-fiction books like The Four Steps to the Epiphany by Steve Blank, published in 2003, and Lean Startup by Eric Ries, published in 2011, study the modern internet-era startup business environment.

Still, one aspect has not been included in the broader public discussion. The tools presented in Lean Startup concentrate on finding the market fit as efficiently as possible but assume that the same level of uncertainties does not exist in the company's internal processes. “We wanted flying cars, instead we got 140 characters” is a famous quote by startup investor Peter Thiel (2011). Behind the quote is the notion that there is something different and more challenging about developing physical technologies compared to online services. Manufacturing, indeed, is an underrated problem. It is much harder to take an advanced technology and bring it to volume manufacturing than to design it in the first place (Fridman 2022).

Companies like Loudcloud, Spotify, PayPal, and Twitter had critical and untested assumptions regarding their business models when they started as startups, but they did not need to doubt if the service was doable technically. The situation is critically different for companies involved in a business where the product or the product’s manufacturing involves innovation. Industries facing these challenges in 2022 are, for example, biotechnology, plant-based alternatives for animal-based products, the space industry, and various forms of CDR, carbon dioxide removal. Examples of these startups are the world-famous Tesla Motors and Space X. This thesis report explores the unique business environment of startups with technological unknowns and ambitions to scale up the manufacturing of their physical product innovations.

The author has worked for different startups for over ten years. While the author’s employers have been from different industries varying from the medical and food industries to space technology and CDR, what is shared with all of them is that they all have been working with physical product innovation. While working with the challenges related to scaling the operations of a startup with physical product innovation, the striking difference to the software startup world so often described in popular culture became evident. The author got interested in understanding the differences between software and hardware startups, and the idea for this thesis research was born.

The thesis research was carried out in 2021 and 2022. The study took place in the middle of the COVID-19 pandemic, which impacted the execution. The pandemic limited the opportunities for the author to execute interviews in person. Instead, video calls were used.

Many industries in the thesis's scope are connected to developing new sustainable technologies to fight climate change and the loss of diversity in nature. To reach the targets set in the Paris climate agreement, humankind has an extreme urgency to find new solutions for its industries. The author wishes that the thesis findings make the Lean and Lean Startup concepts more approachable to companies working for a more sustainable future.

The constructive outcome of the thesis, a strategy guidebook, is presented to the reader in the appendix. The guidebook presents a concept named by the author Lean Production Scale-up, LPS. LPS is a four-step model designed to mitigate the risks and improve the odds of success for companies working with non-software high-tech innovation in untested markets.

2 Objectives

Chapter two presents the thesis's scope, expected outcomes, and research questions.

2.1 Scope: PPI Startups

The research covers the unique business challenge of startup companies scaling up the manufacturing of physical product innovation. More specifically, the scope covers manufacturing from the earliest stages, including the first manufacturing tests, to the level where manufacturing has reached the industrial level. The term used to describe the startup companies in scope is Startups with Physical Product Innovation, PPI startups in short.

There is no limitation geographically or by industry. However, it is worth noticing that the literature sources and the interviews conducted for this research are primarily from European and North American sources. How PPI startups approach topics such as sales, business development, marketing, human resources, and financing are touched upon only when there is a direct connection to the development of manufacturing capacities.

2.2 Expected Outcomes

As described in the previous chapter, the thesis project studies the business environment of a startup with physical product innovation and the scaling of manufacturing in this context. The author aims to identify the key challenges and aspects that the startups in the named scope are facing. Additionally, the target is to collect the best practices for overcoming the challenges based on real-life experiences by entrepreneurs, employees, investors, and other stakeholders in the field. The study results are presented in the form of a guidebook written for a startup at the beginning of its entrepreneurial journey.

2.3 Research Questions

The thesis studies three research questions:

1. What is unique about the manufacturing scale-up of physical product innovation in a startup company?
2. What challenges and risks does a startup with a physical product innovation face when it scales its manufacturing capacities?
3. What best practices should startups consider in the manufacturing scale-up of physical product innovation?

The first two questions examine the business environment of the named subset of startup companies. The author aims to find the answers to these questions through literature review and interviews with domain experts. The research methods are described in chapter four.

The answer to the third question is the constructive outcome of the thesis research. The question is answered in the form of a strategy guidebook of best practices for technology startups. The guidebook is based on a literature review, interviews, and focus group discussions. The guidebook itself can be found in appendix one. The guidebook was created for an EU-based startup in 2022. The unanimous company was in the process of scaling the production capacities of its innovative product.

3 Theory

This theory chapter presents the topics central to the scope of the thesis. First, modern business organizations are presented, and how the concept of PPI startup is situated in the classification of business types. Next, the development stages of a startup and manufacturing are studied. Lastly, the different philosophies of innovation management and business model design are considered, especially in the context of startup companies.

While the focus of the chapter is on theory, brief reflections by the author are provided at the end of each subchapter.

3.1 Modern Business Organizations

A business can be organized in various ways. For example, in the USA, the government recognizes nine different business structures: Sole proprietorship, partnership, Limited Liability Companies, C corporations, S corporations, B corporations, and non-profit organizations. The company's legal structure impacts the owners' liabilities and the tax imposed on them. (SBA 2022.) An example of liabilities is the requirement of companies traded publicly in the stock market to publicly disclose their operations (U.S Securities and Exchange Commission 2022.)

Traditional ways to categorize companies are Global Industry Classification Standard, GICS, developed by MSCI company (MSCI 2020), and International Classification Benchmark, ICB, developed by FTSE company (FTSE 2022), for example. The mentioned two standards categorize companies by the industry they operate in. Together with categorizing the companies, they are also ways to rank companies by their success by different measures. The business media organization Fortune tracks the most successful companies in the world in its Fortune 500 list in various ways (Fortune 500 2022). Standard and Poor's, S&P, has its own list tracking the success in its S&P 500 index. In the S&P 500, companies are ranked by their stock performance in the USA. (S&P Dow Jones Indices 2022.)

It is striking that none of the mentioned ranking and categorization methods evaluate or consider the company's development stage, nor are they concerned about how the companies approach innovation. In fact, it can be said it is hard for an investor to evaluate how even a publicly traded company is approaching the topic of innovation in general and how successful their research and development, R&D, efforts are. The quarterly reports the public companies publish do not explicitly need to describe the company's efforts in the field of research and development. The lack of innovation and R&D focus in the disclosers is a central point of criticism by Eric Ries towards the contemporary stock markets. (The Long Now Foundation 2020.) Eric Ries, the author of the Lean Startup book mentioned in the introduction chapter, founded Long-Term Stock Exchange, LTSE, to counter this fault in the modern stock markets. LTSE is a stock exchange similar to Nasdaq or New York Stock Exchange. What makes it different is that the trading mechanisms are set to support long-term trading, as the name implies. The companies listed in the LTSE market need to report their results, including metrics related to innovation efforts. For example, companies need to disclose their sales in relation to the age of their products. The more sales the company makes from young products, the better its long-term future looks. (FAQ LTSE 2022.)

The ways to categorize companies presented above are not helpful to this thesis report due to the lack of development stage, innovation, and physical product evaluations. Instead, the author presents his own categorization of companies in this thesis report. In the following chapters, the business organizations in the scope of this thesis report are presented one by one. First, the definitions for the highest level of abstraction, Startups, and Established companies are described. Next, the reader is introduced to the two subcategories of startups, Bits and Atoms. Lastly, a subcategory of startup companies and the focus point of the thesis, the PPI startups, is outlined.

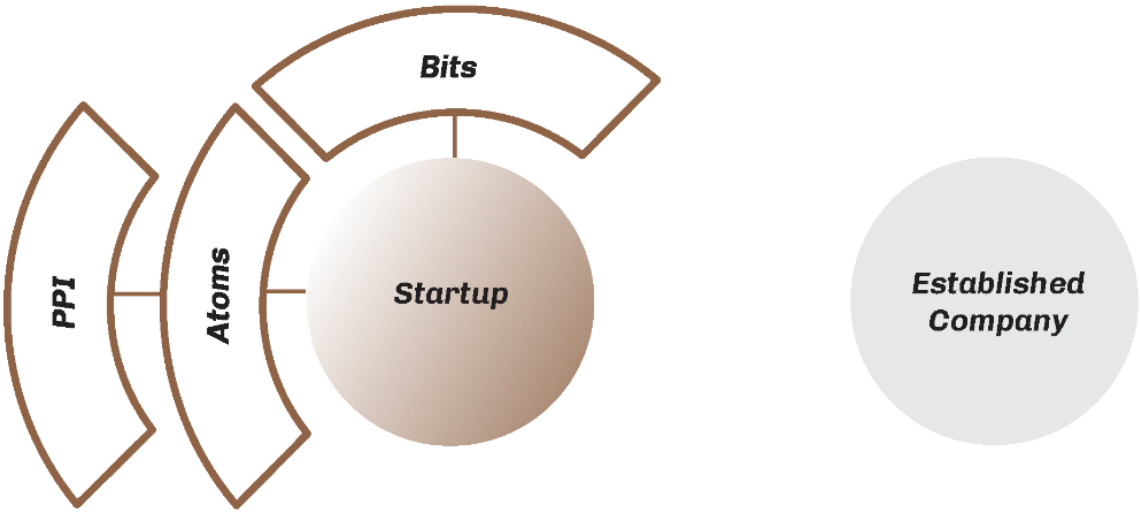

Figure 1. Business organization types in the scope of the thesis report.

3.2 Startups and Established Companies

This thesis report uses Eric Ries' definition of the term startup: "A human institution designed to bring something new under conditions of extreme uncertainty and aiming for high growth (Ries 2011)." What differentiates startups from established companies is the organizations' approach to business opportunities. While established companies are looking to exploit the identified opportunities, startups are exploring them and trying to learn which ones are worth pursuing and how. Entrepreneurship, in general, is about first exploring opportunities and later allocating resources to exploit them. The entrepreneurial process can be divided into three steps: Entrepreneurial, Business startup, and Ongoing business. In the first step, the main activity is opportunity exploration. When reaching the Business Startup phase, the business is formalized, and processes such as capital raising and selecting business partners take place. Lastly, the focus shifts to growth and profitability in the step of the Ongoing Business. In the Ongoing Business stage, we can call the company established. (Butler and Hansen 1991.)

Startups, in general, are a well-researched topic—researchers like Ph.D. George Foster of Stanford University and Professor William Gartner of Babson College have published multiple widely cited papers on entrepreneurship and startup disciplines (researchgate.net 2022). However, their research does not differentiate between different classes of startups. Harrison et al. focused on software startups in their article Financial Bootstrapping and Venture Development in the Software Industry (2004). Similar studies seem not to be available on the hardware side. Studies on individual startups are available, but they might focus on the behavior of individual entrepreneurs, as the study by Volery & al. (2015) suggests.

The limited scientific sources on manufacturing startups are supported by various non-fiction business books. Multiple entrepreneurs and investors have published books about the startup ecosystem revealing insights into the startup world. Additionally, various authors and journalists have written books and articles focusing solely on some of the largest and most well-known PPI companies like Tesla Motors and Space X. Similarly, as in the business literature, blog posts and interviews of startup entrepreneurs offer glimpses into the world of PPI startups. These autoethnographies and biographies can provide interesting insights to researchers about startups and entrepreneurship (Poldner 2020).

Modern internet-era startups did not appear out of thin air in the 2000s. Around the 1980s, Vesper (1980) and Gartner (1982) used the term Business Startup. Also, the study by Van De Ven & al. (1984) is worth mentioning. Gartner's definition of a business startup was "a process that leads to the formation of a business” (Gartner 1982). At the same time, Vesper used the definition “a venture typically emerges from a series of such occurrences spread over time in which its existence becomes progressively more established.” (Vesper 1980). While the word startup is used in these two definitions, they are different than the definition offered by Ries in 2011: “A human institution designed to bring something new under conditions of extreme uncertainty and aiming for high growth.” (Ries 2011). Even though there is something in common, especially between the definitions by Vesper and Ries, the modern startup that utilizes heavily digital tools, accepts a high level of risk, and raises significant high-risk venture capital funds is a case of its own. Thus, research conducted before the 2000s, especially before the emergence of the internet, is less relevant for this thesis research.

There are apparent gaps in knowledge that require further research. For example, it seems that there is no available data qualifying in numbers the differences between different types of startups. Data sets are available on startups in general, but they rarely differentiate various startups based on industries or even software and hardware categories. An exception is an article by van Gelderen, Thurik, and Bosma (2006) that studied the success and risk factors of startups and included technological maturity as one of the studied variables.

The limited available scientific material is a challenge for researchers, especially when discussing PPI startups. Financial success also tells about the focus on the software over hardware: In a list created by analytics company CB Insights (2022), out of the 956 startups evaluated to be worth over one billion dollars, so-called startup unicorns, only 166 were classified as being associated with something else than software products and services. The report offered by CB Insights is rare as it ranks startups by industry. However, it only concentrates on startups with a valuation beyond one billion dollars. Additionally, the report does not consider the company's development stage or its association with innovation. As mentioned in chapter 3.1, data sets and research that classify companies by GICS or ICB standards are not helpful either, as they do not consider the company’s development stage or the question of whether the company is working with physical product innovation or not.

3.3 The Development Stages of a Startup

There are multiple theories on how to best illustrate the development stages of startups. Instead of looking for the best-suited model, it is more beneficial to study various models and identify the most relevant elements from them based on the business case and economic, technological, and societal context. (Saukkonen and Vänttinen 2017.)

In this chapter, three theories of startup developed stages are presented that are the five-step model by Witt (2004) and Growth Stages model by Churchill and Levis (1983), and the Cyclical Two-Loop model by Saukkonen and Vänttinen (2017). Comparing the three offers insights into the topic and together give a comprehensive view of the topic. There are multiple other models as well on the topic. They include, for example, the three-step model by Butler and Hansen mentioned in chapter 3.2, the Customer Development model by Blank and Dorf, and Marmer Stages by Marmer & al. The Customer Development model focuses heavily on the early stages of startup development and actions happening before the official forming of a startup company (Blank and Dorf 2012, p.56). Marmer Stages model is based on the model by Blank and Dorf, extending it to the later stages of startup development (Marmer & al. 2012). However, the Marmer model focuses on the startup subgroup it calls “internet startup,” meaning the startups with physical manufacturing are not central to the model. Thus, the two models do not match the scope of this thesis. Business model design and how startups can use them are introduced in chapter 3.10.

The first two steps of Witt’s five-step model of Idea and Planning take place before the actual founding of the startup and are not in the scope of this thesis research, that is startups and their manufacturing scaling. Manufacturing scaling becomes relevant in the last step of Witt’s model, Growth. According to Witt’s model, growth is a separate phase that happens after the company has transformed from a startup to an established company. (Witt 2004.) However, a startup company must consider the future scaling already in the earlier stages. Thus, the scope of this research is not limited only to the last step of Growth but covers the earlier two: Creation and Proving.

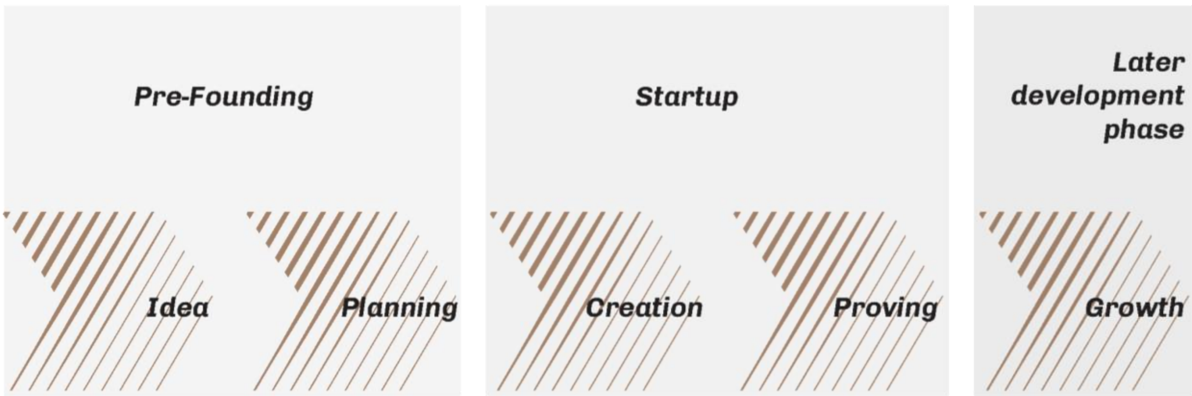

Figure 2. The five development stages of a startup (Adapted from Witt 2004)

The success of a startup in each stage of the model looks different, and there are multiple options to set the goal posts and measure them.

In the first step of Witt's model, Idea, the simplest form of success evaluation is that the entrepreneur makes the conscious decision to start formal business planning. Completing the Idea and Planning phases tells of serious entrepreneurial intent than of true business success. (Witt 2004.) The overall success can be measured by the subjective evaluation of the startup founder. The apparent downside of the self-evaluation is that founders have different expectations of what success means, for example, in terms of growth. (Chandler and Hanks, 1993.) A non-subjective and straightforward way to measure the success of a startup is its survival and persistence in the market (Witt 2004). McGee & al. (1995) suggested that the success of a startup could be measured by calculating the three-year compounded annual rate of sales growth. Established companies can be measured by their profits and return on investments. However, for startup companies, these measuring techniques cannot be applied directly, as it is natural for a startup to aim for growth at the expense of profitability. (Lee and Tsang 2001: 586.)

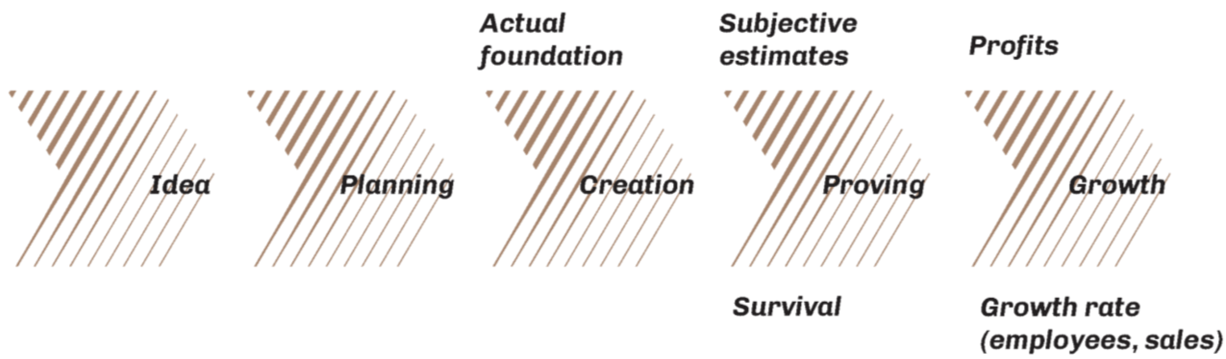

Figure 3. Witt's model and Measures of success for a startup (Adapted from Witt 2004)

Churchill and Lewis (1983) offered a model of five development stages for startup development, as shown in figure 4. The Growth Stages model defines the stages by size, dispersion, and complexity on the vertical axis and maturity on the horizontal axis.

