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THE STAGE GATE MODEL IN PRODUCT DEVELOPMENT: CASE PAL FINLAND OY

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Abstract

In business, there are too many failures that relate to product development. The significance of successful product development cannot be overemphasized. In particular, the medical industry can benefit from comprehensive process models in product development. This case study aims to create a product development system for a company that works in the medical devices industry.

The theoretical framework utilized is The Stage Gate®, and the methodology consists of qualitative research. The research involves an interview with the case company and gathering secondary data. The secondary data consists of literature on product development and literature on the medical devices industry.

After a three-phase analysis, a minimum viable product (MVP) system is drawn for the company. This final work acts as a basis for introducing the Stage Gate ideology in practice. In conclusion, the study has key elements for any medical devices company to implement new product development and provide a pathway in new product development undertakings.

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1 INTRODUCTION

1.1 Background

In business, there are too many failures that relate to product development. Various sources suggest that actually, the majority of new products fail for different reasons. We see how deplorable the state of innovations are, some academics claiming up to 90% failure rates, some 40% (Castellion & Markham, 2013). Regardless of what the reality of failure rates is, that is insignificant for this study. Instead, the significance of successful product development can't be overemphasized.

> *"Generating great ideas is half the battle; the other half is getting from the concept stage through to development and into the marketplace" (Cooper 2007, 25.)*

Indeed, product development is a lengthy process involving many stages that will affect the outcome. The concept "valley of death" describes the gap between making a discovery or an invention and moving it into the market as a commercialized product. (Cooper 2007, 638.) Figuratively, it signifies all the failed products that have not been successfully launched, lying in the desert of oblivion.

Furthermore, many theories and systems have arisen to meet challenges facing companies on the eve of innovation. One of those is The Stage Gate®. The Stage Gate ideology was established in the mid-1980s by Robert Cooper in the original publication *Winning at New Products.* Since then it has evolved multiple decades by Cooper, his fellow researchers, and also a large number of managers and companies utilizing the system in practice.

1.2 Concepts

There are certain concepts used throughout the study which will be clarified in brief in this part. The purpose of this is to provide the reader a more fluent reading experience and make it easier to understand concepts in the study. The concepts are defined in the following table.

Concept	Definition
Product development system	Any means by which to execute product development, can be tangible or intangible.
The Stage Gate® system	A product development system and ideology developed from the 1980s by Robert Cooper et al. Also called an ”idea-to-launch system”. Henceforth “the Stage Gate system” in this study.
Medical device	Any device or instrument to use for medical purposes on human beings. For instance Albio.
Albio	A medical device used to diagnose a patient’s blood ethanol level. Under development by PAL Finland Oy.
PAL Finland Oy	A Finnish company working in the medical devices industry.
Tacit knowledge	Knowledge that exists in person and in one’s experiences that is difficult to share. (Cambridge Dictionary, 2021)

Table 1 – Definitions to concepts in the study

1.3 Company and product

This piece has been commissioned by PAL Finland Oy, a private limited company that operates in the industry of medical devices. Since 2014, the company has developed its main product Albio. Its purpose derives from the company’s name abbreviation “PAL” which signifies Portable Alcohol Laboratory. According to company CBDO Jarno Verso, “Albio is a new type of blood alcohol meter that makes it possible to measure blood alcohol from a patient under field conditions” (Verso, J. 2021). It is intended for the use of patient diagnosis in the first aid. Being a one-of-kind product, Albio establishes quick measurements about blood

alcohol and aids first aid responders in getting the correct diagnosis and giving the best possible care for an unconscious patient. (Verso, J. 2021)

In the past, the company has not utilized any specific product development systems in practice such as the Stage Gate system. Instead, the product development of Albio has stemmed from the expertise and experience of the management. To some extent, the product development path has been similar compared to the Stage Gate, but no tangible systems have been in use. In fact, the knowledge has been mostly tacit knowledge. Verso acknowledges that the company would benefit from a product development tool that would be practical in use. A similar tool would not only benefit the project management but moreover, turn tacit information into something visible and easily usable by the entire team.