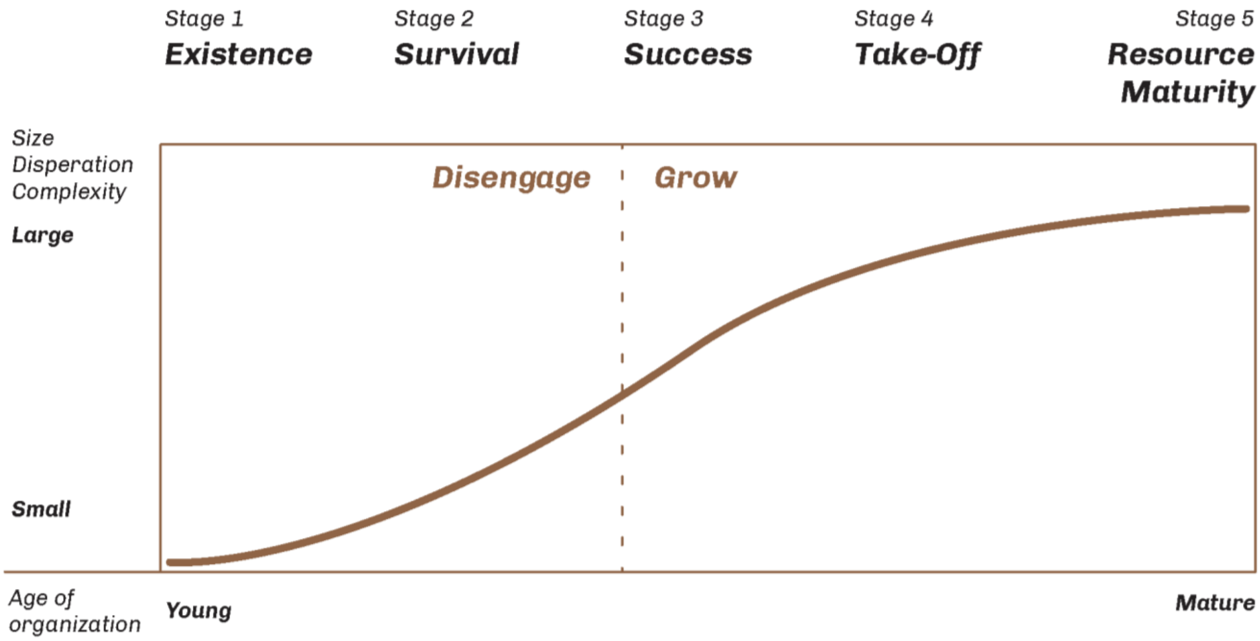

Figure 4. Growth Stages model (Adapted from Churchill and Lewis 1983)

The more detailed characteristics of the different stages are shown in figure 5 below:

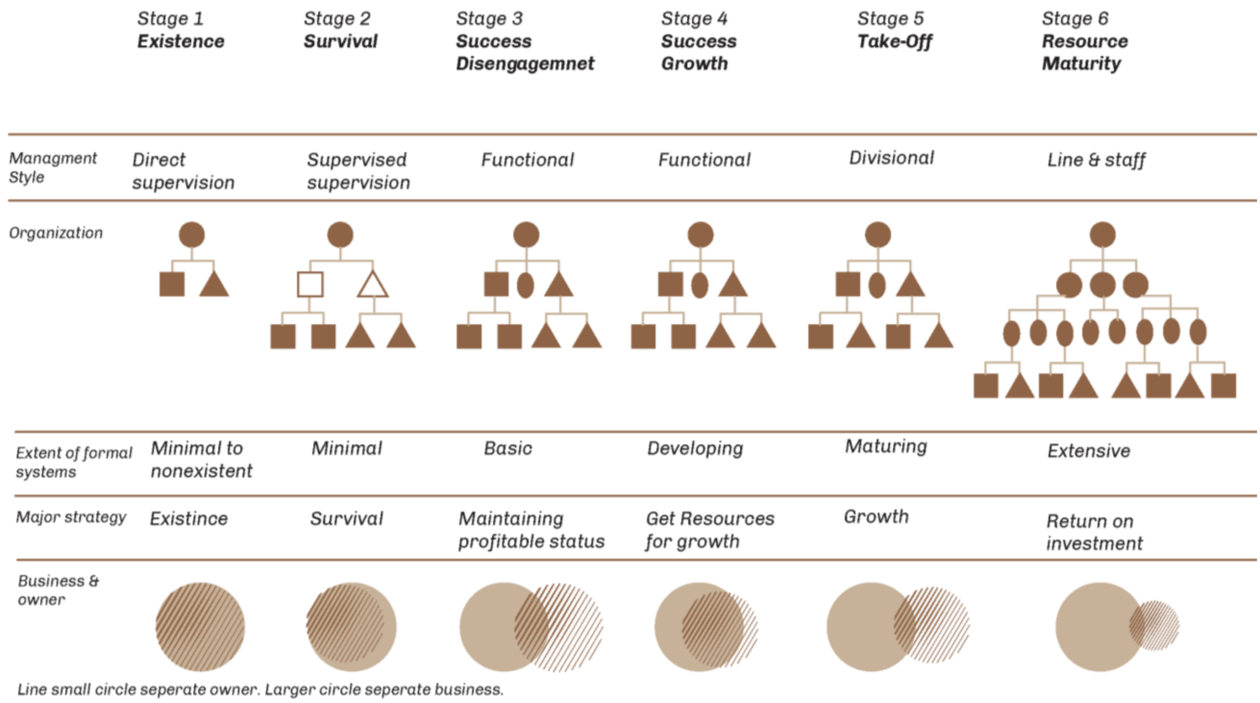

Figure 5. Characteristics of Small Business at Each Stage of Development (Adapted from Churchill and Lewis 1983)

In the first, Existence, stage of the Growth Stages model, the key focus for a startup is finding customers and delivering the product or service to them. The startup is concerned with questions like whether there are enough customers, can the customer base be increased, and does the company have sufficient cash resources. The company structure is flat, and the founder is involved in all the business areas. Formal planning is minimal, as the strategy is simply to survive. The companies that survive move to stage two, Survival. Now, the company has demonstrated that it is a viable business entity. The focus is on questions like is break even is possible and whether the business can grow sufficiently large given the industry and market context in which the business operates. Small companies that are not startups may remain in the survival stage. However, a startup is designed from the start for high growth and must look to reach the final fifth stage of Resource Majority as early as possible. The third stage offers the entrepreneurs two options: Disengagement or Growth. Either way, the company has reached an adequate size, earns profits, and has a stable foothold in the market. With the option of disengagement, the startup entrepreneur exercises the option of exiting the business the pursue other business opportunities or interests. Alternatively, the entrepreneur who sees further opportunities in the business to grow chooses the Growth path and looks to leverage the already viable business to build a more significant and impactful company. Stage four is called Take-Off. Now, the key topics are how fast the company can grow and how the growth is financed. The company has reached a large size in personnel, and the organization chart resembles a large enterprise, including different divisions. Lastly, the company arrives at the fifth stage of Resource Maturity. At this stage, the company needs processes and long-term strategy planning to sustain its position as one of the market leaders. The focus is transferred from market exploration to market exploitation. A company can remain in this position usually until a major change in the business environment. (Churchill and Lewis 1983.)

The third model presented is the cyclical two-loop model. The model shown on the following page in figure six is adapted from the research paper Development Trajectory of An Innovation Based Environmental Technology Startup by Saukkonen and Vänttinen (2017). The figure sums up their findings when studying the growth models of startups in the environmental technology business. While the model was created especially for the specific business area, it can give insights into a broader range of startup companies. The research findings suggest that the cyclical loops are more illustrative for startups than the linear ones, for example, the model by Churchill and Lewis. The model highlights their finding that an innovative company needs to simultaneously run processes leading to scalable and optimized processes, the growth loop, and keep on startup spirited search of novel ideas, the startup loop. Also, the model emphasizes the criticality of funding, and sales revenue must be a crucial part of models for environmental technology start-ups. (Saukkonen and Vänttinen 2017.)

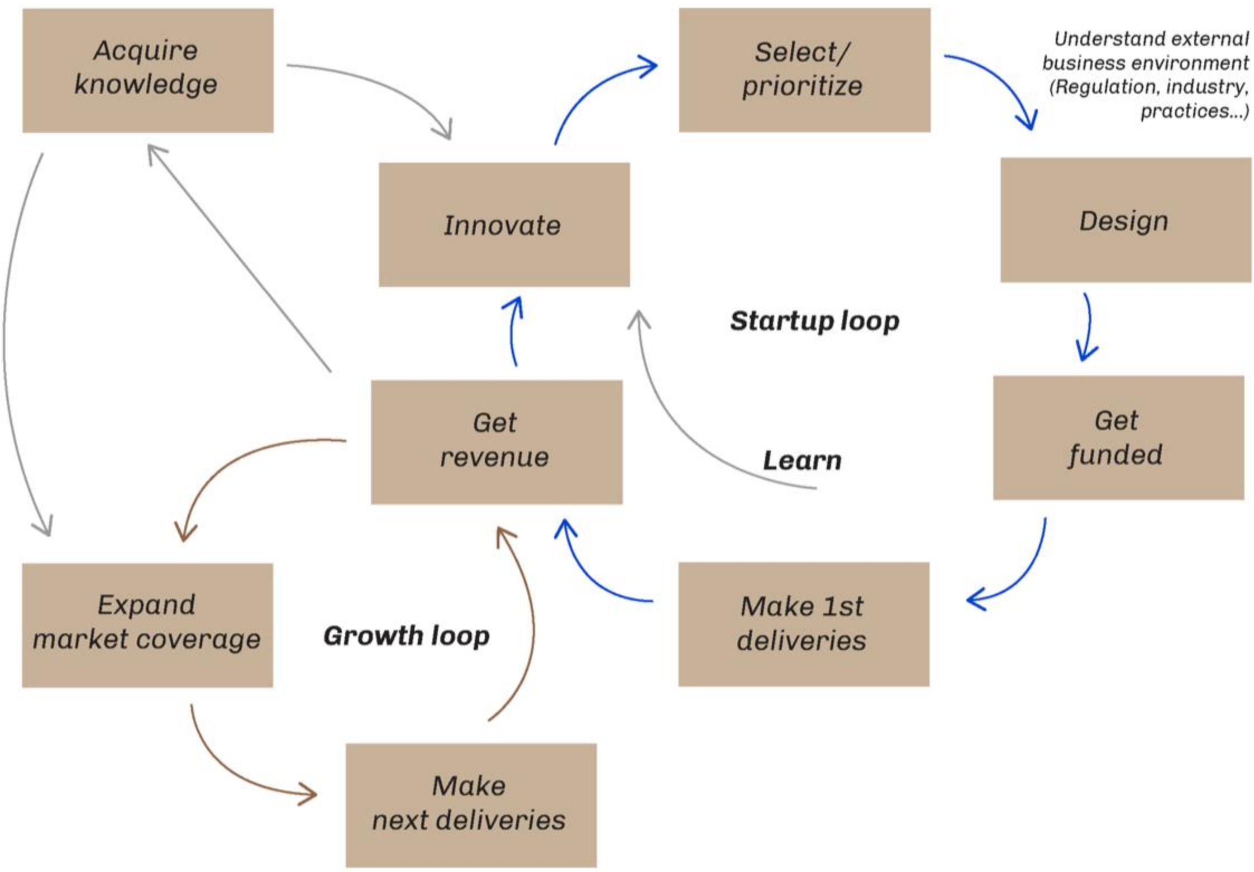

Figure 6: The cyclical two-loop model of startup development in the environmental technology business (adopted from Saukkonen and Vänttinen 2017)

3.4 Startup Classification: Bits and Atoms

Author Nicholas Negroponte introduced the company classifications of “Bits” and “Atoms.” Negroponte wrote that the Bits companies earn their profits by writing algorithms to provide a service or use them to outsmart financial markets. What they do not do is a physical product. Atom companies are the ones that manipulate physical objects. (Negroponte 1996.) Later, the entrepreneur, investor, and author Peter Thiel used the Bits and Atoms to distinguish the two classes of startups. The Bits startups work with software, and Atoms are involved with physical things (Sullivan 2014). Another term similar to Atom startups is “factory startup,” which was used by a startup investor Timo Ahopelto when he commented on social media on an article about a startup with manufacturing-related challenges (Ahopelto 28 May 2022).

Producing physical goods differs significantly from software and service businesses. World-known startup unicorns like Uber, Spotify, Facebook, and many others operate in the digital sector. Netflix is another example of a company leveraging modern digital tools for high-growth (Kotler & al. 2016, chapter 2). When working online to provide customers with software and services, going from an initial idea to launching the first version of their product can be fast. Also, measuring customer traction is low-cost and convenient in the digital industry compared to other sectors due to the direct internet connections between the company and its stakeholders. (Ries 2011.) The high connectivity of the software world enables new and powerful ways of marketing that, for example, shorten the time for brand building and break entry barriers to markets (Kotler & al. 2016, chapter 2).

In the biotechnology sector, it takes around two weeks to go through a design-build-test-cycle, and this timeframe is considered to be too long (Cumbers and Schmieder 2017). Dropbox is a Bits startup company that develops software. In Dropbox's early days, the company utilized a method called High-Tempo Testing to test new features. In High-Tempo Testing, Dropbox implemented new features to their product and received real-time feedback from the users. (Ellis 2017.) This extremely dynamic method cannot be applied when producing and shipping physical goods when delivery times are longer and if online connections are not available. Two weeks is a long time compared to High-Tempo Testing and the IT sector, but the two-week cycle is something sectors like vertical farming only dream of having due to the natural growth cycles of plants.

Elon Musk, the entrepreneur known, for example, for the world-famous Atom startups Tesla Motors and Space X and the co-founder of Bits startup Paypal, discussed the challenges of physical production in an interview published in February 2022. In the interview, Musk described ways to identify different challenges and recognize whether they are related to design or manufacturing. Using Musk's description, startups can be divided into Design-only and Design and Manufacturing startups based on whether or not the company must address challenges related to the manufacturing process and raw materials. (Fridman 2022.)

On a different occasion, Musk described the manufacturing challenges of a startup by saying that building a factory is 100 times harder than building a car. While designing and producing a prototype is easy, making the same on a massive scale is much more difficult. (Rapier 2019.) The difficulty comes from developing the whole system to work at six-sigma quality levels, with no safety or environmental incidents. It is a long process, and startups can find it challenging to acquire a strong enough capital structure to allow it (Hanson 2022).

3.5 PPI Startups

While the startup classifications of Bits and Atoms and division to Design-only and Design and Manufacturing startups are functional and illustrative, in this thesis research, the author uses the term Physical Product Innovation startup, PPI for short. Atom startups include startups all working with physical products but do not specify if the physical aspect of the business is connected to innovation.

Examples of PPI startups are electric car manufacturer Tesla Motors, food technology company Impossible Foods, satellite technology company ICEYE, CDR company Carbo Culture, and biotechnology firm Ginkgo Bioworks. As described earlier in chapter three, PPI startups must validate their business model and find the market fit, just like all startups. However, PPI startups also have internal unknowns related to physical innovation.

The challenges of PPI startups are further extended in the likely case that their product or the manufacturing process includes safety-critical systems. An example of this is offered in the book Ludicrous by Edward Niedermeyer. In the book describing the history of the electric car manufacturer Tesla Motors, the challenges of the manufacturing scale-up are discussed. While testing the unfinished product with real customers is a natural part of the research and development efforts in the software industry, the same processes could not be translated one-to-one at Tesla because the company’s product, a car, is a safety-critical system. If some part of it fails when in use, the brakes, for example, the results can be fatal. (Niedermeyer 2019.) Similar concerns are related to most industries where physical innovations are developed: Biotechnology, pharmaceuticals, transportation, and food technology, for example. There are also safety-critical software products, but they are not exposed to the risk of variable end-product quality. While physical products are built one by one or in batches (Groover 2010), Software products are identical copies of themselves. Manufacturing is presented in detail in chapter 3.7.

Online sales and the Internet of Things, IoT, allow online updating of existing products in the market. IoT is the interaction between the physical and digital worlds. It is an online system of interrelated computers, machines, objects, animals, or people (Nimodiya and Ajankar 2022). IoT offers some tools familiar to Bits startups for the PPI startups, but the applications are limited, especially in the manufacturing step. An example of utilizing IoT in physical products is updating physical product firmware over the internet. For example, a software update can give a smartphone new functionalities and enhanced performance. The electric car manufacturer Tesla is relying on the opportunity to update the car's key functionalities to be enhanced over the internet to be able to ship its physical products earlier (Ruffo 2022).

Some of the best practices of Lean Startup and software industry management can be applied to Design and Manufacturing startups, especially in the early stages of a company.

For example, Tesla could create the first versions of its car fast by modifying an existing petrol car into an electric one instead of building its own model from the beginning. By doing this, Tesla quickly created a Minimum Viable Product, MVP, to test its Leap of Faith business model assumptions. (Niedermeyer 2019.) Using MVPs to test critical hypotheses, called Leaps of Faith, is one of the essential elements of the Lean Startup methodology. (Ries 2011). However, when moving on from the MVPs to delivering high-quality products to customers time after time, the software analogies do not work anymore.

Article “Tesla Tackled Mass Production for Cars as if They Were Software and That’s Biting It Back” by Gustavo Henrique Ruffo in 2022 describes how Tesla’s approach of “deliver now, fix later” mentality familiar to the software industry has led to multiple quality issues and recalls of already delivered cars. For example, the article claims that Tesla delivered around 200.000 vehicles with faulty latch installation. Unlike a defective software product, such errors cannot be easily updated through an online update. Instead, the cars had to be recalled causing direct costs to the company and a negative experience for the customer. (Ruffo 2022).

The untested product innovation in a PPI startup can be the output product, but it can also be the manufacturing process, for example, related new to kind of machinery. Vertical farming is an example of innovations related to manufacturing and business models, but not the output. Vertical farming involves new technology and an opportunity to operate in new ways when food production can happen closer to customers in urban areas and without seasonal variance (Birkby 2016).

Manufacturing new products that do not involve innovation is a different case. When the new but not innovative product is sold in a market that already exists and uses manufacturing lines and supply chains that are already in place, the business environment is very different. Such an operation is market exploitation, not exploration. Companies exploiting markets are not startups, as described in chapter 3.2.

Working with an innovation associated with physical production does not mean the company would not develop software. The example earlier in this chapter of how Tesla uses online updates to improve its cars shows how intertwined software and hardware are (Ruffo 2022).

3.6 Bits, Atoms, and Something in Between

As described in chapter 3.4, Negroponte's rough division between Bit and Atom startup applies to this research only at a high level. Thus, the subgroup of Atom startups, PPI startups described in the previous chapter, is selected as the focal point of this thesis report. Another subcategory worth mentioning here is Bit startups operating in highly regulated industries. Examples of these are medical and financial service startups. Understanding the position of Bits startups in highly regulated industries helps paint the picture of how the different kinds of startups face the same challenges in different ways. While the Bits companies operating in highly regulated industries are free of the restrains of the Atom world, they experience part of the challenges of the Atom startups in the form of regulation.

Challenges related to investments are well described by startup founder Sami Inkinen in his blog post, which comments on the challenges of starting his medical service startup, Virta Health. Before founding Virta Health, Inkinen was a co-founder of the software company Trulia which went public after raising only 33 million dollars in funding over eight years. At Virta Health, he has raised more than ten times the amount in just five years. What is an eye-opening difference described by Inkinen is that solely the regulation of the medical industry leads to a tenfold requirement in investments. (Inkinen 2021). Virta Health is a medical service startup but not a PPI startup (Virta Health 2022). The higher need for upfront investments could be even more significant in the business case of a biotech or a pharma company that would require production facilities.

3.7 Manufacturing Strategy

Manufacturing, the making of things, is essential for the economies of all modern nations. Manufacturing goes hand in hand with technology. (Groover 2010.) Technology, the application of knowledge and science (Merriam-Webster 2022), is transformed from drawing boards and laboratories to actual tangible products and applications by manufacturing (Groover 2010).

3.7.1 The Manufacturing Process

Factories are a central concept in manufacturing (Freeman 2018). The first assembly line in a factory was established in 1913 when Henry Ford was looking for methods to mass-produce the complex product of the Model T car. Mass production and the automation enabled by the electrification of factories yielded enormous increases in manufacturing efficiency. (Groover 2010).

Mass production remained the standard practice until the emergence of Lean Manufacturing in the second half of the 20th century. Lean manufacturing is a school of thought originating from Japan and its automotive industry in the 20th century. The main concepts of Lean manufacturing were taken from Toyota's Toyota Production System, TPS, and introduced to the Western automakers and other industries in the latter half of the century. (Lean Enterprise Institute 2022). The name Lean describes Lean's lesser use of resources than the mass production thinking prevalent before Lean introduction (Womack, Jones, and Roos 1990). Lean Manufacturing answered to mass production developed for resource efficiency by flow efficiency, allowing flexibility and agility to respond to the developing customer needs. Due to inflexibility, mass production processes are vulnerable to disruptions. To mitigate operational risks, mass manufacturers need buffers like additional raw materials to ensure operational flow. In short, Lean is a customer-centric system in which the value created for customers is done by prioritizing flow efficiency over resource effectiveness. (Womack, Jones, and Roos 1990).

Lean manufacturing must not be confused with the concept of Lean Startup mentioned earlier in this thesis research. While TPS and Lean manufacturing evolved to answer contemporary challenges in the manufacturing industries, Lean Startup did the same in the software realm in the 2000s. Whereas Lean manufacturing is about the efficiency of daily work, Lean Startup takes Lean thinking to improve the process of bringing ideas and startups to life (Ries 2017).

In his overarching book, Fundamentals of Modern Manufacturing (2010), professor of Industrial and Systems Engineering Mikell P. Groover describes the basics of manufacturing describes the central operations, restricting issues, and the types of manufacturing as follows:

A manufacturing facility includes a set of processes, resources, and systems designed to transform certain raw materials and components into products of higher value than the raw materials alone. The first dimension, technological capability, is the flexibility of the available technology on the site. A site designed for car manufacturing cannot produce medication, for example. The second dimension is physical product limitations. What kind of products and raw materials are handled at the site? Moving large objects require large cranes, and so on. The physical restraints can be related to quantities in the same way as quality. Thirdly, each manufacturing site has a manufacturing capacity dimension to consider. Manufacturing capacity is the output of products in a given period. The output capacity is connected to all available resources: Machinery, raw materials, supportive systems, and labor. (Groover 2010.)

Manufacturing takes place in dedicated facilities designed for the purpose. The facilities can be divided into three categories based on the output of the facility: Low (1-100 units/year), Medium (100-10000 units/year), and High (10000 to millions of units/year). In a Low-Quantity manufacturing facility, low quantities of specialized and customized products are produced. The equipment in a job shop might be generic, but the employees are highly skilled. Such a facility is designed for flexibility to facilitate the unique nature of each item produced. Medium Quantity Production can serve the manufacturing of both one-by-one production as well as batches of multiple products. When the product catalog includes a range of products, the critical question becomes the changeover time: The setup time between the batches is lost production time, a considerable disadvantage of batch manufacturing. High-volume manufacturing is initiated when a single product has significant demand in the market. (Groover 2010).

There are two subcategories for the high-volume segment: quantity production and flow line production. Quantity production is about producing the same units always on the same machinery. On the other hand, flow line production involves various equipment, and the units are physically moved through the production line to finalize the output product. Examples of flow line production are cars, the product that was produced in the first mass production line by Ford. (Groover 2010).

To successfully promote a product in a marketplace produced on a flow line, it has been considered mandatory to offer customization opportunities for the customer. In the example case of the car, this can mean different colors and types of equipment in the car. Non-standard manufacturing fights against the underlying philosophy of mass production. (Groover 2010.) The famous quote from Henry Ford testifies his focus on finding efficiency from standardization: “A customer can have a car painted any color he wants as long as it’s black” (Ford and Crowther 2017). Lean manufacturing is an improvement exactly for this downside of mass production of enforcing the direction towards standardization and simplification, even if it is against the market demand. Mass production measures the resources efficiency of the available resources. Aiming to maximize the output of resources leads to a situation where a company is pushing products to the market that it is very efficient to produce. However, the ever-changing market demand is not taken into consideration as the mass producer is incentivized only to do bigger and bigger batches of standardized products. (Haapsaari T 29 January 2022.) In the words of Eric Ries, this situation is called a “large batch death spiral.” (2011). Eventually, the market demand falls, leaving the company with a very effective but useless manufacturing capacity (Haapsaari T 29 January 2022).

3.7.2 Contract Manufacturing

The terms Contract Manufacturing and Outsourcing are intertwined and close to each other. Gilley and Rasheed (2000) defined outsourcing as “outside resource using” that is synonymous with contract manufacturing. However, Bengtsson (2008) defines outsourced manufacturing as “manufacturing work that was formerly done inside the organization performed by an external supplier.” The latter definition implies that the work was initially done in-house and later moved to a contract manufacturer.

Using an external company to execute its production processes is a growing trend in manufacturing industries (Bengtsson 2008). In the business relationship, an Original Equipment Manufacturer, OEM, hires a Contract Manufacturer, CM, to do the manufacturing instead of in-house capabilities. (Arruñada and Vazquesz 2006.) Using a CM can be regarded as both a complementary and an alternative strategy to investments in in-house manufacturing (McIvor 2005). Using a CM can yield significant benefits: Reduced labor costs, freeing capital, and increased worker productivity. Using a CM can allow the OEM to concentrate on improving the product’s value by focusing on R&D, design, and marketing. The potential downsides of using a contract manufacturer include risks of leaking valuable intellectual property, IP, and the CM might eventually start producing a similar product with their own brand leading to increased competition in the market. (Arruñada and Vazquesz 2006.)

Using a contract manufacturer reduces the level of vertical integration of the company. The level of vertical integration describes how much control of the value stream of the product manufacturing the company has. A high level of vertical integration means that the company controls most of the functions by doing the tasks in-house, integrated into the company itself. High-integration lowers the risks as the company controls the supply chain. However, the company's high vertical integrations come with a high cost as it needs to focus its resources on multiple frontiers instead of buying the same service from a specialized company (Schlegel and Trent 2014; 42). In a modern supply chain, contract manufacturers are used, for example, for assembly work. Using the contract manufacturer, thus lowering the level of vertical integration, adds a new link to the value chain and has a negative impact by increasing the throughput time and exposing the company to higher risks. Still, it can be worth it as the arrangement can save the company a significant amount of money (Grant 2012; 1).

3.7.3 Manufacturing Processes in Startups

The research questions of this thesis ask about the characteristics of PPI startups, how they can manage risks, and how they can scale up their manufacturing capabilities. While there is a wide range of literature sources on startups and manufacturing scaling separately, they have not been widely studied together.

Scientific resources are abundant for risk management, operation scaling, and manufacturing management; Studies like Skinner and Wickham (1969), Platts & al. (1990), Hill (1993), Swamidass and Darlow (2002), Acur and Bititci (2004), and Groover (2010) focus on manufacturing strategy but assume that the manufacturing infrastructure is already in place. By definition, as described in chapter 3.1, startup companies start their entrepreneurial journey without any infrastructure.

The time it takes to acquire the required manufacturing capacities leads to an extended time-to-market period and delayed first revenue. The time-to-market period is the time it takes to bring a product to the market. Building the manufacturing infrastructure is challenging for two reasons: It requires significant upfront investments and takes a long time to complete. (Lim & al. 2008.) The challenges of manufacturing adding to the prolonged time-to-market can also include the long development time of regulations that affect decision-making ability internally and externally, the depth of volume of required R&D efforts, and the need for multiple real-life demonstration units before a full-scale unit can be built (Saukkonen and Vänttinen 2017; 106).

A startup can consider outsourcing the manufacturing to a contract manufacturer to tackle the challenges. Through contract manufacturing, the startup has the opportunity to access manufacturing capabilities faster than building the needed facilities themselves. (Lim & al. 2008.) Other motivations for using contract manufacturing for a startup include improved flexibility and lower operating expenses compared to in-house manufacturing. Using a contract manufacturer reduces the need to invest and hire, which is a significant benefit, especially when the startup is yet to learn the best way to operate. Using a contract manufacturer, a startup is more flexible in altering the manufacturing process as it has not itself an investment in costly manufacturing facilities and a large employee pool. (Selden 11 April 2022.) On the other hand, when talking about the scaling of his food technology startup’s manufacturing in a webinar, entrepreneur Flavio Hagenbuch explained that a startup might not be able to outsource even if it would like to; If the technology used for the manufacturing is novel and not widely used, there might not be any potential contract manufacturers available (Hagenbuch 16 June 2022).

When giving a presentation for startup companies working with food technology, consultant Emil Virag offered the following tables to illustrate the pros and cons of contract manufacturing and in-house manufacturing in this specific context.

Table 1: Contract Manufacturing. Pros and Cons for a food tech startup. (Adapted from Virag 16 June 2022).

Contract Manufacturing. Pros and Cons for a food tech startup		
No	Pros	Cons
1	Speed to market	IP Risk exposure
2	Product Development Experience	More expensive (Min. 20%)
3	System and Standards in place	The contact manufacturer can become a competitor
4	End-to-end supply chain management	Lack of transparency
5	Administration process	The minimum order quantity might be high
6	Role of subject matter expert	No leverage on performance
7	No, or less capital needed	

Lines 1,3,4,5,7 of the Pros list are related to the fact that the contract manufacturer already has existing and functioning manufacturing capacities. Lines two and six can be helpful for a startup company, especially when there is no internal manufacturing experience. From the Cons list lines, two and five are cost-related. While there is less capital needed compared to in-house manufacturing, the costs are higher on the operational side. Not only are the operational costs higher, but the lack of transparency and no leverage to challenge the manufacturing process's performance adds to the Cons list of serious downsides. When outsourcing manufacturing, the intellectual property is exposed to the partner, increasing the risk of sensitive information leaking through the CM. Lastly, there is the risk of the manufacturer becoming a competitor. In the example provided in the presentation, a contract manufacturer canceled a contract with the OEM company after learning the ins and outs of the manufacturing process of a specific product. After a while, the competitor came out with a competing product. (Virag 16 June 2022.)

Table 2: In-house Manufacturing. Pros and Cons for a food tech startup. (Adapted from Virag 16 June 2022).

In-house Manufacturing. Pros and Cons for a food tech startup		
No	Pros	Cons
1	Full transparency on financials	Capital intensive
2	Flexible minimum order quantity (only technology-driven)	Rely on in-house expertise
3	Full IP control	Starting costs might be high
4	More trial-and-error possibilities	Administration process
5	Opportunity for profit-enhancing (formula change, organization, etc.)	Regulatory / Food safety requirements
6		Might extend the time-to-market

Logically, the In-House Manufacturing table displays mainly a mirror image of the Contract Manufacturing table. Items highlighted from this table are lines two and four from the Pros. These two aspects are precious for a young company that is still learning fast. From the Cons side, lines four and five are resource-intensive tasks that take the focus away from scaling and learning. (Virag 16 June 2022.)

One of the risks mentioned above was the risk of losing valuable IP through the contract manufacturing partner. According to Lean consultant Timo Haapsaari, one should also be conscious of where the tacit knowledge of manufacturing processes is building. In a new manufacturing process, especially in the case of an innovative product, there are various unknown unknowns that will be discovered in the execution of the process. If the process is executed at a contract manufacturer, the learning happens outside of the OEM company. (Haapsaari 29 January 2022.) To limit the downsides of contract manufacturing, a startup can consider a model in which it is only outsourcing a part of the manufacturing process (Selden 11 April 2022).

Forming a joint-venture with an established company could be a solution for a startup to solve the challenges of manufacturing scaling. For example, a battery technology company QuantumScape formed a joint venture with the Volkswagen Group to build a pilot manufacturing site. Comments by the CEO of QuantumScape, Jagdeep Singh, tell that the motivations for creating the joint venture are specifically cutting the time-to-market and the manufacturing scaling in general: “Our goal has been to bring our solid-state lithium-metal batteries to market as soon as possible.” (Crider 2021.)

Further research is required to understand how relevant the manufacturing strategies of established companies are to startups. Lim & al. (2008) and Lubik & al. (2012) came to the same conclusion: Even though high-tech startups play an important role in the economy, research related to manufacturing strategy development in the startup context is scarce.

3.8 Risk Management

A risk is a situation where the involved parties are exposed to danger or a loss (Schlegel and Trent 2014; 2). Risks are unavoidable and present in every human situation (Kandati 2013). Risk management is essential for the success of any firm. Risks can be viewed from multiple angles. While a supply chain manager aims to mitigate and control the risks as much as possible, an entrepreneur can see risk as an opportunity more than a danger. (Schlegel and Trent 2014; 2.)

As the first step of risk management, a risk analysis is carried out in which the company aims to recognize all possible risks to which it is exposed to. The risks are evaluated by the probability and the impact of the risk if it occurred. There are multiple ways to assess the seriousness of the risks. Regardless of the type of analysis, the results are reviewed against the risk tolerance level of the company. The risk tolerance level defines which risks can be tolerated and which require mitigation. The company creates a risk response plan as the final step of the risk management process. The risk response plan defines the steps the company will take to take the situation under control when a risk occurs. (Schlegel and Trent 2014; 12-16.)

The many types of risks can be divided into four categories: Strategic, Hazard, Financial and Operational. A strategic risk has the potential to affect the whole business and endangers the company’s ability to execute its operational strategy. Hazard risks are randomly occurring events such as wars or natural disasters. Financial risks mean the possibility of losing money on an investment or business venture. The most common financial risks include credit and liquidity-related risks. The operational risks are the most common and individually less harmful, but they can have significant effects if occurring often. Operational risks include late deliveries, quality issues, and mismanaged inventory, for example. (Schlegel and Trent 2014; 16-17)

The examples above related to late deliveries and inventory management are especially associated with companies related to physical manufacturing. In the software design domain, risk management can be defined as a systematic process to treat risks to mitigate or minimize their effects and produce a high-quality product that meets customer needs within estimated time and costs (Nogueira and Machado 2014).

According to investor John Doerr, a “climate forward” business must be ruthless in identifying and removing key risks upfront. Founders and investors must tackle four risk areas:

1. Technology risk: Will it work?
2. Market risk: Will it stand out?
3. Consumer risk: Will it sell well?
4. Regulatory risk: Will it get approved?

After looking at all these aspects, the key question is what the most relevant risk is and whether capital can be used to remove it. If not, the company will have difficulty raising later-stage capital. (Doerr and Panchadsaram 2021, chapter 10).

3.9 Innovation Management

According to Clayton Christensen, there are two types of innovations: Disruptive and Sustaining. Sustaining innovation has two subcategories: They are either Evolutionary or Revolutionary. Evolutionary innovations improve the existing markets and products in an expected, non-surprising way. Revolutionary innovations are unexpected. However, they do not disrupt the markets. (Christensen 1997.)

The unique nature of disruptive innovation can be illustrated with the example familiar from the earlier chapters, car and mass manufacturing. The first automobiles alone were not a disruptive innovation, just an innovation, as they did not overtake the market from other means of transportation. However, the mass-produced car introduced by Ford was a disruptive innovation as it lowered the car price, thus making it accessible to a broader audience. (Christensen and Raynor 2013.)

A business model is a way to define the logic of value creation in a business organization (Teece, 2018). Business model design is a central theme in business strategy, especially for startups and innovation management, as the business model design offers a central tool for turning an opportunity into a successful business (Snihur and Zott 2020).

Innovation management methods enable organizations to turn ideas and opportunities into processes or products. Innovation management includes tools and standardized processes for an organization needed to manage innovations systematically. (Kelly and Kranzburg 1978). Continuous improvement and growth are expected by common investors. To drive the required growth, innovations play a central role. (Christensen and Raynor 2013.)

3.10 Business Model Design

As described in the Introduction chapter, research, for example, by Rindfleisch & al. (2017) and Teece (2018), shows that the digital age is reshaping the way how business is done. Through digitalization, the business environment has become highly open (Chesbrough and Appleyard 2007) and widely connected (Priem & al. 2018, Kotler & al. 2016, chapter 2). First of all, the combinations of digital technologies like edge computing and AI, artificial intelligence, enable new business model opportunities (Teece 2018). Secondly, through the direct and seamless communication channels between companies and their consumers, digital innovation creates various business models options that can identify, analyze, and answer consumer needs in a very efficient manner (Wirtz & al. 2010).

There are two philosophies of business model design in the digital economy: “technology push” and “market pull” (Guo & al. 2020). Market-pull-oriented companies develop and produce products to address expressed market needs in specified and existing market segments (Chidamber & al. 1994). Technology-push-oriented companies bring to market innovations that might face higher risks, but if successful, they can yield a higher return on investment, ROI, significant market penetration, and better long-run prospects (Hayes and Wheelwright 1984). While the market-pull strategy is connected with incremental development building on existing solutions, technology-push-oriented development can start from the earliest stages of research (Guo & al. 2020.)

The market pull strategy is based on the company's current resources; thus, the market pull option is natural, especially for larger and established companies (Lubik & al. 2012). However, in the case of an established company that seeks to pursue novel technology, it might follow the technology-push method. The technology push for an established company may lead to the cannibalization of its own business as the new technology rivals against the company's existing business. (Hayes and Wheelwright 1984.)

Startup companies have a completely different starting point: They start their operations with no functioning business model, just a hypothesis of one (Witt 2004). Although beginning from zero means a lack of resources, it provides the flexibility to pioneer new business models and technologies in a way that established companies would struggle with (Shane 2004). Startups in emerging industries can be either technology-push or market-pull in their approach, which impacts the formation and evolution of their strategy (Lubik & al. 2012). Finding a balance is necessary. Whatever the balance between the two options might be, it has significant ramifications for manufacturing strategy. (Hayes and Wheelwright 1984.)

The discussion about technology-push strategy versus market-pull strategy has long roots (Chidamber & al. 1994). More recently, the importance of the technology push has been highlighted, for example, by Herstatt and Lettl (2004). Both strategies have good arguments, and it might be natural for a single company to use both options in different development stages. For example, the study by Rosenberg (1994) highlights the importance of market-pull in the early development stages of new technology. The market-pull gives the signed for the industry to understand what problem needs an answer in the first place. While the argument for the market-pull direction for technology development has some merit, it must be considered that sole focus on market-pull could have a negative impact by taking away the focus on early research and development work. (Mowery and Rosenberg 1979.)

Researchers have suggested that technology-push companies are the ones responsible for the creation of new markets. However, only a limited number of studies have concentrated on the topic of market-pull and technology-push in the startup context. Startups do not have the financial, personnel, or market resources established companies have. (Lubik & al. 2012.)

Chris Dixon, a partner at the Venture Capital company Andreessen and Horowitz, used the term Full-Stack Startup to describe the business model of startups that provides a complete end-to-end user experience. The full-stack approach allows startups to bypass incumbents and overcome cultural resistance to new tech. Ride-sharing startups Lyft and Uber started with a business model in which they offered their software to existing taxi companies. Only after switching to the Full-Stack model of providing a ready technology product that serves the customer as well as the key stakeholders, the drivers, in this case, was the technology widely adopted. (Dixon 2015.) Tesla Motors is another example of a full-stack startup. Unlike most other car companies, it does not offer only the car; it also has its own networks of stores and charging stations. It can be argued that Tesla resembles the technology company Apple more than the car manufacturer General Motors or Toyota. (McKenzie 2018; chapter 9).

A Full-Stack Startup is a highly vertically integrated company. The level of vertical integration tells how much control of the logistics up and downstream the company has. A high level of vertical integration means that the company has control of most of the functions and that the risks are low. Still, the company has to pay a high price for it as it needs to focus its resources on multiple frontiers instead of buying the service from a specialized company (Schlegel and Trent 2014; 42).

3.11 Theoretical Framework

The central concept in this thesis research is Physical Product Innovation startup, PPI, a subcategory of startup companies. The theoretical framework is presented below in the form of a graph followed by a description.

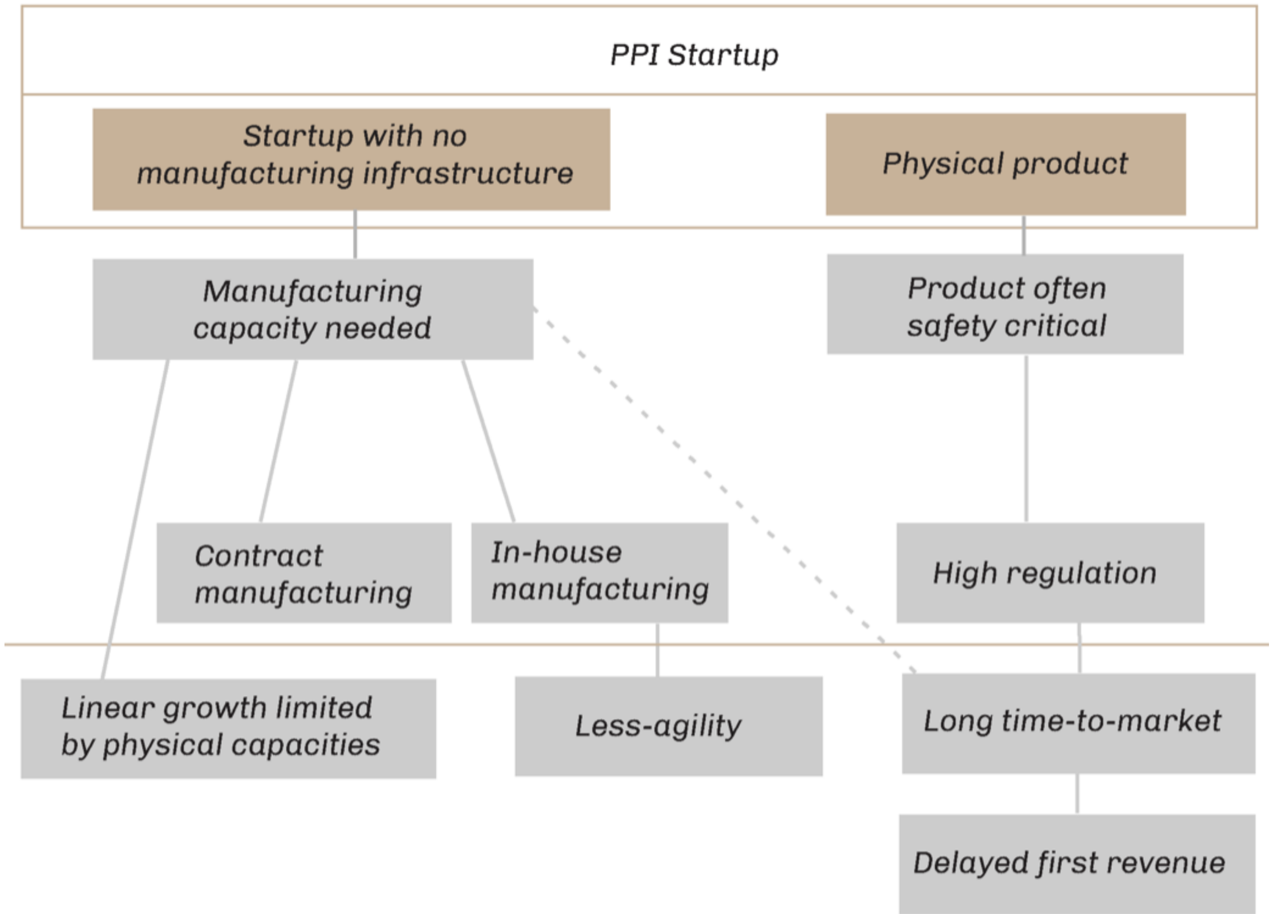

Figure 7. The Theoretical Framework

A startup company is a human institution designed to bring something new under conditions of extreme uncertainty and aiming for high growth (Ries 2011).

A startup goes through a series of development stages to become an established company. First, the entrepreneur looks to validate the business model and find the market fit. Once a foothold has been found, the company has the opportunity to settle into a profit-making company or continue further and aim for market dominance. Measuring the success of a startup varies between the different stages but also depends on the subjective evaluation and ambition of the entrepreneur and their stakeholders. The various models to define the development stages include the five-stage model (Witt 2004) and the Growth Stages (Churchill and Lewis 1983).

Startups, in general, can be divided into two categories: Bits and Atom startups. Bit startups are software-only companies working in the digital world. Atom companies must take into consideration the physical world, the atoms. (Thiel 2011). Another way to group companies in a similar fashion is to ask if their business is only about designing something new (Design-Only startups) or do they do manufacturing as well (Design and Manufacturing startups) (Fridman 2022). PPI startups are a subcategory of Atom and Design and Manufacturing startups. While Atom startups are defined by their association with physical products, PPI startups also have an innovation related to the product. As shown in the theoretical framework graph, by definition, a PPI startup has a physical product and starts the entrepreneurial journey without infrastructure.

The key challenges PPI startups face compared to Design-only startups are the extended time-to-market and higher risk exposure due to the need for more extensive infrastructure and cash constraints. When studying startups with physical products, the topic of manufacturing is relevant. While manufacturing is a widely studied topic, rarely has it been studied in the context of startups. Manufacturing and the needed factories and machinery required significant upfront investments unfamiliar to the software and service industries. (Lim & al 2008.) What is characteristic about startups is that they, by definition, do not have the infrastructure like factories in place when starting their business. As an alternative to in-house building the manufacturing infrastructure, the startup company can consider outsourcing the production to a contract manufacturer with the facilities and resources already in place. However, using a contract manufacturer has its downsides as well. For example, learning the manufacturing details is not happening within the startup itself. (Haapsaari T 29 January 2022.)