1.4 Aim & purpose

The piece aims to create a product development system for PAL Finland Oy. The case study is utilized in establishing the current state of product development in the company, and to research the needs, and utilize the primary and secondary data in creating the new product development system for the company.

The aim is to apply the Stage Gate, an idea-to-launch system, to the case. The final work created can then be scaled, developed, and utilized in future product development projects in the company. It will also serve as an important learning point to the author who will benefit from the gained knowledge in the area of product development.

In the broadest sense, the purpose of the piece lies in making an impact on new medical technology. Where this piece aims to provide value for the innovation of medical technology, the importance can be seen in the continuous stream of new innovation in the medical field. That in turn will benefit patients and helps saving lives in the revolution of new technology.

1.5 Outline of the thesis

Firstly, the study gives insight into product development and the case selected for this study. After that, the theoretical framework is introduced and how it links to the industry that revolves around the case. Then, the discussion chapter is divided into three parts which analyze the primary and secondary data sources Finally, the data analysis draws up to the final work and conclusion.

2 THEORETICAL FRAMEWORK

2.1 The Stage Gate Model

The Stage Gate model is a commonly used product development model. It is used worldwide, and it is written by many authors to a great extent in various academic pieces. The context of the Stage Gate is the fact that new products are essential for businesses. If they succeed, they hold a unique selling proposition in the competitive market, creating benefit for the company. When planning for a product launch, the Stage Gate model aims to increase the success - and, in turn, lower the failures related to the product development. (Edgett, 2018)

2.2 Stages in the Stage Gate

In the broadest sense, the model is a process of different stages and gates. There are five stages which are followed by gates. The stages represent product development activities executed in a specific stage. The gates, in turn, are checkpoints that determine moving the project into the next stage. Gates involve a set of validation, e.g. scorecards, procedures of quality control. When a project has reached the final stage it is ready for market launch and it has been gone through several evaluations to justify its market potential. The model is based on the belief where ideas are accelerated through several gates and then launched into the market. (Edgett, 2018) Figures 1 and 2 illustrate two typical representations of the model.

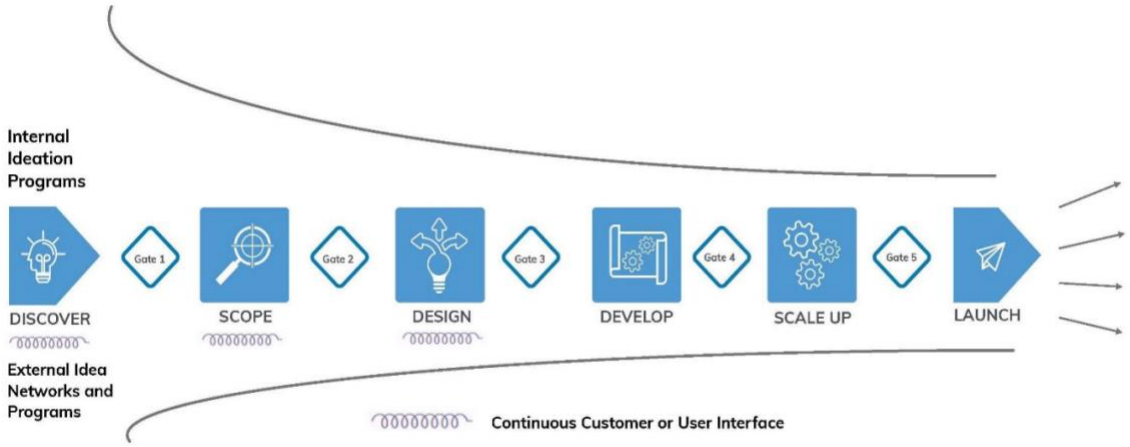

Figure 1 - Typical Stage Gate process (Edgett, 2018)