Another challenge for PPI startups is high regulation due to the nature of the products and businesses they are naturally part of. Physical products such as food, medication and transportation methods like cars can be lethal if there is a quality issue. There are high-regulated software products as well, but when talking about software products, less often, they are defined as safety-critical. Regulation is related to risk exposure and risk management of business organizations. PPI startups, like all businesses, are exposed to a wide range of risks, including strategic, hazard, financial, and operational categories (Schlegel and Trent 2014). For a startup that is working with an unproven business model, the risk landscape can be understood as well through four questions to understand risks related to technology, market, customer, and regulatory: Will it work, will it stand out, will it sell well, and will it get approved (Doerr and Panchadsaram 2021, chapter 10)?

Innovation management and Business Model Design are central concepts for PPI startups. Unlike established companies, startups do not have an existing foothold in the markets, directing them to the technology-push business model.

In the technology push model, a company's starting position is to identify a technology or innovation worth bringing into the market. Thus, out of the models and innovation types presented, the Disruptive Innovation and Technology Push business models are the most relevant for PPI startups. (Guo & al. 2020.) According to Clayton Christensen, there are two kinds of innovation, sustaining and disruptive. Sustaining innovation builds on existing markets and products, while disruptive innovation is about disrupting and overtaking markets with something totally new. For a startup, the natural position is to look at disruptive innovations for the same reason they are directed towards the technology push business model; Established companies are strong in Market Pull and Sustaining Innovation, while startups have their chance with Technology Push and Disruptive Innovation (Christensen 1997).

4 Methodology

In chapter four, the research methodology is presented. The subchapters describe the methods used and the research type of the thesis.

4.1 Research type: Constructive Research

The author selected Constructive research as the research method for this thesis.

Constructive study starts by identifying practical questions and problems. Once the research problems are set, the research questions can be defined to which the research aims to find answers to. The questions are answered by developing a solution that is taken into use to determine its appropriateness. (Oyegoke 2011.)

Kasanen & al. (1993) used the graph shown below to describe the structure of the constructive research approach. The critical part is the constructive outcome of the research: It is not only a study paper but a practical and functioning solution. The construct is the solution provided by the research to the existing problem. (Hyötyläinen & al. 2014.)

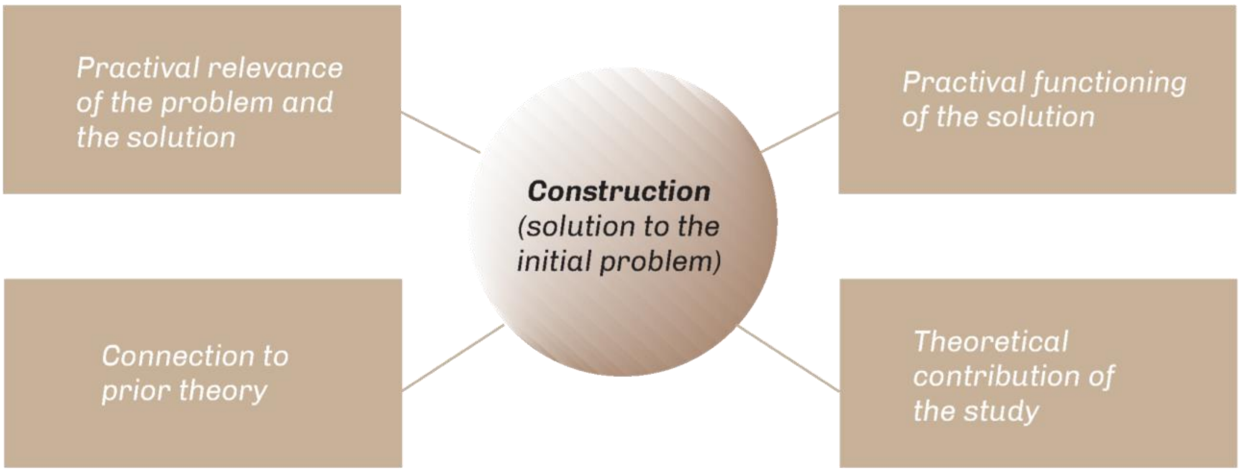

Figure 8. The central elements of the constructive research approach. Adapted from Kasanen & al. (1993)

The constructive outcome is a strategy guidebook created for a startup company that needs answers to the study's research questions. The guidebook can be found as an appendix to this thesis report.

4.2 Data Collection Methods

A key method of knowledge collection in this research is interviews. Together with the literature review, interviews form the core of the study offering a comprehensive picture of the topic and answers to the research questions. Additionally, the focus group method was used.

4.2.1 Interviews

Interviews are a significant category of data collection and are considered one of the most effective ways of collecting data in the social sciences (Easterby-Smith & al. 2002). Interviewing has many forms and types. Usually, it is a verbal exchange between the interviewer and one or more interviewees. Interviews can also take place in written form, and they can be structured, semi-structured, or free form. There are four main categories of interviews: Fully structured, half-structured, theme, and open interviews. In a fully structured interview, the questions are defined upfront and presented in a specific order. In a half-structured interview, the questions are defined beforehand, but the exact wording and the order they are presented to the interviewee may differ. In a theme interview, the themes are prepared carefully, but the structure is flexible. Additionally, the later interviews can be modified in case the earlier interviews reveal interesting new information. In the open interview, the interviewer and the interviewee discuss the topic or issue given by the interviewer. Both parties actively take part in the discussion. (Ojasalo & al. 2014; 108-109.)

The length of an interview can vary significantly (Fontana and Frey 1994). Conducting an interview requires various skills that the interviewer must be familiar with. The interviewer must prepare well for the interview upfront by doing background research and designing the structure. Additionally, the interviewer must have interpersonal skills to conduct the interview successfully. Lastly, the interviewer must analyze the data and turn it into useful information. (Lancaster 2005.)

4.2.2 Conducted Interviews

In this study, open interviews were conducted. As presented in the previous chapter, 4.2.1, open interviews vary in type, length, and form, and the interviews did not follow a strict structure. Instead, the interviews took place in the form of a discussion according to specific themes and questions around the themes. The open interview type was selected to allow the interviewee to bring up aspects they consider most important openly.

The majority of the interviews were conducted by video calls, but a portion was also done face-to-face. The video calls were conducted with software tools like Zoom and Teams. When using video call software, the calls were recorded using the same software. In the cases of face-to-face interviews, the recording was done by using the author's smartphone.

The length of the interviews varied as well. The shorter interviews were only 30 minutes long, while the longest took two hours. Most interviews lasted for one hour. The language used in the interviews was English, except for the case in which the interviewee felt more comfortable using Finnish, the native language of the author.

The interviewees were found through various channels. Firstly, the author reached out to his network of connections who he knew personally. Secondly, the author asked his direct contacts to recommend other people to reach out to. Thirdly, the author used online communities like ResearchGate and LinkedIn to reach out to professionals in the field.

The people the author reached out to regarding the interviews were mostly positive about participating. Even though the interviewees held demanding and time-constraining roles like CEO, they were mainly happy to contribute as they considered the topic exciting and important. However, at times it was difficult to book time in the calendars of the interviewees. In the worst cases, no time was found during the thesis research work. The challenge of finding suitable times was increased by the need to find interviewees from multiple geographical areas. The large time difference between the author's home country Finland for example, the home region of many interviewees, California, limited the suitable timeslots.

In 2022, the author conducted 20 individual interviews. The sample size of 20 was selected as it was recognized as the saturation point by the author. The saturation point in the interviewing process is when new interviews do not anymore yield further information (Ojasalo & al 2014).

The author interviewed industry experts internationally and from multiple different roles to avoid biased views. The heterogeneous group of interviewees includes entrepreneurs who have just entered the field and veterans with over decades of experience, researchers, engineers and managers working for startups, and investors of these companies. The group includes Finnish, French, Polish, Swedish, British, US, and Icelandic nationals. 16 of the 20 interviewees hold or previously held a C-level position in a PPI startup. Seventeen of them are founders of PPI startups. The interviewees shared their experiences from more than 20 companies founded between 2006 and 2020. These companies' industries include agriculture, food, medical, automotive, CDR, and space. Most notably, the interviewees include two founder-CEOs who have founded both software startups as well as PPI startups. The list of interviewees is provided in the table on the following page.

Table 3: List of Interviewees

No	Relevant experience	Experienced collected from	Years of relevant experience	Interview type
1	CEO and co-founder of two startups: One software, one PPI startup	Finland and the USA	15	Video call
2	CIO and Co-founder of PPI startup	France	14	Video call
3	Various CEO, CFO, and board member roles in startups and established companies	Finland, USA	26	In-person
4	CEO and co-founder of PPI startup	Finland	10	In-person
5	CEO and co-founder of PPI startup	USA	6	Video call
6	Various VP positions in startups, partner at a Venture capital company	Finland, USA	21	In-person
7	Board member in two PPI startups. Partner at a venture capital company	Finland	9	In-person
8	CSO and co-founder of PPI startup	Finland	10	Video call
9	Investor and advisor for multiple PPI startups. Head of Strategy at a PPI startup.	Sweden, USA	17	Video call
10	Various roles in startups: Founder and investor	Iceland	7	Video call
11	Co-founder and CTO of two PPI startups. Investor.	Finland	14	Call
12	CEO and co-founder of PPI startup.	Finland, USA	9	Video call

13	CEO and co-founder of PPI startup	Finland	8	Call
14	CTO and co-founder of PPI startup	Finland	6	Video call
15	CEO and co-founder of PPI startup	Finland	6	Video call
16	CTO and co-founder of PPI startup	Sweden	4	Video call
17	CEO and co-founder of two startups: One software, one PPI startup	Sweden, USA	15	Video call
18	CEO and co-founder of two PPI startups	Finland	14	Video call
19	CEO and co-founder in multiple startups. One PPI startup.	Finland	12	Video call
20	VP of Finance and startup founder	UK	11	Video call

As mentioned, the interviews did not have a strict structure. Instead, the author invited the interviewee to a discussion that was directed to focus on the scope of the thesis research. The questions listed below served as a tool to guide the conversation. Sometimes lengthy discussions and follow-up questions accompanied the questions. The specific set of questions was selected to ensure that the interview touches upon the research scope from different angles inviting the interviewee to the insightful discussion. The questions were based on the theoretical framework. The questions were presented with an introduction and background depending on the interviewees' familiarity with the topic of the question.

With a portion of the interviews, the complete list of questions was not covered due to lack of time. Also, with a portion of the interviews, the questions were covered in a different order if the natural flow of the conversation led from one question to another differently as planned by the author.

Table 4: Interview questions

Question 1. According to Negroponte (1996) and Thiel (Sullivan 2014), there is a division between Bits and Atoms companies. Based on your experience, what are the key differences between these two classes when talking about startups?
Questions 2a. When looking at the subsection of Atom companies, the startups with Physical Product Innovation, what are the key challenges these companies face in the scale-up phase?
Question 2b: According to Niedermeyer (2019), the biggest challenge for a PPI startup is the transition period from a startup to an industrial company. What are your thoughts on this?
Question 3: Christensen (1997) described the different innovation types. How do the challenges vary between Sustaining Innovation and Disruptive Innovation when talking about production scaling?
Question 4a: Lin & al. (2008) describe that startups feel high pressure to reduce their time-to-market. How does this pressure show in PPI startups?
Question 4b. Lin & al. (2008) suggest outsourcing as one possible way to reduce time-to-market for manufacturing startups. What are the pros and cons of outsourcing for PPI startups?
Question 5: Negroponte wrote that Atoms companies are more heavily regulated. Do you agree, and if yes, how does this show?
Question 6a: According to Karlgaard (2019), “Investments pour in for Bits companies, but tend to avoid Atoms.” Is this correct?
Question 6b. Follow-up question for question 6: What other differences are there?
Question 7: In their 2008 study that interviewed multiple manufacturing startups, Lin & al. identified two key challenges in the scale-up phase are limitations in resource availability (often due to cash constraints) and uncertainty in sales. Do you recognize these challenges?

4.2.3 Interview Analysis

Interview results are analyzed with the appropriate methodology based on the interview type. Theme interviews and the open interviews are recorded and transcribed. The transcribed data is read carefully, after which the answers are categorized by themes and evaluated how the answers match the theory and research of the topic in question. The categorizing can occur by placing the answer in opposing brackets or possibly to common responses and outliers. Lastly, the researcher returns to evaluate the larger research concept to conclude how the data collected from the interviews enhance the contemporary understanding of the topic. (Ojasalo & al. 2014.)

The interviews conducted for this thesis report were recorded. When using video call software, the calls were recorded using the same software. In the cases of face-to-face interviews, the recording was done by using the author's smartphone. After the interviews, the author carefully listened to the recordings before transcribing the discussion. The transcribing took place on the same day as the interview to ensure that the fresh memory of the interviews was considered helpful in understanding the tone and exact meaning of the interviewee's answers.

After the interviews, the author collected the topics and claims raised by the interviewees in a spreadsheet. In the spreadsheet, the author used columns to identify key topics raised by the interviewees. Each interviewee was marked on the spreadsheet as a line. The interviewees' approach to the listed claims was marked to the corresponding cells as one of the four color options:

1. White: the topic was not discussed.
2. Green: The interviewee agrees with the claim.
3. Red: The interviewee disagrees with the claim.
4. Yellow: The interviewee has a neutral stance toward the claim.

Together with the color, the cell also includes text describing the comments the interviewee gave. During the analyzing phase, when a key topic was recognized, a new column was created, or a corresponding color code was added to the spreadsheet cell. The column names were adjusted throughout the interviewing process to cover a broader topic instead of having two similar ones. In addition to the key topics listed in the columns, more information from each interviewee was collected in the cells and in the last column of the spreadsheet titled "Comments." In the comment column, various important points were collected that did not naturally fall into one of the key topics listed.

Using the spreadsheet, the author was able to conclude the findings presented in this research in chapter five. The interview template and the analysis spreadsheet can be found in appendices two and three of the thesis.

Analyzing the answers to the ten questions, 11 key topics were found that surfaced in repeatedly in the interviews. As shown in the example below in figure 9, analyzing the answers to questions 2A, 3, and 7, the author concluded that out of the 20 interviewees, 16 agreed with the statement “PPI startups are more complex than solely software startups.” One interviewee disagreed with the statement, one did not have a clear opinion, and two interview discussions did not touch upon this topic. The names and comments in the example have been removed from the spreadsheet cells to ensure anonymity.

Topics recognized based on the answers and discussion					
				Question	2A, 3, 7
No	Name	Relevant experience	Location	Years of experience	PPI are more complex than solely software companies
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
16					
17					
18					
19					
20					

Agree with the statement
Neutral stance on the statement
Disagree with the statement

Figure 9: Example from the spreadsheet used to analyze the interviews.

4.2.4 Focus Group Method

Together with the individual interview presented in the previous chapter, the author conducted also focus group interviews. The focus group method is an interview type, but instead of just one interviewer and interviewee, there is a small group of people, for example, between six and nine participants (Denscombe 2007). If the group includes, for example, two interviewers instead of just one, the discussion can be more fruitful due to a more relaxed atmosphere and varying discussions. Also, the second interviewer can make notes on the reactions and answers of the group while the first one facilitates the discussion. The length of a focus group event is usually between one to three hours. (Ojasalo & al. 2014.)

The first step to organizing a focus group is to define the goal and what information the organizer is looking to find. Next, the participants who can help achieve the focus group's goal can be invited. It is not enough to find a participant candidate who just knows about the discussion topic. The organizer must evaluate whether the person matches the rest of the group. Also, the organizer must consider how different perspectives will be presented in the group. For example, suppose the topic is well-being in the workplace. In that case, it is vital that the group consists of employees with various roles and levels in the organization hierarchy. (Ojasalo & al. 2014.)

4.2.5 Conducted Focus Groups

After completing the interviews and analysis of the results, two focus group sessions were held. The goal of the focus groups was to challenge the findings of the literature review and interviewees to find either further evidence that the findings had been correct or needed adjusting. Secondly, the focus groups worked as a method to develop the Startup strategy guidebook.

During the sessions, domain experts with experience as startup investors, advisors, founders, and CEOs joined the discussion with the author. The first session took place in July 2022 and lasted approximately an hour. In the session, the author was joined by a group of three experts. One of the attendees was an interviewee earlier in the thesis research, while the others joined without an earlier in-depth discussion with the author. The second session took place in August 2022. The second session included two attendees, and the discussion took around two hours.

During both sessions to start the discussion, the author presented his early findings of the thesis research to spark conversation on the topic. See appendix four for the slides shown at the beginning of the focus group sessions.

The sessions were recorded by the author using his smartphone. The recording was analyzed directly after the session, and critical points were recorded in a notebook. Lastly, the findings were incorporated into the thesis.

While the focus group sessions were smaller in terms of participants than suggested by Denscombe (2007), both sessions were successful in refining the findings of the literature review and the interviews. There were no clear findings that the focus group members would have disagreed with, and the group further confirmed most key findings. However, the members were able to identify new angles initially missed by the author and add new details to the angles agreed upon on the higher level.

5 Interview Outcomes and Focus Group Analysis

In this chapter, the information collected from the interviews and the focus groups is analyzed and evaluated in relation to the information gathered from the literature review. Statements presented in the following chapters are based on the analysis by the author.

5.1 The Business Environment of a Startup

When talking with the interviewees about the research questions about what makes PPI startups unique and what challenges and risks they especially face, the discussion led naturally to the high-level concepts behind the challenges. Looking at these concepts, one can recognize the differences between different types of companies and how they are positioned against them, PPI startups included.

Throughout the interviews and focus group discussions, seven key business areas were recognized that define the business environment of a startup, not just the PPI startup. The key areas are:

1. Design-Only or Design and Manufacturing
2. Technology Maturity
3. Manufacturing Technology
4. End Product Type
5. Gross Margin
6. Safety Criticality
7. Raw Material and Component Availability

As mentioned in chapter 4.2.5, the focus group sessions mostly confirmed the findings of the interviews conducted before them. Together with providing further evidence of the interview findings, the focus groups offered more details and additional angles on the identified topics. The exception was identifying the seventh key area of the business environment; raw material and component availability. The following chapters present the seven key business areas one by one.

5.1.1 Design-Only or Design and Manufacturing

When answering question one of the interview, the interviewees generally recognized that PPI Startups are a natural subcategory of startup companies. However, there were various views on the higher-level division of Bits and Atoms or Software and Hardware startups. The two mentioned ways to divide startups did not feel natural to many interviewees as it was pointed out that hardware companies are also working on software. Additionally, if the grouping is based on software and hardware products alone, services provided and developed by the startups would not be addressed. The concept of Bits and Atoms was new to most interviewees, and even after the description of it, this way of categorizing did not feel right to the majority. Instead, the most matching way to divide startups between the ones associated with manufacturing and supply chain-related challenges and those free of them is “Design-only” and “Design and Manufacturing” startups. This division was used by Elon Musk when describing the operation scaling of his PPI startups Tesla Motors and Space X (Fridman 2022).

Service and Software startups are Design-only companies and are free of the challenges related to physical manufacturing. Their challenges are associated with designing a product or a service that finds a market fit. The Design and Manufacturing startups must deal with the same challenges as the Design-only startups, but additionally, they face the challenges of manufacturing. A focus group member argued that a startup always has the Design part associated with it. Manufacturing-only companies do exist, but they are not startups as startups, by definition, are designing something new.

As described in chapter 3.5, PPI startups are a subgroup of Design and Manufacturing startups. The high-level group can include startups creating something new to the marketplace with manufacturing that is not innovation-related. However, it can be said that in many cases, Design and Manufacturing startups have innovations related especially to the manufacturing side.

Manufacturing processes come with a wide range of challenges that the PPI startup must address. The processes include raw material sourcing, warehouse management, manufacturing facility management, and machinery. While the challenges are irrelevant for Design-only startups, solving them is a question of life and death for a Design and Manufacturing startup. What these challenges mean and what is their impact on PPI startups are analyzed in detail in chapter 5.2.

5.1.2 Technology Maturity

The maturity of the technology used and created by a startup dictates what type of challenges and risks it will face. There are two areas in which the technology maturity is relevant: First, the value creation phase of the internal processes, like manufacturing or coding, for example. Secondly, the output of the internal processes, the product or service provided to the market. When talking about Physical Product Innovation startups, the word innovation in the name already tells of the novelty at some level. There are one or more innovations associated with the manufacturing, the output product, or both.

As described in chapter 3.7, Innovation Management, there are different kinds of innovation: A disruptive innovation implies a more significant technological jump than sustaining innovation. When answering interview question three, a Co-Founder and Chief Technological Officer, CTO, of a PPI startup described the difference between working with sustaining and disruptive innovation as “dramatic.” According to the CTO, while sustaining innovation can be manufactured with mostly existing industry knowledge and machinery, disruptive innovation requires a radically different approach to all business areas, increasing uncertainty, higher risks, and high upfront investment. Thus, working with innovation alone does not automatically tell if the used technology is of low or high maturity. However, keeping in mind the startup definition used in this research, “A human institution designed to bring something new under conditions of extreme uncertainty and aiming for high growth (Ries 2011),” a company only with a sustaining innovation might not be defined as a startup.

In the cases where a startup’s technology maturity level is low, there are more unknown unknowns in the value creation process that must be addressed at the same time as the unknowns related to the market fit. The characteristic of PPI startups having both internal and external unknowns was identified uniformly by all the interviewees. One of the rare research papers published about manufacturing startups is research done by Lim & al. (2008). However, the scope of their study was manufacturing startups with no mention of innovation. A manufacturing startup might be using high-maturity technology and producing high-maturity products while having market-related unknowns.

In discussions around interview questions one and two A, three interviewees highlighted how the PPI startups lack some key infrastructure elements available to software and the Design-Only startups. No-code tools to set up basic functionalities like servers and cloud-based computing power offered globally are essential to startups operating in the Bits realm making operational scaling fast and cost-effective. The ready infrastructure tools used by software developers are high maturity, meaning they are reliable, cost-effective, easily accessible, and of high quality.

Similar tools are not available for PPI startups that require scaling elements in the form of manufacturing space, workforce, raw materials, and machinery. However, as noted by an interviewee, having low technology maturity cannot be said to be a case of only companies with physical products. While Design-only startups primarily work with high-maturity coding languages, computer hardware, and IT infrastructure, Artificial Intelligence is an example of low-maturity technology a design-only startup might be working with.

The technology maturity also impacts the manufacturing options available for the company. If the technology used in the manufacturing process is very new, there might not be any contract manufacturers who could directly offer their services (Hagenbuch 16 June 2022).

The low technological maturity leads to increased risk exposure in all risk areas of hazard, strategic, financial, and operational risks, as there are more unknowns. The risks include operational risks such as increased fluctuations in quality and quantity. When there is an increased risk that a company cannot deliver the agreed quality and quantity to its customers with high confidence, the customers are more hesitant to engage in business. A portion of the interviewees mentioned that Design and Manufacturing startups have a higher challenge in finding their first customers because of the described reason. Interestingly, in his answer to interview question 6A, a CEO and founder of a PPI startup claimed that customers generally expect a higher quality from a physical product than from software. If this claim is valid, it partly adds to customers' high barrier to entering into a business relationship with a Design and Manufacturing startup.

A method to counter the challenge of potential customers having low confidence due to the low technology maturity was suggested by an interviewee: In the early developed stages of technology, the company can sell the product as a service, not as a product to be owned by the customer. In an imaginary example case, a company is producing a flying car. The company producing the flying cars could initially offer its customers a taxi service to generate revenue and collect invaluable experience and customer feedback. Even if the flying car would require servicing every day, the operations could commence. However, a car that needs so frequent servicing would not be accepted as an owned product by the customer. Later on, once the technology has matured, the business model can be revisited.

5.1.3 Manufacturing Technology

Based on the interviews conducted, especially around questions two A and six A, the technology used in the manufacturing processes impact a PPI startup's business outlook. In industries where manufacturing requires high technology, higher complexity is expected. Example industries where high technology is needed for the manufacturing of the end product are the car industry and space technology, the industry from which multiple interviewees were found. On the other hand, PPI startups might use low-tech solutions in manufacturing. Examples from this end could be found in food technology.

Hight technology often means a higher capital expenditure, Capex. Following the car industry example, a car manufacturing line involves extensive facilities, large die machines, and numerous robots. A plant-based food technology company presents an example from the other end of the spectrum. To create meat-like textures from plant-based raw materials and extruder machines, a limited selection of post-processing machines and a packing line form most of the investments needed. While a food production line costs only a fraction of a car manufacturing line, it is still significantly more than a Design-only startup would be required to do where an office, laptops, and cloud services are sufficient.

In the context of PPI startups, having low or high-technology manufacturing processes impacts the needed Capex. Together with Capex, a company must also consider its operational expenditure, Opex. With the strategic decision described next, a PPI startup has the opportunity to balance between the two: For the PPI startups, running the manufacturing process might cost a lot, even for testing purposes, because of the expensive raw materials. This challenge was highlighted by a biotechnology startup founder. According to the founder, their company decided to purchase multiple smaller bioreactors instead of fewer larger ones. Looking only at Capex, this is counter-intuitive as the direct and total costs of ownership are higher. However, the smaller bioreactors allow the company to use fewer raw materials in the R&D phase, thus saving money on the Opex side. Lastly, the founder pointed out that investors are more willing to finance Capex than Opex as the machinery investments can be recovered to a certain extent should the startup go under. Operational costs cannot be retrieved; they only translate into intangible factors like knowledge and experience. Balancing between optimizing costs away from Opex to Capex can be a way for a PPI startup to attract more investors.

5.1.4 End-Product Type

Just as with the manufacturing technology, also the end product type can be either low or high technology. However, according to the overall interview analysis, the two topics have their separate impact on the business environment of the PPI startup and thus must be considered separately. The car industry continues to serve as an excellent example. The car is manufactured with high-technology in a complex process. Additionally, the output is high-technology and a complex system on its own. To repeat high-quality output time after-time with little error margin on a complex system is a situation that requires significant resources in both Capex and Opex from the organization. The view was shared with the majority of the interviewees, as well as Niedermeyer (2019) and Ruffo (2022), who studied the car manufacturer Tesla Motors in their publications.

Food manufactured in bioreactors and biotechnology, in general, are examples of a process where the manufacturing process is high-technology, but the output is simple: food products packed in plastic and carton. The plant-based food manufacturing example presented in the previous chapter is a case where the technology used for manufacturing and end-product are low-technology.

In conclusion, the more complex the end-product is, the more challenging, riskier, and expensive the manufacturing is for a PPI startup.

5.1.5 Gross Margin

Gross margin is a profitability measure for a specific product. The lower the margin, the more products must be manufactured and sold to reach profitability. (Stobierski 2020.) Gross margins vary between industries and product segments. Low gross margin sales mean the company must conduct more significant volume business to reach similar total sales as a company with a high gross margin. (Sherman 2019) For a startup company, reaching high volume and repeating a standard quality each time is a major challenge. While the goal of Tesla Motors from the beginning was to serve a wide audience and to offer an affordable car, they understood the challenge of lower margins of the regular cars versus luxury models. In a blog post describing Tesla’s strategy, the CEO Elon Musk wrote that the company's master plan is first to build a sports car, then use the earned money to build an affordable car, and after that, use the earner money again to build an even more affordable car (Musk 2006).

Food products are a commodity that is generally always a business of low gross margins. However, an aspect pointed out in the focus group discussion is that the selling margins sometimes vary significantly between different markets. For example, the oat milk brand Oatly is selling its products at approximately double the price in the USA compared to the Nordics due to the local market conditions.

Selecting the right customer segment, selling channel, and geographical market can play an essential role in reaching profitability for a startup. Also, a plan to use different market segments as a growth plan can be considered, as shown by the example of Tesla Motors. However, a founding partner of a venture capital firm stated in a webinar that searching for the right channel or market should not be a focus point for an early-stage food startup. According to him, the topic is not a deciding factor in whether or not the company will succeed. Instead, he suggested that as long as the team and the startup’s product are good enough, these questions will be solved later. (Böhi 16 June 2022.)

5.1.6 Safety Criticality

Most interviewees brought up safety criticality as a key factor when discussing PPI startups during interview questions two A, three, and seven. In industries like space technology, food, medical, and automotive, failures of the products can, in the worst case, be catastrophic leading to serious injury or death. In general, many physical products fall into this category. The topic of safety criticality is not related only to the end product. Manufacturing that involves heavy machinery, high voltages, temperatures, and pressures involves an element of risk that must be addressed carefully.

Poor safety and risk management can lead to enormous costs for the startup, even without the risks occurring. For example, a food industry company must recall its products if it suspects that there is even a slight change that its product is unsafe for consumers.

To prevent severe risks from occurring, startups with safety-critical systems are forced, also by regulation, to have multiple processes in place for quality control. As described by multiple interviewees, the prevention measures increase operational costs and add complexity. Additionally to the quality control processes, documentation like the General Manufacturing Practice, GMP, are required. The authorities and customers of the medical industry, which is an example of a highly regulation business area, expect companies to comply with strict quality certificate programs like various ISO, International Standardization Organization, standards. Compliance with the standards is confirmed in regular audits. All these mentioned factors mean that a significant amount of resources must be used by the startup to ensure the safety of its employees, customers, and other stakeholders.

Introducing the MVP products to a real audience as early as possible to collect user data is a corner stone of the Lean Startup school of thought and a standard practise in the software industry (Ries 2011). Unlike non-safety critical products and services, safety-critical systems cannot be beta tested with the actual customer in a similar way impacting the critical time-to-market timeframe.

5.1.7 Raw Material and Component Availability

Raw material and component availability is a factor that did not come across as a key point during the interviews but was recognized as a critical question that can impact a startup's fortunes during the first focus group session. Raw materials include products like chemicals, food ingredients, and components include mechanical or electrical components, for example. The computer chip, a critical component in various products from smartphones to vehicles and everything in between, was in short supply during the

Covid-19 pandemic. Most companies, including the world's largest like Volkswagen Group were impacted. (King, Wu and Pogkas 2021.) On the food industry side, the supply of specific raw materials is also affected by global phenomena like the pandemic, but they are also influenced by the weather conditions. As an example given by an interviewee, a harvest of a specific berry failed dramatically in 2021, leading to a worldwide shortage and forcing the startup of the interviewee to make drastic changes in their product portfolio.

The variation in raw material availability is also industry-specific. For example, unlike the Nordics, the USA is a region that is ineffective in industry sidestream utilization in the fields of agriculture and forestry, for example. Thus, the prices of the same sidestreams in the Nordics are significantly higher. (Holmes 17 August 2022.)

Startup companies are specifically vulnerable to raw materials and component supply fluctuations. Unlike an established company, a startup lacks negotiation power due to lower volumes. Additionally, startups rarely have the capital to build buffer stock and endure high inventory carrying costs. Lastly, forecasting is especially challenging for a startup due to the lack of historical data: Learning late the quality and quantity of raw materials required leaves the startup exposed to a higher risk of not being able to acquire the needed products or needing to pay a higher price.

When looking at PPI startups specifically, the innovation might involve raw materials that are not widely available due to their novelty. In these situations, the horizontal integration of the supply chain upstream is limited. An example was provided by an interview from the field of cellular agriculture. A key component in the process of growing muscle cells in a bioreactor requires growth mediums. The traditional growth mediums are expensive and have fluctuating quality unsuitable for high-scale operations. Also, they are unethically sourced by a method that is not scalable. The lack of supply in this area exists simply because there has not been a demand for higher qualities and higher quality. The lack of supply has led multiple companies in the field to develop their own growth medium, notching them toward the full-stack startup business model described in chapter 3.10. Similar findings of cellular agriculture are also presented by Kleeman (2020; chapter 8).

5.1.8 The Startup Challenge Multiplier

Discussing the key factors presented in chapter 5.1, the focus group played with an idea of if it would be possible to give a score to the challenge level a startup is taking on depending on its business environment. While understanding that scoring does not have concrete scientific value, it can indicate issues the startup must focus on during its journey from founding towards established business operations. The table and score card drafted are shown in tables five and six on the following page. In table five, each column presents one of the seven business areas presented in chapter 5.1. Selecting the most appropriate option for each column, the test maker is given a challenge multiplier score that reflects the challenge level of the startup or business idea. Depending on the business challenge, there are two or three options to choose from. The higher the score is, the more significant the business challenge is for the startup. Table six offers a way to interpret the score level.

Table 5: Startup challenge calculation table

Challenge Multiplier points	Business Type	Technology Maturity	Manufacturing Technology	End-Product Type	Gross-Margin	Safety Criticality	Raw Material & Component Availability
2	Design + Manufacturing	Low	High-tech	High-tech	Low	Yes	Limited supply
1	Design Only	High	Low-tech	Low-tech	High	No	Wide supply
0			No manufacturing	No manufacturing			No manufacturing

Table 6: Startup challenge score card

Challenge multiplier	Startup phase	Established company phase	Example industry
12- 14 points	Extremely hard to succeed	High protection from competition	Mobility, quantum computing
8-11 points	Very hard to succeed	Some protection from competition	Food tech, bio tech
5-7 points	Hard to succeed	Low protection from competition	SaaS

Using Tesla Motors as the example, the table is used as follows:

- **Business Type:** The company is involved in manufacturing, meaning that at the beginning, Tesla was a Design + Manufacturing startup: 2 points.
- **Technology Maturity:** Electric cars and battery technology were low maturity areas when the company was founded: 2 points.
- **Manufacturing technology:** Manufacturing a car is a complex operation that requires high technology: 2 points.
- **End-Product Type:** A car is a complex high-technology product: 2 points.
- **Gross-Margin:** Automotive industry is a low gross-margin business: 2 points
- **Safety Criticality:** A failing car can lead to serious accidents: 2 points
- **Raw Material and Component Availability:** At the beginning of its journey, Tesla had a limited supply of components. To tackle the challenges, Tesla has built a vertically highly integrated supply chain. For example, Tesla manufactures its batteries, unlike its competitors (Jin,2022). Limited supply: 2 points.

In this simple exercise, Tesla receives the maximum challenge points. Tesla's challenges in 2022 are much different, but then again, it cannot be considered a startup anymore. The list of failed startups working on electric cars during the same time is long, including names like Faraday Future and Fisker Karma (McKenzie 2018). Fisker Karma testifies to the magnitude of the challenge to build a PPI startup when all the seven recognized categories are against you: The company raised two billion dollars in funding but filed for bankruptcy only after producing some two thousand cars. (Eisenstein 2019). In August 2022, Rivian estimated that is annual losses would pile up to 5,45 billion dollars. The target for the company for the whole year is 25.000 cars, but by the end of Q2, it had delivered only under 5700 units. The reasons given for the enormous losses and falling behind manufacturing targets were "supply chain challenges" and "raw material inflation." (Weber 2022).

However, a few interviewees and the first focus group suggested that the higher the challenge to enter the market and reach profitability, the better the company is protected from new entrants to the market if it succeeds. In the software business, everyone with coding resources, an internet connection, and computing power can make a copy of a successful product. In the food technology field, for example, the risk of copy products appearing fast on the market is lower because it is a common scenario that the company has multiple years of university research behind the innovation before spinning off to commercialize it as a startup. (Founder's Institute 2021). Also, when a PPI startup emerges as a successful business, it is most likely many years ahead in terms of long-delivery time purchases and setting up complex manufacturing processes than a company wanting to follow the successful example.

5.2 The Business Environment of PPI Startups

In chapter 5.1, the seven business areas were presented on a high-level. Now, in this chapter, the key points learned from the analysis of the interviews and focus groups related to PPI startups are presented.

5.2.1 What Makes PPI Startups Different

Based on the answers to interview questions two A, three, six A, and seven, PPI startups stand out from other startups because they also have internal, not just external, hypotheses they need to validate. Externally, the market fit is unknown, and this challenge is shared with all startups at the beginning. The internal questions of PPI startups are related to unproven innovation and manufacturing. At the start of the PPI startup's journey, open internal topics include whether the technology works at all at scale, and if it does, can it be done with profit?

For Design-only startups, scaling means finding the market fit; if that is found, it is mostly about human skills to create the product or service. The people either do the work efficiently or not, depending on their talent and management. With PPIs, managing human resources well is not enough. The success of the scaling also depends on multiple stakeholders in the supply chain of the company. When working with physical supply chains that sometimes have significantly long delivery times, the PPI startup must rely on forecasts that are never 100 percent correct. In other words, at times, the processes' bottlenecks and critical parts are outside the company that is operating on a forecast. The presented factors show a significant difference compared to Design-only startups.

The entrepreneurs interviewed who had the experience of both Design-only and Design and Manufacturing startups clearly agreed that regardless of the way the startup arranged their manufacturing, having manufacturing together with the design aspect adds a significant amount of complexity to the startup. Manufacturing processes come with a wide range of challenges that the PPI startup must address. The processes include raw material sourcing, warehouse management, manufacturing facility management, staffing, and machinery operations.

In practise, a startup has three options to arrange the processes: Build in-house capacities, use contract manufacturers, or use a hybrid model in which manufacturing is partly done in-house and partly by a contract manufacturer. The mentioned topics are described in detail in chapter 3.6.

The complexity of PPI startups becomes evident when looking at an example industry of cultured meats. Cultured meat products are produced in bioreactors instead of farming and slaughtering the animals. The field is one in which multiple PPI startups are looking for a breakthrough on the industrial scale in the 2020s. A website called CellAgri, focusing on the industry released The Cell-based Meat Supply Chain Report 2021 in early 2022. The report calls the companies in the field to focus on in-house raw material development, the development of bioreactors, packaging, and up- and downstream supply chain development. (CellAgri 2022.) According to a founder-CEO working in the field and most interviewees, all the mentioned areas are challenges that require significant time and effort to tackle. While the challenges are irrelevant for Design-only startups, solving them is the key to success for PPI startups.

While there are clearly identified significant challenges that Design and Manufacturing startups must address that Design-Only does not, there was no consensus whether or not it can be said that association with manufacturing would automatically mean that the business environment would be more difficult than with startups without manufacturing. An interviewee commented that the difference between the two startup groups is that with manufacturing, there are more open questions to answer, both internal and external. According to Elon Musk, designing advanced technology is easier than bringing it to high-volume manufacturing (Fridman 2022). However, the quantity of questions does not automatically tell the quality of the challenge. Another interviewee said we cannot say that PPI startups are more complex and challenging. What we can say is that a startup with technological unknowns is more complex and challenging than one without them. However, the challenging technology can be software as well, like in the cases of complex medical systems or AI.

Elon Musk offered a way to recognize where the key issues are located within a PPI startup in an interview on the Lex Fridman podcast in 2022. He suggested asking if your product will be expensive when you produce one million units. If the answer is yes, the issue is in the design, not the manufacturing. The argument is based on utilizing economies of scale. Continuing on the topic of manufacturing costs, Musk added: “If you think only about the raw materials of a ready product, the answer is usually very low. But how you arrange the raw materials into the ready product is where you have the cost. Elon adds that you need to aim as close as possible to the cost of raw materials plus license costs of IP. (Fridman 2022.) Interestingly, the license cost for IP, which Musk mentioned as a significant cost factor in manufacturing, did not come up during the literature review, interviews, or focus group sessions.

Another challenge for PPI startups is high regulation due to the nature of the products and businesses they are naturally part of. Physical products such as food, medication and transportation methods like cars can be lethal is there is a quality issue. There are high-regulated software products as well, but more often, when talking about software products, they are not defined as safety-critical. There are also safety-critical software products, but they are not exposed to the risk of variable end-product quality. When describing the differences between hardware and software manufacturing, a founder-CEO said: “While physical products are built one by one or in batches, Software products are identical copies of themselves with no quality fluctuations.”

5.2.2 Extended Time-to-Market

When discussing PPI Startups with interviewees around interview question four and focus group members, the need for manufacturing facilities, warehouses, and the complete supply chain were mostly the first things pointed out. What these requirements mean in practice is that everything takes longer than in the digital world: Things travel from place to place in these supply chains in days, not seconds, like in the IT sector. While a Design Only company can multiply its manufacturing just by a few clicks to increase its cloud server capacity, Design and Manufacturing companies like PPI startups rely on long-lead-time machines, rental contracts, and physical raw materials and components. Similar challenges are related to changing or downgrading the manufacturing capacity; unlike the cloud capacities, physical factory layout and machine selection are difficult to adjust. The prolonged timeframe translates into extended time-to-market and delayed first revenue, the key challenges also pointed out by Lim & al. (2008). The extended time-to-market again leads to various challenges described in the following three chapters.

5.2.3 High Need for Upfront Investments

Manufacturing requires significant upfront investments, and the pressure to invest can grow high at a stage where the market fit has not been confirmed, and technology is still developing. The pressure comes from the startup’s stakeholders, like the investors who recognize the long time-to-market estimations. No matter how the manufacturing is arranged, the missing must-have infrastructure leads to extended time-to-market and delayed first revenue for the startup compared to Design-only startups.

Together the high investment and longer time-to-market mean that PPI startups need to acquire more funding than Design-Only startups. Still, at the same time, the potential investors are promised an extended return-on-investment time. According to a PPI startup founder, PPI startups must be very cautious when negotiating funding with venture capital firms. In the case that the investors do not fully understand the business environment of PPI startups and expect the startup to develop as fast as a Design-Only startup the relationship can be detrimental to the startup.

In their answers to questions two A, five, and six B, multiple interviewees brought up that the association with manufacturing processes means that a wider workforce is needed as there is a broader range of processes to manage. Organizationally, this means that there are more departments and a larger number of titles the employees carry. It is likely that the number of employees needed is higher compared to Design-only startups. Even if the organization would, by the number of people, be like a Design-only startup, the organization would be more complex and thus more challenging to manage.

5.2.4 Less Flexibility

The manufacturing-related processes make the startup less agile. As described by multiple interviewees, having to make significant investment decisions is a major hurdle for startups that usually are cash restricted. For example, a piece of machinery can have a delivery time of close to a year. Not only does the long lead time slow the progress of the company, the machine, once it arrives, is not as easy to adjust if needed. Making long-term decisions requiring significant funds is a major risk for a young company. As described by an interviewee, the “fail fast to learn fast” mantra familiar in the startup culture is valid also with PPI startup, but each test run and failure are just an order of magnitude more expensive.