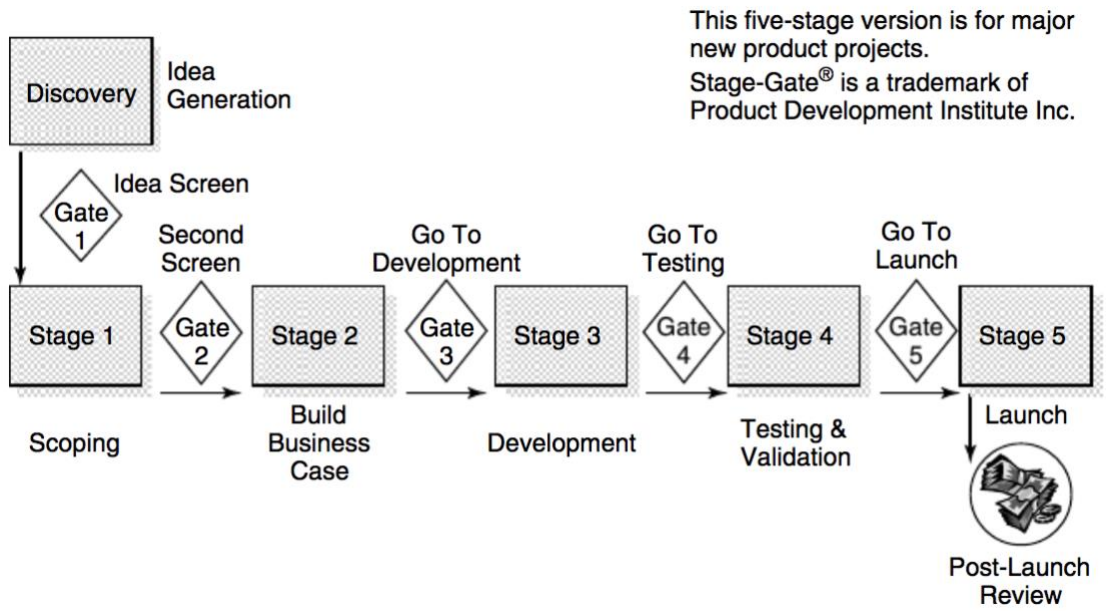

Figure 2 – Typical Stage Gate process (Sheth and Malhothra 2010)

For the purposes of this study, a comparison was made with two different visualizations of the Stage Gate. Figure 1 pictures mainly the stages in the process. In turn, Figure 2 has a better ability to portray the gates which are the essential decision points in the process. It also depicts the Post-Launch Review which Figure 1 does not. For this reason, Figure 2 recognizes the whole process more equitably compared to Figure 1. Thus, Figure 2 is selected for this study.

Discovery

Initially, there's a robust idea creation stage preceding, called Discovery. It aims to create plenty of ideas that could have market potential and development into new products. The idea creation can be internal and external. Ideally, ideas can be screened with various stakeholders such as employees from each department and getting customer feedback through Voice of Customer research. Plenty of valuable possibilities, disruptions, and gaps in the marketplace can be found when discussing when capturing needs that have been unarticulated. (Cooper 2007, 152.) (Edgett, 2018)

Gate 1 – Idea screen

The first gate decides if there would be resources to implement the project. There can be preliminary research in feasibility, opportunity, and market potential. Besides, it is evaluated whether the idea would fit in the company strategy. The first Gate is rather light, involving no financial decisions. (Cooper 2007, 153.)

Stage 1 – Scoping

Stage 1 – Scope, involves scoping of the project. It aims to determine the project's technical and marketplace capability. Through secondary research, the preliminary technical assessment involves e.g. operations, costs, supply, and legal feasibility. A preliminary market assessment aims to determine market size and potential. At this stage, the research is mainly desk research which means there are no major investments put into the project. Timewise, scoping can take one calendar month's work effort for one person. (Cooper 2007, 154.)

Gate 2 – Second Screen

Similar to Gate 1, Gate 2 screens the project in the light of new information gathered in the preliminary market and technical assessments. A checklist or scorecard becomes particularly essential in this point since the project has to be able to meet certain "must-meet" and "should-meet" conditions in order to move

forwards with Go decision. If the must-meet criteria are not met, the decision can be either Kill, Hold or Recycle. (Cooper 2007, 156.)