The low flexibility is also related to the factors described in earlier chapters: raw materials availability and reliance on external stakeholders and forecasts. Increasing the vertical integration level in a similar fashion that Tesla Motors did when they started to manufacture batteries in-house is an option to tackle both challenges and increase flexibility. The obvious downside is the increased capital requirements and all associated risks, as described in chapter 5.2.3. However, vertical integration cannot be done realistically so much that the company would not be at least partly at the mercy of its supply chain of components and raw materials. The value stream extends beyond the company since it is unrealistic for a car manufacturer, for example, to produce all its components, let alone the raw materials to components. For a Design-only company, these challenges do not exist in practise. They can scale down their cloud capacity as fast as they increase it, even during the same day. Also, the needed services and tools are often available from multiple different vendors.

5.2.5 High Risk Exposure When Scaling

With PPI startups, the success depends on multiple external stakeholders like machine suppliers and the complete supply chain's functionality, which again is impacted by world events like pandemics, wars, and even the weather. The reliance on external stakeholders means that the challenges and the risks are significantly out of the company's control, no matter how good their risk management processes are. With Design-only startups, success depends on human labor done mainly on a computer. In risk management terms, Design and Manufacturing startups are more exposed to external risks.

The high-risk exposure culminates in the topic of scaling: While software products and services offer the path for “infinite scaling,” as described by an interviewee, PPI does not. With PPI, you can not go directly to the industrial scale because of the market-related unknowns but also due to technical questions. A PPI startup must take one or more intermediate steps toward the industrial scale to allow validation of the technology with less risk and investment. In a study focusing on environmental technology startups, multiple real-life demonstration units must be tested before a full-scale unit can be built (Saukkonen and Vänttinen 2017; 106).

When describing the methods to tackle the high risk exposure, a founder-CEO of a PPI startup said that when planning the steps toward the industrial scale, the company must consider three things: The capacity increase with each scaling step, the specific technology used in each step, and the vision of the final stage of development. He illustrated the need for the three with the following example: When drying organic matter, different technologies are feasible depending on the needed capacity. With small volumes, a cheap and fast technology type might be available, but the same drying method is not available anymore when volumes reach a specific level. If the final stage is not understood by the company already in the early stages of scaling, it might choose a drying method that must be discarded before the last steps of the scaling process. This change would undo the value created by the scaling steps.

The question if modularity could be an answer to the risks and high investment related to scaling divided the opinions of interviewees. An argument against modular designs in manufacturing equipment is the loss of economies of scale. For example, a round bioreactor increases capacity in volume according to pi, meaning that making one bioreactor bigger increases capacity more efficiently than multiplying the same unit. However, the purpose of the intermediate scaling steps is not to reach profitability but to validate the technology. An argument against using larger units at the beginning can be found when thinking of the Opex, not only the Capex of the machinery investment, as already introduced in chapter 5.1.3. In this example of the bioreactor, running a larger unit would cost more for each trial if it needs to run full of costly raw materials. Thus, a company looking to leverage the economies of scale by making a more considerable Capex investment might make at the same time a significant commitment in Opex that might again mitigate the benefits gained by the larger unit.

As discussed in chapters 5.2.3 and 5.2.4, PPI startups need large investments for long lead-time projects that are hard to adjust once ordered. Due to the association with new innovations, the investment of a PPI startup in a piece of machinery like a bioreactor can turn out to be the wrong one. There is a considerable sunk cost, as fixing faulty purchases is expensive in time and money. According to an interviewee, founders might be afraid to commit to iterations due to the high cost against better judgment.

Outsourcing the manufacturing to an external partner has already been discussed from different perspectives in the previous chapters as one potential solution to tackle the issues PPI startups must address. From the risk management perspective, outsourcing can indeed address some of the issues described in this chapter, but there are clear downsides to it as well. In essence, using a contract manufacturer means trading Capex into Opex and changing the set of risks the company is exposed to. While the investments needed are lower and the time-to-market faster with a contract manufacturer, the short-term gains might be lost in the long-term. In the long-term, the risks are related to potentially losing the IP as the operations are handled outside the company but most importantly, the tacit knowledge is being collected by the contract manufacturer. If a single contract manufacturer holds the tacit knowledge, the OEM becomes dependent on it, the only organization that has learned the manufacturing process details.

Going for in-house manufacturing instead of outsourcing might lead to extended time-to-market as the manufacturing infrastructure is built from scratch. The time-to-market is a crucial challenge for PPI, according to multiple interviewees and the study by Lin & al. (2008). The pressure to reduce time-to-market and the challenges of manufacturing scale-up were illustrated in a news article describing the failed scaling of PPI startup Gold & Green Foods. The organization started to build its second factory while the first was still doing test runs. Eventually, the factory was one of the key reasons the company failed: "Our manufacturing process was so expensive that scaling it to a profitable level would have taken too long, " said the anonymous source in the article. (Lappalainen and Pyhäranta 2022.) It is interesting to notice that the source did not consider that it would not be impossible to manufacture with profit, but it would have taken too long. One can also speculate that the building of the second factory was started so early due to the pressure of bringing more volume to the market, leading to further challenges.

5.2.6 The Challenges of Transitioning to Industrial Scale

A critical point for PPI startups is to crystallize the purpose of the manufacturing processes. The purpose of manufacturing in the context of PPI startup should be considered learning, not profit generation. Multiple interviewees described the challenges of understanding this mindset in their answers to interview question two B. At the point where the startup has acquired manufacturing capacities, it has already traveled a long way. It can now finally start serving customers and sending invoices. At this stage, it is easy for the mentality to change to thinking that the manufacturing process should generate a positive gross margin, even though, for the manufacturing part, the learning has just begun. Switching from the exploration to the exploitation phase must be a conscious strategic decision, not something to sneak in from the manufacturing department. Managing the shift from exploration to exploitation was named as the biggest challenge of a PPI startup by an interviewed CEO. 17 of the 20 interviewees agreed that the transition is a major challenge for a PPI startup. Another interviewee said that manufacturing scale-up and cost optimization could not be done simultaneously, meaning that if the mentality shifts to optimization and profit-seeking, it means moving away from the scaling and thus learning.

Another challenge related to the transition to the industrial scale is the possible identity crisis within the startup. The transition was named by the interviewee CEO as the most significant challenge because the whole mentality needs to change for the company. If a PPI startup reaches this stage, it does it because it has been able to carve out a place in a market for itself where it has been competing against established companies with significantly more resources. The startup has been more innovative, effective, and flexible than the large established corporations. However, when the company reaches the industrial scale, the qualities that made the organization successful are no longer suited for success. Instead of flexibility, consistency is now the key. The critical question is can the PPI startup facilitate this cultural and operational change without losing innovativeness and efficiency?

6 Conclusion

In this chapter, research questions and the identified key challenges around them are studied.

6.1 Research Outcomes

The three research questions of the thesis are:

1. What is unique about the manufacturing scale-up of physical product innovation in a startup company?
2. What challenges and risks does a startup with a physical product innovation face when it scales its manufacturing capacities?
3. What best practices should startups consider in the manufacturing scale-up of physical product innovation?

The first two questions are answered through the literature review, interviews, and focus group sessions, as presented in chapter five. Question number three was partly addressed in chapter five when discussing the topics identified during the research, but the answer is completed in the comprehensive collection of the best practices are presented in the strategy guidebook for PPI startups, the constructive output of this thesis. The guidebook can be found in appendix one. The conclusions presented in this chapter are based on the interviewees, focus group discussions, and the literature review.

The questions of what is unique about PPI startups and their challenges were answered in the thesis thanks to the wide range of knowledgeable interviewees who participated in the research. PPI startups' unique nature includes exposure to a wide range of business challenges, extended time-to-market, high need for capital for manufacturing-related investment, decreased flexibility, and increased business risks due to the combination of high capital need, long infrastructure projects, and the extended time-to-market. The business environment of startups when manufacturing and physical innovation are involved is very different than designing a software product or a service. Unlike in software, repeating the same top-quality time after time is an enormous challenge. Additionally, a manufacturing startup relies more on external stakeholders for its success. While a software product's success is about human skills and organization, manufacturing in the physical world means reliance on global supply chains that are prone to disturbances.

The best practices to manage challenges and mitigate the risk when scaling manufacturing in a PPI startup are presented in the strategy guidebook named Lean Production Scale-up by the author. There are three key messages in the guidebook:

Firstly, the scaling model offered by the guidebook seeks to allow the company to make its manufacturing-related investments as soon as possible time-wise, but as late as possible in the learning curve. To enable this, the company must maximize its capability to learn internally about its manufacturing processes. The key to achieving this is to view the first manufacturing lines as processes to learn, not to generate profit. Only after the company has collected evidence of the type of machinery and processes it needs to generate profit comes the time to make the significant investments and shift the mindset from exploration to exploitation. The guidebook is presented in detail in the next chapter.

6.2 Developing the Guidebook for Physical Product Innovation Startups

The guidebook "Lean Production Scale-Up. A Strategy Guidebook for PPI Startups" is the constructive outcome of this thesis research. The guidebook is a tool created for an EU-based PPI startup preparing for the manufacturing scale-up of its physical innovation in 2022. The guidebook's purpose is to present practical guidelines and best practices on how to scale up efficiently and with controlled risk exposure.

The guidebook has three parts. First, key concepts like the definition of PPI startup are presented to the reader in the introduction chapter. While the guidebook reader is encouraged to read this thesis report, the guidebook includes the same key concepts presented in the thesis, so the guidebook is also useful as a stand-alone document as well. After the key concepts, the guidebook itself starts. First, two high-level principles are described. Secondly, a four step-model to guide the decision-making in manufacturing scaling from the very first tests to the industrial scale is described. Lastly, a chapter called "Things to consider when scaling up your manufacturing" collects together various individual ideas and best practices.

The presented topics and recommendations in the guidebook are based on the thesis research. The knowledge base is shaped into the form of the guidebook by the author, keeping in mind the audience of leadership teams of PPI startups: Reading the guidebook, a PPI startup leadership can find guidance concisely. Also, the guidebook is a tool to revisit when a company faces a strategy decision. The guidebook is a tool that helps decision-makers think about the challenges they face from different angles and thus helps them find the best answer to the question.

While the guidebook was prepared for a specific company, the theoretical models in it are universally applicable to any PPI startup company preparing or executing the production of a physical innovation. Additionally, startup stakeholders like the board of directors and potential investors could consider using the guidebook to identify key strategic points a

PPI startup will face in the future. The guidebook can be found in appendix one of this thesis.

6.3 Feedback on the Guidebook

As the last step in the research work, the strategy guidebook was presented to multiple PPI startup founders for review. The executive review chapter that starts the guidebook in the final version was added based on the reviewers' feedback. The chapter was considered essential to evaluate if the guidebook was worth their time to dive into in detail. Two of the reviewers recognized the build-measure-learn-double-loop as a topic that caught their attention and underlined the key message of the guidebook: the PPI startup is not just about finding the market fit but also finding evidence the technology works. The most encouraging feedback came from a CEO of a PPI startup. He found the topic of the guidebook so vital that he forwarded the guidebook to his management team to read.

6.4 Thesis Research Process

For the author, writing this thesis was demanding but rewarding. It was a pleasure to see how passionate people working in startups are about their work and how helpful they were by sharing details of their experiences. The Covid-19 pandemic impacted the thesis research limiting the author's ability to travel to meet interesting people in person. Videocalls were used as a substitute, but it is possible some nuances were lost due to the lack of in-person connection in most of the interviews. The interview type selected was the open interview. The open interview that offers the interviewer and interviewee to engage in a discussion more than a strictly structured interview worked well to invite the industry expert to bring up topics they considered important. The downside of the open interview format is the lack of uniformity in the answers, and a significant proportion of interpretation of the answers was left to the author. One option to tackle this challenge could have been using survey tools like the Likert scale.

The Likert scale is a data analysis and rating format for survey data. An example of a Likert scale response is a scale from one to five in which one stands for strongly agree and five for strongly disagree. (Allen and Seaman 2007.) Using a Likert scale after first identifying the key topics using open interviews could have added more confidence in the research findings.

Looking back, the process could have been smoother. The exact scope of the research was redefined a few times in the early stages, which could have been avoided with more detailed planning and focus by the author. However, the project got on its way and was completed in a reasonable timeframe after a slower start.

The author is proud of the outcome. Especially happy he is of the quality of insights gathered from the industry experts. As mentioned, the outcome could have been even more insightful if in-person interviews could have been possible. Also, some exciting candidates did not find time to talk with the author in their calendars. They could have added new perspectives that are now left for other projects and researchers to discover.

Many aspects require further research. While the author made an effort to collect knowledge and data points from various angles, the list of interviewees is limited mainly to the USA and European countries. Also, the industries they present could be more comprehensive. Further studies are needed to understand if the conclusions presented in this study are also valid in other continents.

Also, it is worth noting that many interviewees had been in contact with the author, for example, by working in the same company. Some of the interviewees were introduced to the author through a common acquittance. While these pre-existing connections encouraged the interviewee to agree to the interview in the first place and to trust the interviewer with sometimes confidential insights, there is a potential downside to this as well. Having the majority of the interviewees from the same circles might have narrowed the perspective on the topics discussed.

A prominent larger topic connected to manufacturing scaling, but that was of the scope of this research, is startup funding. As mentioned multiple times throughout the thesis, startups, in general, are a relatively well-researched topic, but startup manufacturing is not. Thus, it would be important to see new studies on this topic and how manufacturing scaling can be financed.

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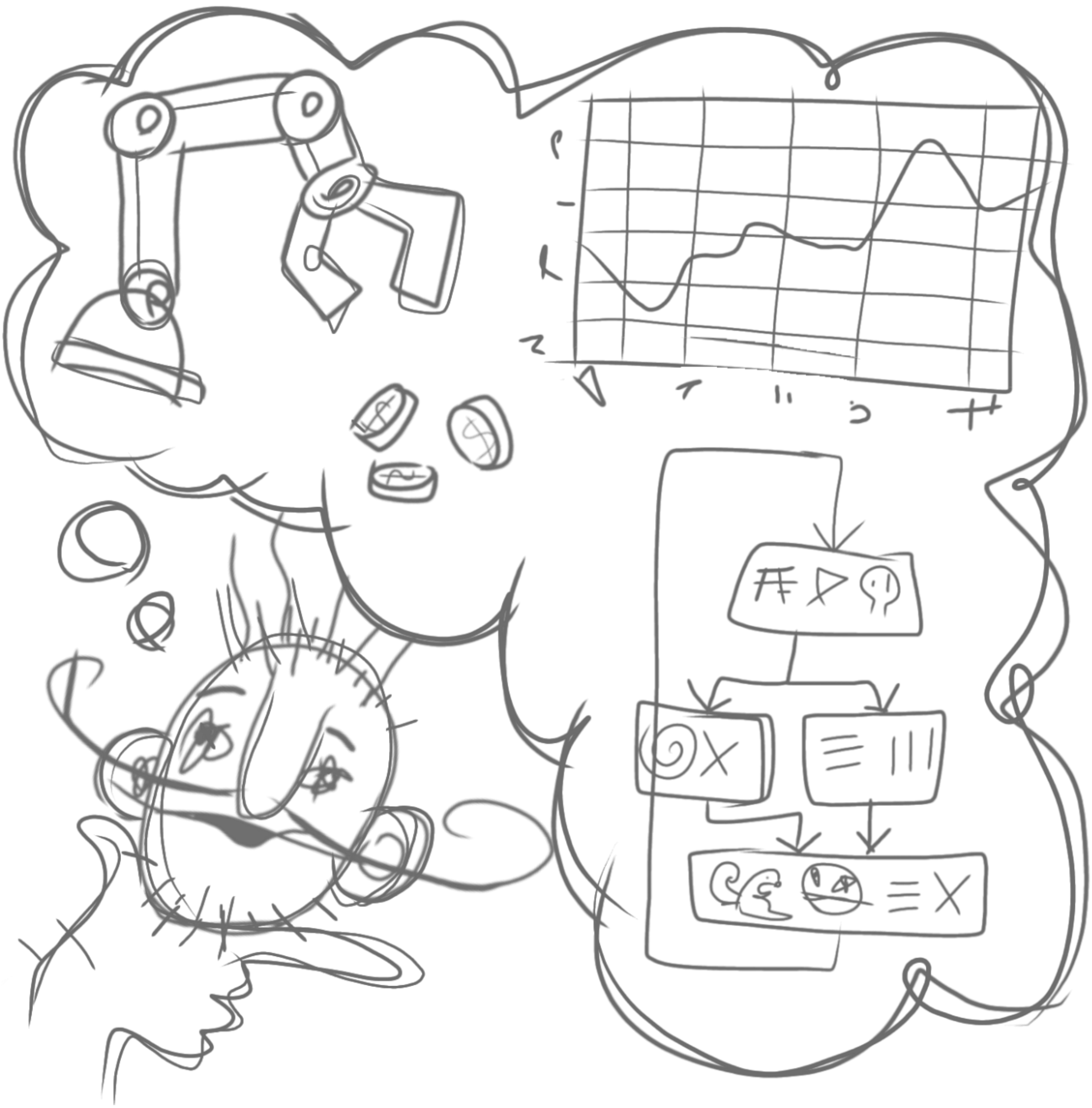
Attachments

Appendix 1. Lean Production Scale-up. A Strategy Guidebook for PPI Startup

Lean Production Scale up

A Strategy Guidebook for PPI Startups



Contents

1 Executive Summary

Lean Production Scale-Up is a strategy guidebook that offers a four-step model for startup companies operating in untested markets with untested technology. The purpose of the model is to reduce the high capital risk and the long time-to-market associated with companies using new technology and innovations.

A software or service company must look into improving its working process for improvement as well, but in most cases, a software company is using existing coding languages, software, and hardware. When working with building new physical products with new machines, manufacturing processes, raw materials, and so on, the need for internal learning and improving the working process in the company is multiplied.

A significant part of the financial risk involved in the production scale-up is associated with relatively large upfront investments. Setting up a workshop, let alone a high-tech laboratory requires tools and machines. Acquiring suitable working space and needed tools is intensive investment-wise. Making these investments as soon as possible timewise, but as late as possible in the learning curve, is the goal of Lean Production Scale-Up.

The Lean Production Scale-Up model consists of four steps. The model is divided into these exact four questions to maximize the efficiency of the scale-up process. Each step asks the question the company must answer using the Build-Measure-Learn Double Loop method. The questions are responded to one by one in the specific order.

The primary goal of early manufacturing when working with innovation is not to generate profit for the company, and it is not to have a positive gross margin but to reach the learning goals of each step and to take those steps as fast as possible. If the focus is elsewhere than the step at hand, the expenditure and risks are increased, and what is worse, learning and business assumption validation are slowed down. The steps of the model are:

1. Is there demand?
2. Is the demand sustainable and scalable?
3. Is a positive gross margin achievable?
4. Continuous development. Take the final step to profitable manufacturing using the knowledge from earlier steps.

2 Introduction

This guidebook is part of the MBA thesis **Lean Production Scale-up. How a startup can scale the manufacturing of physical product innovation**, by Ilkka Taponen, published in 2022. The reader will get the most out of this guide after first reading the thesis document itself, but the guidebook will also work as a stand-alone document.

The theoretical models presented in this document apply to all startups preparing or already executing the manufacturing of a physical innovation. Additionally, startup stakeholders like the board of directors and potential investors could consider using the guidebook to identify critical strategic points a PPI startup will face in the future.

2.1 What is a PPI startup?

PPI stands for Physical Product Innovation. Eric Ries, the author of the book Lean Startup (2011) defined the word startup as "a human institution designed to bring something new under conditions of extreme uncertainty."

On a high level, startups can be divided into two groups: Startups that do only design (service and software industries, for example) and companies that do design but also manufacturing. The two categories are called Design-only and Design and Manufacturing. PPI startups are a subcategory of Design and Manufacturing startups. In the case of PPI startups, the company does not need to address the challenges of manufacturing alone but also the added uncertainty related to innovation, something that has never been done before.

When working with physical product innovation, the untested hypotheses of the business are not only related to the market, as is the case with startups that are not associated with physical manufacturing. Even if there is a market fit for the company and its products, the question remains can it also be manufactured? If the product can be manufactured, can it be done at scale and with profit? Lastly, even if the answer to the first two questions would be positive, PPI startups must be concerned about consistent manufacturing quality. Consistent quality is of particular concern for end products that can be described as safety-critical systems. An example of this is offered in the book Ludicrous (2019): In the book describing the history of the electric car manufacturer Tesla Motors, the challenges of the production scale-up are discussed: While testing the unfinished product with real clients is a natural part of the R&D efforts in the software industry, the same processes could not be translated one-to-one at Tesla because the company’s product, a car, is a safety-critical system. If some part of it fails when in use, the brakes, for example, the results can be fatal. Similar concerns are related to most industries where physical innovations are developed: Biotechnology, pharmaceuticals, transportation, and food technology, for example. There are also safety-critical software products, but they are not exposed to the risk of variable end-product quality. While physical products are built one by one or in batches, Software products are identical copies of themselves.

Some of the best practices of Lean Startup methodology and software industry management can be applied to PPI startups, especially in the early stages of a company. For example, Tesla could create the first versions of its car fast by modifying an existing petrol car into an electric one instead of building its own model from the beginning. By doing this, Tesla quickly created a Minimum Viable Product, MVP, to test its Leap of Faith business model assumptions. Using MVPs to test critical hypotheses, called Leaps of Faith, is one of the essential elements of the Lean Startup methodology. Also, Tesla has significantly reduced the need for recalls of faulty cars by utilizing cloud-based fixes (Hetzner 2022). However, physical properties cannot be changed only by software updates. A 2022 news article about Tesla describes how Tesla's approach of "deliver now, fix later" mentality familiar to the software industry has led to multiple quality issues and recalls of already delivered cars. For example, the article claims that Tesla delivered around 200.000 vehicles with faulty latch installation. Unlike a defective software product, such errors cannot be easily updated through an online update. Instead, the cars must be recalled causing direct costs to the company and a negative experience for the customer (Ruffo 2022).

The untested product innovation in a PPI startup can be the output product, but it can also be the production process, for example, related new to kind of machinery. Vertical farming is an example of innovations related to the production process and business models, but not the output. Vertical farming involves new technology and an opportunity to operate in new ways when food production can happen closer to customers in urban areas and without seasonal variance.

Manufacturing new products that do not involve innovation is a different case. When the new but not innovative product is sold in a market that already exists and uses manufacturing lines and supply chains that are already in place, the business environment is very different.

2.2 The Challenge of Manufacturing

When looking at PPI startups and physical manufacturing, the need for manufacturing facilities, warehouses, and a complete supply chain is apparent. Things travel from place to place in these supply chains in days, not seconds, like in the IT sector. While a Design-only company can multiply its capacities just by a few clicks to increase its cloud server capacity, a Design and Manufacturing company relies on long-lead-time machines, rental contracts, and raw materials. Before a Design and Manufacturing company can commit to increasing its manufacturing, it must collect evidence that the action is worth doing in the first place. For a Design-only company, this challenge does not exist. They can scale down their cloud capacity as fast as they increase it, even during the same day.

The special needs of a PPI startup can be further explained with an example: A marketing company can be hired to create a new logo, and they are expected to execute the work within the agreed time and budget. The company hiring the logo designers is not concerned about what tools and methods they use if the output comes as agreed. When talking about manufacturing involving innovation, the situation is the opposite. The methods and processes used are the most important for the company to know how to make the products, what factors affect the quality, costs, and so on. After all, this is the first time this type of production is done anywhere.

The differences translate into two key challenges: **Extended time-to-market** and **higher risk exposure** due to the need for more extensive infrastructure and cash constraints. Manufacturing and the needed factories and machinery required significant upfront investments unfamiliar to the software and service industries. What is characteristic about startups is that they, by definition, do not have the infrastructure like factories in place when starting their business. The missing infrastructure leads to extended time-to-market and delayed first revenue for the startup. As an alternative to building the manufacturing infrastructure in-house, the startup company can consider outsourcing the manufacturing to a contract manufacturer with the needed facilities and resources already in place. The pros and cons of using a contract manufacturer are discussed in detail in this guidebook.

Another challenge for PPI startups is high regulation due to the nature of the products and businesses they are naturally part of. Physical products such as food, medication and transportation methods like cars can be lethal if there is a quality issue. There are high-regulated software products as well, but more often, when talking about software products, they cannot be defined as safety-critical. For a detailed description of the topic, see the thesis report.

2.3 Lean and Lean Startup

In this fast-changing environment, the most important thing is to learn as fast as possible what to do next and what is worth doing at all. In the 2000s, the Lean Startup movement evolved to answer this need. Lean Startup got started in Silicon Valley first by Steve Blank. Blank's work and ideas are presented, for example, in his book The Four Steps to the Epiphany, published in 2003. Afterward, the movement got its name and went global with Eric Ries and his book Lean Startup, published in 2011. Since Lean Startup was published, Lean Startup and its Build-Measure-Learn loop and Minimum Viable Product methods have become the basic framework for startups to increase their odds of success.

Lean Startup has its foundation in Lean manufacturing that has its roots in the Japanese car industry. Lean is a school of thought that originates in Japan and its auto industry pioneer Toyota. Womack and Jones brought Lean to Western societies in the 1960s. Jones describes Lean in The Lean Sensei book published in 2019: "Lean thinking is the alternative business model for our age focused on value, learning, growth, and improvement in contrast to the finance driving share-holders-first business model described by Michael Porter." Jones continues to add that Lean can be described rather a learning system than a manufacturing system. Another way to describe is to define it as "a customer-centric system in which value is created for customers by prioritizing flow efficiency over resource effectiveness." In Lean, the main focus is on people and how their and the organization's learning can be enhanced. The lean principles form the basis for modern manufacturing regardless of the type of business organization.

Whereas Lean is about the efficiency of daily work, Lean Startup takes Lean thinking to improve the process of bringing ideas and startups to life. Lean Startup serves many types of startups from the very beginning to running a profitable company. Since the publication of the mentioned books, multiple startup books have been followed to enhance startup thinking and management further. The long list of great and insightful books includes, for example, The Hard Thing About Hard Things by Ben Horowitz (2014) and Toyota Kata by Mike Rother (2009).

Three essential tools related to the Lean Startup movement are presented in the following chapters. These tools are valuable methods for all companies working with innovations.

2.3.1 RAT, Riskiest Assumption Test

All business models include various assumptions and risks. Business risk is the quantitatively defined impact of an event multiplied by the defined probability of that event occurring. Outlining risks deals with a specified impact and defined probability, which should be the starting point of putting risks in order and identifying the riskiest ones.

RAT, the Riskiest Assumption Test, is a process that asks from all assumptions in a business model which ones are the riskiest for the startup's success. For example, the assumptions could include that consumers are willing to pay a premium for environmentally friendly products, are eager to eat food grown in a bioreactor, and that the sale of bioreactor-grown food is allowed by the regulators in the future. All these assumptions are related to the startup- idea, but they are not equally risky. Once the most dangerous assumption has been identified for the business idea's success, the company investigates the fastest and cheapest way to validate or invalidate the hypothesis. In the early stages, the best way to validate is by interviewing consumers and experts without the need to build anything expensive.

2.3.2 MVP, Minimum Viable Product

Minimum Viable Products, MVPs, are a way to test business assumptions. The MVP includes only the functions and parts of the product or service that must be in place to get helpful feedback from potential clients. For example, there is no need to spend time and money early on package design if no one wants the product inside.

Both the RAT and the MVP have the same goal of validating or invalidating the assumptions of the company's business model. While RAT looks more at the business case assumptions, MVP relates more to the actual product or service.

There are a couple of issues with MVPs to be aware of. When customers get their hands on unfinished products, they might be disappointed before the significantly improved product is available. You can only make the first impression once! A second possible issue is biased reviews when a customer has an actual product at hand. When discussing with a customer on a more abstract level when conducting a Riskiest Assumption Test, customers have less tendency to give biased feedback to please the interviewer. A company should investigate using RATs before MVPs, but a test not involving an MVP can only go so far when working on physical goods.

2.3.3 Build- Measure- Learn Loop

A business idea's critical assumptions can be validated using Build- Measure- Learn loops. In the first step of the loop, the company creates an experiment to test the assumptions as quickly and inexpensively as possible. Simplified products called Minimum Viable Products, MVPs, are built for the experiments. In the second stage of the loop, feedback data is collected from the customers who have used the MVPs. Analyzing the feedback happens in the third step. The loop starts again when the learnings are taken to the build step for an improved version of the Minimum Viable Product. The faster the company can run the loop, the faster it learns and finds the market fit.

3 Guidebook for PPI Startups

The guidebook for PPI startups starts by presenting two fundamental principles: **Focus on learning, not on gross margin,** and **Build-Measure-Learn Double loop**. After the principles, the strategy framework **Lean Production Scale-Up**, LPS, is presented. LPS is a four-step model designed to be used as a guide for the strategy work for emerging startups who are associated with physical product innovation.

The model suggests how a PPI startup can maximize learning speed to achieve profitability as quickly as possible with controlled risk exposure. Following the model allows a startup to make its investments as soon as possible time-wise but as late as possible in the learning curve.

3.1 Focus on Learning, Not on Gross-Margin

When an innovation is introduced to an industrial scale for the first time, the project is exposed to a wide range of risks. Along with the external unknowns, there are internal unknowns. Suppose the market fit for a product utilizing this new technology is found. Can the product be produced with consistent quality, in high enough quantities, and cost-efficiently? To answer the presented questions, the operation must be set up first on a demo scale to find evidence that the industrial scale is worth investing in.

When preparing for scaling in an unknown environment, the company must understand the purpose of demo-scale manufacturing: It is not to generate profit, nor is it to have a positive gross margin. Instead, the goal is to find evidence of whether or not the technology also works in scale and if industrial-scale manufacturing could be profitable. In other words, the demo-scale operation is designed for learning, not operational efficiency.

When running the manufacturing operation, learnings of the internal processes are collected, but at the same time, the output product is sold in the market. The products are sold to find answers to the leap of faith assumptions related to the marketplace. Here we come across a counter-intuitive factor: Even though products are sold in the public market, the factory is not a full-scale factory designed for optional manufacturing efficiency. This means that selling with a negative gross margin is expected.

A demo-scale factory is an additional step between the laboratory scale and the full-scale level, but strong arguments support having it. First of all, building a full-scale factory is very expensive. When the knowledge level of the technology at hand is limited, the risk of committing to the wrong equipment type, for example, is high. Also, it is unknown what kind of product variant produced with the new technology will find traction in the market, if any. What is positive about taking a smaller step is that a demo-scale factory will be operational faster than a full-scale one. **In conclusion, having a demo-scale facility will allow the company to move in the learning curve as quickly as possible but commit to significant investments as late as possible.**

3.2 Design Your Factory for Learning

Facilitating the counter-intuitive mindset that "our factory that in some ways looks like a full-scale factory is not one" to all stakeholders is of utmost importance for a successful scale-up project. For example, if new investors or management members of the company do not understand the purpose of the demo-scale factory, learning will not be collected efficiently. Also, achieving high operational efficiency in a factory designed for other purposes will be very difficult.

The primary goal of early manufacturing when working with innovation is not to generate profit for the company, and it is not to have a positive gross margin but to learn as fast as possible if the manufacturing can be profitable in the future. In some cases, it could be possible to have a positive gross margin before reaching full-scale manufacturing. Still, if you expect to achieve a positive margin early on, you should have your alarm bells ringing. Firstly, the fact that your very young product manufactured in the very young manufacturing line is having positive gross margin could tell you are charging customers a high-end price, and that is acceptable if the product is a high-end product, but in most cases, it is a sign of focusing on wrong things. No matter how tempting fine-tuning manufacturing is from the cost perspective, the manufacturing cost considerations must be put aside and focus on learning about both the market and manufacturing processes.

The topic we look into in detail later in the chapter Subcontractor Is the Devil in Disguise is the question of who is executing the tests and manufacturing the products. Companies should avoid outsourcing these processes always when it is feasible. When the startup’s employees run the core operations, the learning of the tacit knowledge happens within the company. No report or analysis can replace the value achieved by being highly involved in the manufacturing process.

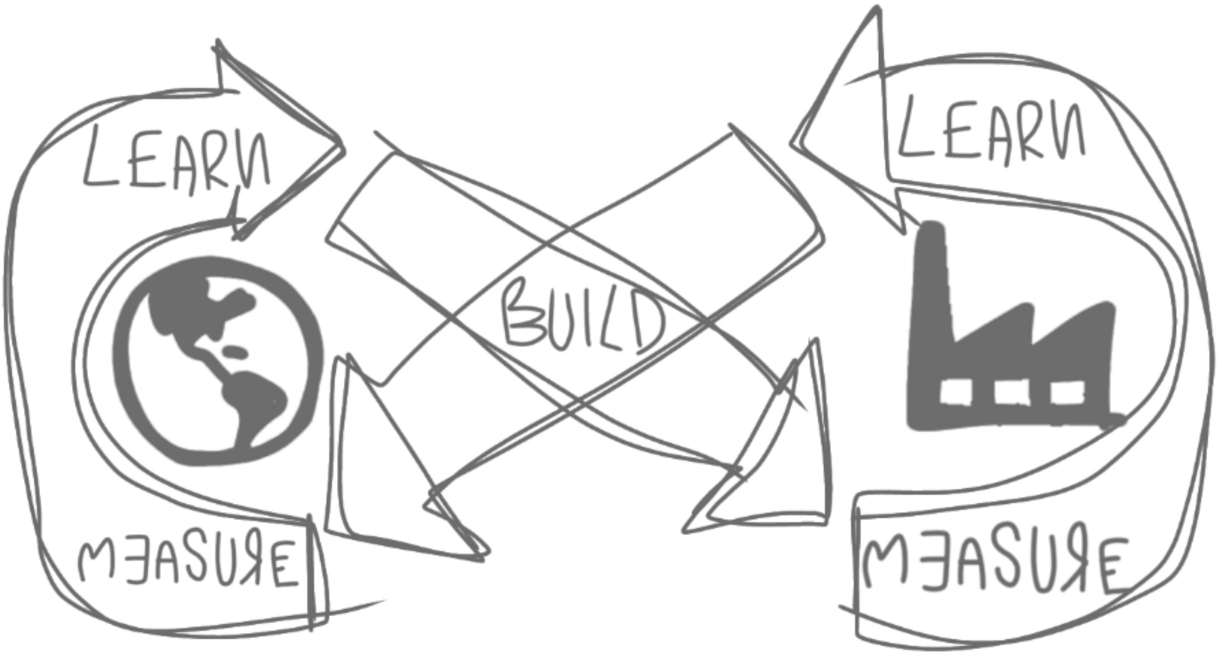
By focusing on learning, an early company is also setting the foundations for its working culture. While cost-wise suboptimal and temporary solutions are encouraged at the manufacturing line, the working culture should not have any room for compromises. When starting from zero, you are not primarily building a manufacturing line but a work culture. First, understanding and then consciously developing the working culture can be seen as a preceding task to process development (Forsgren, Humble and Kim 2018). Continuous improvements, fact-based decision-making, root-cause analysis, all the Lean methodology principles must be followed from day one. Manufacturing is hard, but changing the work culture could be even more challenging. Unlike purchasing new machinery, the working culture cannot be altered by spending money.

A startup can categorize its manufacturing processes into two classes: standardized and innovation-related. Processes like logistics can be outsourced and invested in more freely as they are widely known, and the learning the startup is looking to gain is unrelated to them. The unique and innovation-related parts are the ones that require complete focus, and the suggestions presented here are related to these.

3.2.1 Build-Measure-Learn Double Loop

One of the tools made famous by the Lean Startup book was the Build-Measure-Learn loop. Learning from the external environment alone is not enough for companies with internal technological unknowns. A second loop is needed that is for the manufacturing process. When manufacturing new physical products with new machines and machine setups, new raw materials, and so on, the need for internal learning and improving the working process in the company is multiplied. Together, the two Build-Measure-Learn Loops form the Build-Measure-Learn Double Loop.

The Build-Measure-Learn Double Loop is an essential part of the Lean Production Scale-Up model. The loop starts from the middle by manufacturing a product. The manufacturing process data is collected from all relevant aspects, such as throughput time and quality deviations. The data is taken to the Learn step on the right-hand side of the double loop. Now when the product has been built, it is brought to the left-hand side of the loop: the markets. Similarly, relevant data is collected and analyzed. After the market data is analyzed and needed alternations to the production are identified, the manufacturing process is updated accordingly, and the loop can start again.



Build-Measure-Learn Double Loop

4 Lean Production Scale-up Model

Working in untested markets with untested innovations exposes the company to a unique range of risks and challenges. A model for the systematic learning and specialized risk management is required to manage the manufacturing scale-up from start to end successfully. The Lean Production Scale-up- model is the author's suggestion to meet these requirements.

In an interview, battery technology startup QuantumScape's CEO Jagdeep Singh spoke about the importance of their partnership with Volkswagen: "When you work on new technology, there's a couple of key problems you have. One, of course, is can the technology itself work? So, we demonstrated that with the data we presented last month. But an equally important part of it is, does anybody care? You know, is there a customer that is excited enough about this new technology to where they're willing to bet their product line on the technology? (Crider 2021) The LPS model asks very similar questions, but they are defined differently.

The Lean Production Scale-Up model consists of four steps. Each step is a question that the company must answer before moving to the next one. If the answer to the question is yes, the business model and the innovation pass the step. If the answer is no, the startup must stop to reassess its business model. After changing their approach, taking the steps can start from the beginning. The questions are responded to one by one in the specific order.

Step 1: Is there a demand? The question is similar to step 2 but asking first if there is any demand for your product idea and business model at all; key assumptions can be validated without the need for financial commitments to production space and machinery that must be in place in step 2.

Step 2: Is the demand sustainable and scalable? After confirming that there is some interest comes the time to validate that the demand is not too limited and that the customers will turn into returning customers and advocates. Some investments are now needed, but only the ones necessary to collect the learnings are taken. Ideas related to improving production efficiency are postponed.

Step 3: Is a positive gross margin achievable? Once demand and market fit are clear, it's time to confirm that the product can be produced on an industrial scale and that a positive gross margin is possible. At this stage, when still operating with suboptimal machinery (the quick & dirty solution you have put in place so far), actually having a positive gross margin is difficult, but you can collect evidence that a positive gross margin can be reached. For example, changing a too small warehouse to a larger one and investing in an automated packing line can improve your operational costs significantly.

Step 4: Continuous development. At this step is the time to acquire the full-scale profit-generating manufacturing line. Learning is still essential for the young company, but the learning curve starts to slow down, and development starts to resemble established companies: The development in the manufacturing process is now numerous small steps. In contrast, the previous steps were mostly fewer but substantial. At this stage, the Lean Production Scale-Up has run its course and hands the control over to Lean Management, which specializes in continuous development.

Following the four-step model, a company with new physical innovation can navigate from an idea to full-scale manufacturing. Alternatively, if innovation or the business model using it does not add value to customers or is not technically feasible, it can be identified as soon as possible.

A significant part of the financial risk involved in the manufacturing scale-up is associated with relatively substantial upfront investments. Setting up a workshop and a warehouse, let alone a high-tech laboratory requires a large set of tools and machines. Acquiring suitable working space and needed tools is investment-intensive. Making these investments as soon as possible time-wise but as late as possible in the learning curve is the goal of Lean Production Scale-Up. When significant investments and working methods are not locked down right away in the beginning, the operations remain as adaptable as possible. Adaptability is the key benefit of the model, and by following it, the company is setting itself on a stable course. There are many unknown unknowns, and the best way to prepare against them is adaptability.

A couple of critical rules are used throughout the Lean Production Scale-Up model. In all steps of the model, data is collected from all tangible aspects identified as a key assumption when running the Build-Measure-Learn Double Loops. Focusing on data accuracy is essential already starting from the first steps. All tests, even the smallest, must be well prepared regarding test plans and instructions for execution. Also, tools and machines and the used parameters must the written down. These actions reduce significantly, for example, operator-based variance in the results. These tips sound apparent, for instance, in biotech or medical companies, but when operating on the factory floor, these principles are not always the standard.

4.1 Step 1: Is There a Demand?

When starting the LPS process, companies can have very different starting points. One scenario is that innovation is a technology that exists only in theory, and there is no evidence that the technology will work at all. Another company might start from a point where the innovation is working on a laboratory scale, but everything else is unknown. The third scenario is a situation where the technology is proven both on a small and large scale, but the innovation is related to new ways of operating, for example, creating a new product category with contemporary technology. No matter what the case is, the most important thing is to get going as fast as possible, even if the company knows there have suboptimal steps in the process from the beginning and the product is missing some elements.

Step 1 asks if there is a demand for the product. The first task for the new company is to identify how to answer this question the most effectively. When using the RAT- method in step 1, there is only one build-measure-learn loop as manufacturing is not running yet. If the company concludes that a RAT or RATs are insufficient to confirm demand for the product, a MVP must be built. In this case, the manufacturing loop is needed as well.

Questions for the market build-measure-learn- loop in step 1:

- What beliefs about the business plan must be true for the startup to succeed?
- How can the company find evidence about the beliefs being true or not in the most efficient way?
- Questions that are out of the scope: Efficiency of supportive functions like finance management, marketing, etc. Note! Customer service is at the core of step one but worrying about how much money is used per customer contact is irrelevant at this stage.

Questions for the manufacturing build-measure-learn loop in step 1:

- What aspects affect product quality? Machines, tools, raw materials, part variants, machine settings, working methods, storing conditions, etc.
- How to run the process without compromising worker safety?

Questions that are out of the scope:

All manufacturing and supply chain efficiency-related questions: How long it takes to make a product, number of defects, production costs, delivery times, and supply chain in general.

4.2 Step 2: Is the Demand Sustainable and Scalable?

In step 2, the company works to collect evidence that the customers not only like the product and are willing to pay for it, but they will also turn into returning customers and people and companies that will refer you to their networks. In other words, the company looks to validate whether the customer base will grow from the small sample size and a selected market segment or segments tested in step 1.

At this stage, more substantial quantities of products are needed. Likely also, a more extended period is required because of the nature of the questions presented in this step. How significant the growth should depend entirely on the case and the specific assumptions the company is looking to confirm. No matter how big the step is, it should be as small as possible that is enough for collecting the validation data. In some cases, more staff must be hired, but it is as likely that there is no need for further investments and hiring when moving from step 1 to step 2. Choose the fastest option.

It might be possible to answer the question even without producing the products. Methods like crowdfunding allow a company to take in financial commitments from clients upfront. Another option could be asking for a partial prepayment. When customers are willing to pay upfront for your product, you can be very sure they are serious when they say they like it. If end users cannot give a concrete commitment, could a partner like a wholesaler be willing to sign a letter of intent?

In the case where manufacturing is needed, expanding the product distribution brings more aspects of the industrial stage manufacturing into play. The company must now consider where the products are sold and distributed and possibly also the first marketing steps are taken. Additionally, office work like customer service takes considerably more time.