Stage 2 – Build Business Case

In one of the most essential stages, in Stage 2, an actual business case is constructed for the project. Particularly, primary research is carried out at this stage. Information on customer and market is gathered in order to find about needs, wants and preferences. Besides, a target-market is defined. Business tools such as the business canvas tool (Osterwalder, A. 2010) can be utilized to systemically build up the business case. Five Forces tool can be implemented to find about competition and rivalry (Porter, M. E. 2008) Financial and risk analyses are constructed to support the business case. This “critical homework” stage aims to create a unique value proposition which the customer will find superior. (Cooper 2007, 157.) (Edgett, 2018)

Gate 3 – Go To Development

When the initial business case is constructed, criterion Gate 3 assesses if the project goes into further development. In case there’s no a business opportunity, the project can be killed at a relatively low cost. The purpose of Stage 3 is to assess the activities executed in Stage 2 and if the criterion is met prior to the development stage. (Sheth and Malhothra, 2010) (Cooper 2007, 160.)

Stage 3 - Development

Stage 3 aims to develop the actual product or design of the case. Also, a production process can be developed which would be required for full-scale production. Often, prototypes or minimum viable products (MVP) are developed at Stage 3. This includes multiple prototypes followed by multiple testing. Feedback is received from the customer in the entire stage which is called “build-test-feedback-revise”. Through this empirical research, the steps (build, test feedback, revise) are repeated after each prototype version. This is done to

achieve the best fit for the market and customer needs and wants – aiming to improve the product continuously. (Sheth and Malhothra, 2010).

Gate 4 – Go to Testing

Gate 4 reviews activities done in the development stage. The project should be developed in a quality fashion in terms of product, marketing, operations, and finance. The product should be consistent as specified at Gate 3. As in any gate, there are a set of “must-meet” and “should-meet” conditions that are evaluated. (Cooper 2007, 162.)

Stage 4 – Scale Up

At Stage 4, the product is taken into field trials, to the actual environment or marketplace, in order to test its validity in practice. In addition, this stage validates plans for areas like marketing and operations, for instance, final details of the product such as final packaging layout. Revised business and finance analyses are executed to check viability in the areas. (Cooper 2007, 163.)

Gate 5 – Go to Launch

Gate 5 evaluates whether the project can be commercialized. The project can still be killed at this final point. If Stage 4 test results have yielded a positive result, the project can be passed onto the final stage. The operations and market launch plans are reviewed as well. (Cooper 2007, 164.)

Stage 5 - Launch

Finally, at the launch stage, the final product is launched and introduced to the market. It involves the market launch plan and the operations plan which have been validated already at Gate 5. At this stage, in addition to operations and production and sales begins. Generally, the longer the project proceeds in the Stage Gate model, the more it costs. (Edgett, 2018)

2.3 Complementary systems

In addition to the traditional model, there are two systems used for lower-risk projects: Stage Gate Xpress and Stage Gate Lite. In these systems, stages are connected and there are fewer gates. Xpress is used for moderate-risk projects whereas Lite can be used for very minor changes such as salesforce requests. These vary from the full Stage Gate system in a way the stages and gates are combined into processes that contain fewer stages and decision points. (Sheth and Malhothra, 2010)