When working with more substantial volumes, supply chain management requires more focus. Learnings are collected from partners in the raw material and machinery sector. Also, questions like whether there are seasonal limitations and import tariffs, for example, are now becoming visible. Even though these topics are essential in the long run, and learning about these topics can start in step 2, the focus is still only on the actual manufacturing. Keep these topics in mind and collect data that will become handy in following the last two steps of the scale-up.

Manufacturing's focus remains on constant improvement that comes from running the process itself, the manufacturing side of the Build-Measure-Learn Double Loop. The thing that is now relevant in step 2 is also delivering on time. Late deliveries can be a deal-breaker, especially in the b-2-b business.

Questions for the market build-measure-learn loop in step 2:

Questions for the market loop in step 2 are the same as in step 1, but what questions are now out of scope is harder to answer. When the very basics are already confirmed in step 1, the market Build-Measure-Learn loop can start asking more specific questions that might involve the topics of marketing and customer service.

Questions for the production build-measure-learn loop in step 2:

- What aspects affect product quality? Machines, tools, raw materials, part variants, machine settings, working methods, storing conditions, etc.
- How to run the process without compromising worker safety?
- How do improvements and additional functions to the product impact the production process and the product quality?
- What is required from the process to upkeep high standards with continuous production?
- How to ensure reliable functions of the supply chain in both up and downstream parts of it?

Questions that are out of the scope:

All manufacturing and supply chain efficiency-related questions: How long it takes to make a product, number of defects, production costs, delivery times, and supply chain in general. Note! Even though the number of defects and other aspects do not have a central role in decision-making, the cause of these must be understood so that step 3 can be completed successfully. Collect the data now in step 2 for later use.

4.3 Step 3: Is the Positive Gross Margin Achievable?

The third step of the model is to find evidence that the products can be produced on an industrial scale and with a positive gross margin. At this point, the questions the company is asking market and manufacturing-wise are similar to what an established company would ask, so a particular list of example questions is not provided here.

Having demand for a product and being able to produce it with a positive gross margin are equally important in business, but there are compelling reasons why the demand is validated before the manufacturing costs. Firstly, in the first two steps of the model, the company is still learning which variant of the product gets traction in the market and what are the customer segments. Only after this, the company knows to which price category it can compare the manufacturing costs to and what are all the required process steps. Secondly, confirming the demand is quicker to achieve than finding evidence that a positive gross margin can be obtained — no need to produce efficiently something that nobody wants. Third, and maybe the most critical aspect, is that if you have confirmed the demand, you will have the motivation to find a way to make the manufacturing work profitably even if the task seems almost impossible. If the evidence of demand is strong, the company's investors have good reason to invest in it long-term to give it the chance to achieve profitable operations.

At this point, it might be difficult actually to have a positive gross margin, but you can find evidence that a positive gross margin is achievable. It is also likely that manufacturing efficiency suffers from inefficient supply chains, not inefficiencies related directly to the innovation itself. In such a situation, the company can be confident that improved facilities and possibly new hires in sourcing and warehousing will make the needed efficiency improvements possible. Also, young production processes are likely suffering from the high standard deviation of quality, causing below-bar quality and thus wasted resources due to the lack of experience. Suppose the gross margin of a production line is negative due to unreliable product quality. In that case, the company can dig through its data and see if the quality trend has been consistently improving. The claim that a positive gross margin can be achieved is validated when consistent results of improving parameters can be seen for an extended period, even if further improvements are still needed for the positive gross margin.

Once proof of all these three steps has been gathered, the company is ready to build a manufacturing line that will not only have a positive gross margin but that can produce in such high volumes that it will cover the overhead costs and generate profit as a company.

4.4 Step 4: Continuous Development

At the final step of the model, the company's mentality changes. Demand for the product has been confirmed, and the producing the products will generate profit once full-scale operations are in place. The only thing left for the company to achieve profitability is to increase sales and manufacturing.

In step 4, the company acquires the full-scale profit-generating manufacturing line. Learning is still vital for the young company, but the learning curve starts to slow down, and development starts to resemble established company: The development in the manufacturing process is now numerous small steps, while in the previous steps, it was mostly fewer, but substantial steps. At this stage, the Lean Production Scale-Up has run its course and hands the control over to Lean Management, which specializes in continuous development.

As the manufacturing development will slow down and the company already holds the core knowledge of the production, the company has a couple of options for acquiring the full-scale production capacity: In-house production, subcontracting or licensing. The topic of outsourcing and using subcontractors is discussed in the following chapter Subcontractor is the Devil in Disguise.

4.5 Things to Consider When Scaling Up Your Manufacturing

The last part of this guidebook goes through various topics related to scaling up manufacturing involving untested innovations. First, the critical question of where manufacturing happens is discussed in the next chapter. Later, smaller chapters introduce a wide range of topics under the headline Practical Tips.

4.5.1 The Subcontractor is the Devil in Disguise.

What happens throughout the Lean Production Scale-Up model is a lot of learning in two equally important sectors: From the market and customers (the market build-measure-learn loop) and the manufacturing process (the manufacturing build-measure-learn loop). It is tempting to outsource manufacturing or parts of it to speed up development and reduce the need for capital investment. Subcontracting can indeed offer very tangible and attractive benefits: Facilities and supply chains are ready, and the need for upfront investments is limited, to name a few, but these benefits are not related to the primary goal, which is effective learning. If a subcontractor does the manufacturing at an early stage, the learning will happen at the subcontractor, not internally at the company.

All the work of the startup must focus on optimizing the learning process that can be best achieved when the production is done in-house. When using a subcontractor in the early stages of development, the company will also find it challenging to continue to the later stages of scale-up because the subcontracting partners hold the tacit knowledge and thus the negotiation power in the developing partnership.

Finding a suitable subcontractor can be difficult for a young company. A startup company as a partner is not ideal; Volumes are low, and the exact path forward relies heavily on estimations and is rapidly changing. Even if the subcontractor welcomes a startup as a partner when it has the free capacity, and for risk pooling purposes, the uncertain startup company is the first to be cut off if a larger established company wants to increase output from the same subcontractor.

Using a subcontractor also fights against some of the Lean principles. A subcontractor adds additional management and material handling layers that do not add value to the customer. Additional material handling is especially the case if the subcontractor is used to do only some parts of the production. In such arrangements, materials are loaded and unloaded between different locations, which does not serve as a value-adding function.

An additional difficulty of using subcontractors in the early stage is the lack of incentives for the subcontractor to do continuous development of the manufacturing process and the suboptimal operational infrastructure of the subcontractor. The focus of the development and optimization efforts of the subcontractor are directed towards the most significant clients.

One clear benefit a subcontractor can have is access to better prices and hard-to-acquire parts and machines. If this is the case, a subcontractor could be used to produce subassemblies involving these parts and machines. Yes, this would be a step for a more complex and expensive, most likely also slower, manufacturing process, but if this way is the fastest way to learn, then it is the correct way.

There are specific environments where in-house production is not a feasible option. Examples of these are regulated industries where you might have very long and expensive processes to get a certified production facility working from scratch.

Another case where a subcontractor can be utilized is in step 1 of the LPS model when the topics to be evaluated are very general. Using a subcontractor in the very beginning can be considered to get the very first products out as soon as possible with minimal capital expenditure, but in this case, the parent company must be present at the subcontractor and, if possible, take part in the manufacturing process to maximize learning. If the results of the first trials encourage the team to continue production to step 2, it should be done in-house.

If, after careful consideration, the use of a subcontractor is identified as the best alternative, the following three chapters present methods that can be put in place to minimize the downsides explained earlier.

4.5.2 Have Your Own People at the Subcontractor.

If using a subcontractor is a must, the best possible option would be to have the company's own employees run the processes at the subcontractor's facility. The need to hire employees can be restricted to the core functions of the production and the parts related to the innovation, but the more extensive the scope of collected knowledge from the day-to-day work, the better. Warehouse management, packing, maintenance, and logistics are examples of the areas that could be left for the subcontractor to handle.

4.5.3 Use Multiple Subcontractors.

Hiring more than one subcontracting company is a method to position the hiring company better in long-term negotiations. When the subcontractor is not the only one with the needed skills and machinery, the hiring company has a good position when difficulties eventually arise. In case of poor performance of the subcontractor or if the subcontractor wants to charge you more for their work, having an alternative or two gives the hiring company good negotiation power. Having a second subcontractor means increasing costs related to managing the co-operating, but the costs should not double.

4.5.4 Form a Partnership with the Subcontractor.

As explained earlier, one of the risks of working with subcontractors is the level of commitment to long-term cooperation. Financial investments for the joint manufacturing development project by both parties can lower the risk. The subcontractor could invest in the hiring company and thus creating a clear incentive for developing the production together in the long term. Another option could be establishing a joint venture owned collectively by the innovation owner and the subcontractor. In the new company, the day-to-day management would be handled by the manufacturing professionals from the subcontractor, and the innovation owner would concentrate on research and development, marketing, and other aspects of the business. The co-ownership would give both parties security as the success of the owners of the newly created company is intertwined.

4.6 Using Subcontractor in Step 4 of the LPS Model

When the manufacturing development has gone through the first three development steps of the LPS model comes the time to consider the options for building the industrial-scale manufacturing line. Even though the mentality changes from rapid learning to profit generation and continuous development, the technology, and the products are still very new, meaning that the development of the manufacturing process will continue relatively fast.

Let’s imagine a company that has gone through the first three steps and is now ready to start industrial manufacturing in the domestic market using a subcontractor. The subcontractor takes all the learnings of the demo plant where the company has done steps 1,2, and 3 internally. In cooperation with the company, the subcontractor puts in place a manufacturing line. Meanwhile, a license to manufacture the products using the technology is sold to an international partner. The international partner manufactures its manufacturing line as well. At this stage, there are three separate companies, the company itself, the subcontractor, and the license partner. These three companies are using the same nascent technology and collecting learnings daily. The parent company must pay attention when building these partnerships so that all three members of this network have the incentive to share the knowledge with each other. If this is not carefully studied early on, the company might have a situation where the subcontractor is generating profit after altering the process while the licensing partner is struggling with the demo-plant level technology, for example.

4.7 Practical Tips

This chapter presents three ideas for the reader to consider when scaling the manufacturing capacities during the four steps of the LPS model. They are Extreme Simplification, Location Management, and Karakuri and Automation.

4.7.1 Extreme Simplification

Scaling of manufacturing and the daily work on the shop floor are complicated tasks. No matter how simple you would make it, it still would be difficult. For this reason, simplifying as much as possible should be at the core throughout the scale-up project. Simplifying applies to work done when designing the Riskiest Assumption Tests and Minimum Viable Products and to the daily decisions on the factory floor. The high uncertainty surrounding the project is also a reason for extreme simplification. When building something entirely new as a startup company, the building happens in a highly uncertain environment. The simpler the project is, the fewer assumptions and uncertainties are included. If you simplify operations so much that your co-founder says you are going too far, you are on the right track! The co-founder might be alarmed initially because simplification can cause higher direct costs and lost sales, but this can be accepted if the learning process is accelerated.

Kindergartens are great examples to follow for offices, factories, and warehouses; The children and teachers can upkeep clean and functional spaces because storing locations are marked by using pictures instead of long instructions. Anyone can understand, regardless of age, expertise, or language skills, that jackets belong to this rack with a picture of a jacket and board games on this shelf that has a picture of a board game. Extremely simple and easy! If the idea feels ridiculous, go and look at your office's storage: If labels are marking storing the location of all items, the warehouse is in order. If there are no labels, the storage, and the shelves are a mess. Correct?

When operating in step 2 and onwards of the Lean Production Scale-Up model, manufacturing output reliability and quality standards became important factors when real customers start to pay for your products and expect high-quality service. To help all the novice people at the manufacturing, simplifying the operations only to the core topics that are essential to learning. The process is simplified at the expense of gross margin but not at the cost of learning. As already mentioned, running manufacturing is very difficult, even for established companies. When you combine the running of manufacturing with the fact that no one in the company has long experience with it and a lot of changes are happening all around due to rapid learning and scaling up, manufacturing is extremely difficult.

Customer segments that the company is focusing on must be carefully selected. You cannot successfully serve everyone, especially not in the scale-up phase. **When the company limits the customer segments, it also limits the needed products and product variant catalog.** Producing 1 product out of 10 parts or raw materials is much more straightforward than 5 out of 40. The product catalog will be optimized only in step 4 or earlier if the increase is needed to validate the company's assumptions.

Some parts and raw materials are always needed, but using subassemblies can reduce the required handling in a warehouse and production line. Also, by buying raw materials ready mixed instead of individually, the same kind of simplification is achieved.

4.7.2 Location Management

The topic of outsourcing was discussed earlier from multiple perspectives. One of the points raised was the unnecessary management level needed when operating with a second company. Also, working in two locations slows operations, and worse, some of the learning does not happen in the hiring company. It also fights against the idea of extreme simplification.

Similar downsides will also come into play if the company operates in multiple locations internally. Even if the manufacturing is all done internally, having a separate office and manufacturing site will complicate communication and slow down learning. If having the needed office spaces in the manufacturing site cannot be arranged, ensure the locations are so near that visiting both on the same working day is possible.

4.7.3 Karakuri and Automation

Early automation of a manufacturing process has many downsides. When manufacturing is done by human operators instead of machines, they can use all their senses to learn and improve the process. While running the process, the operators do not only learn about the process and get ideas for improvements; they also do quality control. Learning from where the failures originate from first-hand experience gives the company a better position than a fully automated manufacturing line where the raw materials go in one end and the ready and faulty products out in the other. First-hand knowledge from the manufacturing line is essential for process development. In the early stages when the understanding of the process is low, long hours of human labor are needed to learn what could be automated in the first place. Automating too early in the learning curve will hinder learning for the presented reasons. Additionally, machines and other types of automation hardware are costly, acquiring them involves long lead times, and they have a high risk of becoming obsolete when build-measure-learn double loops are completed.

Instead of automation by robotics and other complex machines, a cheap and fast way to improve the output of production and reduce the workload of human operators are Karakuri- methods. Karakuri is Japanese, and the word's literal translation to English is “mechanism.” Small makeshift automation solutions in a production line are examples of Karakuri. Let’s say an operator needs to move a heavy machine to their workstation frequently, but it must be returned after use because it would be blocking the operator from executing the next process step. The machine moves on wheels a small distance back and forth, but the high frequency of moving makes it exhausting for the operator. Instead of building a larger workstation (expensive!) or automating the movement of the machine by a motor (very expensive!), a wire can be attached to the machine on one end and a bucket full of sand to the other. Also, a rail is placed on the floor for the wheels to move on. Now, the operator can pull the machine to her and lock it in place while in use. After releasing the lock, gravity will pull the machine pack automatically (and cheaply!) due to the weight of the sand bucket. A more straightforward example of Karakuri solutions is shelves tilted slightly, making the products on the shelf fall to the edge closer to the operator. Self-made Karakuri solutions are generally cheaper, easily maintained and improved compared to purchased automation solutions.

Data collection is one of the only places where automation can be recommended early on. Data collection and analysis tools such as data loggers and analyzing software are relatively cheap, but they are also much more reliable than human operators. Data is at the core of the learning process, unlike improving the speed or quality of manufacturing, where automation could be considered.

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Appendix 2. Interview Template

Interviewee, time, and date:	
Place and interview method (live or a video call):	
Question 1. According to Negroponte (1996) and Thiel (Sullivan, 2014), there is a division between Bits and Atoms companies. Based on your experience, what are the key differences between these two classes when talking about startups?	
Answer:	
Questions 2a. When looking at the subsection of Atom companies, the startups with Physical Product Innovation, what are the key challenges these companies face in the scale-up phase?	
Answer:	
Question 2b: According to Niedermeyer (2019), the biggest challenge for a PPI startup is the transition period from a startup to an industrial company. What are your thoughts on this?	
Answer:	
Question 3: Christensen (1997) described the different innovation types. How do the challenges vary between Sustaining Innovation and Disruptive Innovation when talking about production scaling?	
Answer:	
Question 4a: Lin et al. (2008) describe that startups feel high pressure to reduce their "time to market." When thinking about how long it takes to bring a product to market, are the characteristics related to PPI startup?	

Answer:
Question 4b. Lin et al. (2008) suggest outsourcing as one possible way to reduce time to market for manufacturing startups. What are the pros and cons of outsourcing for PPI startups?
Answer:
Question 5: Negroponte wrote that Atoms companies are more heavily regulated. Do you agree, and if yes, how does this show?
Answer:
Question 6a: According to Karlgaard (2019), "Investments pour in for Bits companies, but tend to avoid Atoms." Is this correct?
Answer:
Question 6b. Follow-up question for question 6: What other differences are there?
Answer:
Question 7: In their 2008 study that interviewed multiple manufacturing startups, Lin et al. identified two key challenges in the scale-up phase are limitations in resource availability (often due to cash constraints) and uncertainty in sales. Do you recognize these challenges?
Answer:

Appendix 3. Interview answer analysis template.

The answer template is shown below in two parts.

					Topics recognized based on			
				Question	1,2A	2A, 5, 6B	2A, 3, 7	2A, 7
No	Name	Relevant experience	Location	Years of experience	PPI startups do not have the ready infrastructure tools avaialable that software startup have	PPI startups need a wider range of skills	PPI are more complex than solely software companies	Scaling speed is a lot slower with PPI
1								
2								
3								
4								
5								
6								
7								
8								
9								
10								
11								
12								
13								
14								
15								
16								
17								
18								
19								
20								

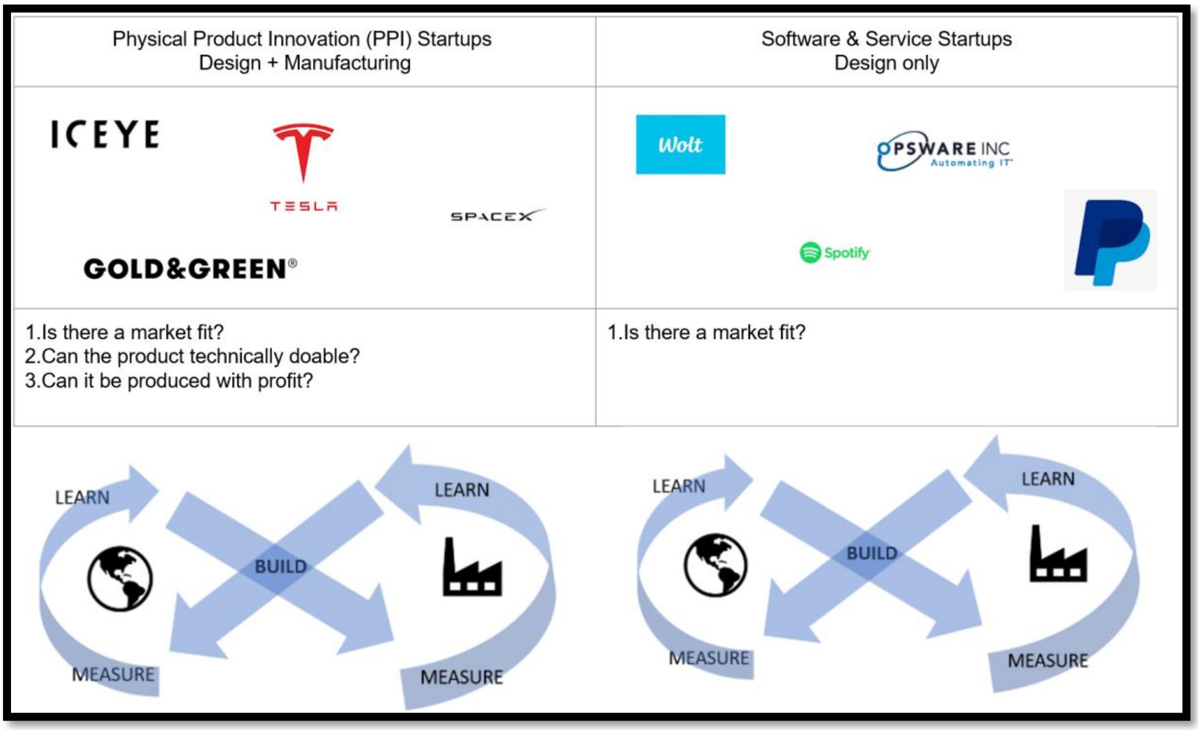
Agree with the statement
Neutral stance on the statement
Disagree with the statement

the answers and discussion							
2A, 7	2B	2A,6A	4A	4B	5	6B	
PPIs are less agile: Longer leadtimes and less flexible.	Transition to industrial scale is a major challenge	PPI need significantly higher investments	There is a high pressure cut the Time to market	Contract manufacturer should be used	PPI startups are protected by a barriers of entry.	Customers expect higher quality from PPI startups	Comments

Appendix 4. Focus Group Presentation Slides

Slide 1:

Slide 2:



Slide 3:

6 key areas that define the business environment of a startup

1. Design Only or Design + Manufacturing
2. Technology Maturity
3. Manufacturing Technology
4. End-Product Type
5. Selling- Margin
6. Safety Criticality

Slide 4:

Challenge Multiplier	Business Type	Technology Maturity	Manufacturing Technology	End-Product Type	Selling-Margin	Safety Criticality
2	Design + Manufacturing	Low	High-tech	High-tech	Low	Yes
1	Design Only	High	Low-tech	Low-tech	High	No
0			No manufacturing	No manufacturing		

Slide 5:

Challenge multiplier	Startup phase	Established company phase	Example industry
8- 12 points	Extremely hard to succeed	High protection from competition	Mobility, quantum computing
6-8 points	Very hard to succeed	Some protection from competition	Food tech, bio tech
4-6 points	Hard to succeed	Low protection from competition	SaaS