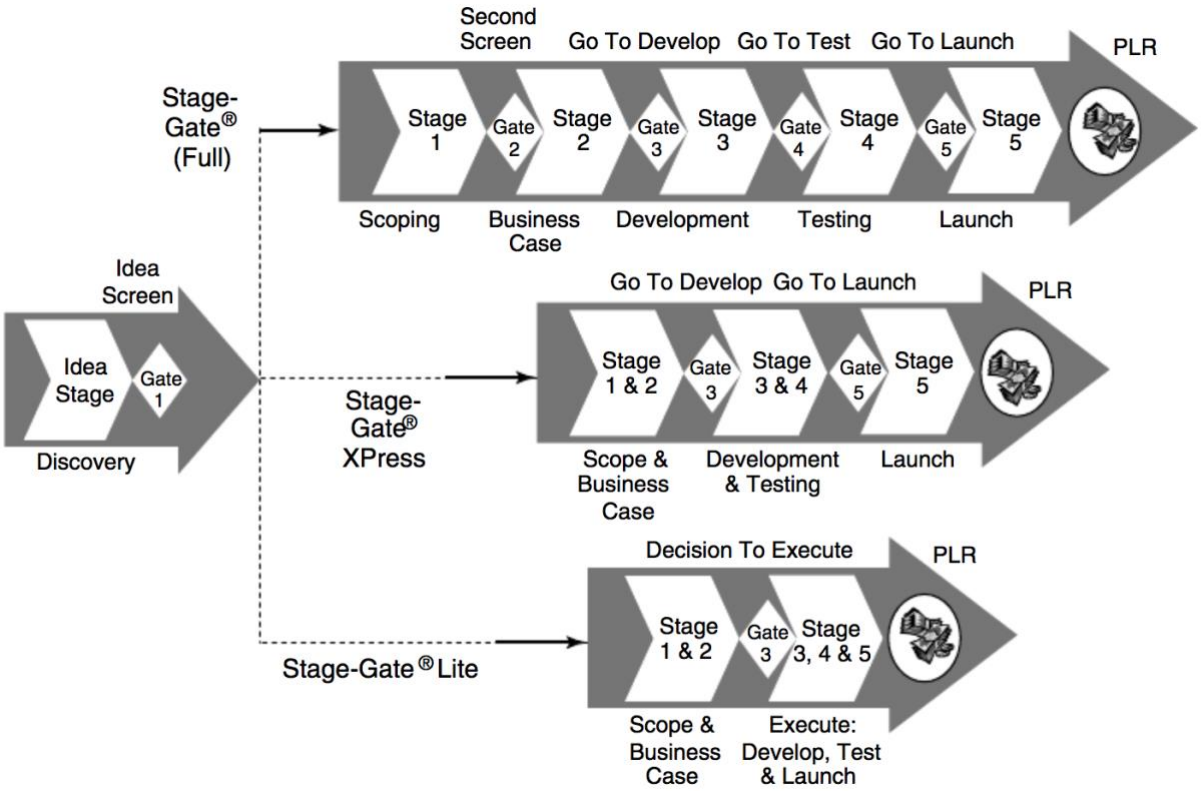

Figure 3 – Three Stage Gate systems (Sheth and Malhothra, 2010)

2.4 Stage Gate in Medical devices companies

As the industry of medical devices concerns itself directly with healing and saving human lives, it's is essential the products under development go through proper development processes and comply with global standards. In particular, the ISO has established global standards for the medical devices industry. Specifically, the major standard in the industry is ISO 13485. (ISO, 2016) The ISO standard

distinguishes a company that demonstrates a specific quality management system. For medical device companies, the ISO 13485 standard specifies requirements for providing medical devices in any stage of the product life-cycle (ISO, 2016). Although the ISO standards are not governmental nor legally binding, regulators, governments, and companies can count on them for ensuring the quality and safety of new products (Approachable, 2016).

An extensive study by Pate-Cornell et al. shows that the Stage Gate is a major system that companies incorporate in their development (Paté-Cornell, M. et al. 2009.). It also reveals there are no comprehensive process models for the medical device industry. The need for the Stage Gate can e.g. be seen as a consequence of more strict regulations and requirements. In order for a product to successfully enter into the market, it needs to go through assessment such as clinical trials. Clinical trials are performed in people that validate whether the product is safe and furthermore determine readiness for a market entry (NIH, 2020). If the process and the trials are not properly organized, the project is likely to be unsuccessful. Utilization of the Stage Gate has created standard operating procedures and best-practice approaches which are the key-determinants in successful device commercialization. (Paté-Cornell, M. et al. 2009.)

3 RESEARCH METHOD

3.1 Methodology

The research method which will be used for this study is case study. A case study involves selecting a real-life context and analyzing it in a qualitative manner (Dul & Hak 2008. 4.) The study involves gathering primary data by an interview with the case company and also through secondary data. Secondary data consists mainly of literature on product development and literature on the medical devices industry.

The implementation of the study is divided into three phases. Phase 1 discusses and analyses the need for a product development system at the company. Phase 2 discusses industry research on medical devices. Phase 3 creates the product development system for PAL Finland Oy.

3.2 Validity and reliability

When it comes to validity, it shall be discussed if the study has measured what it has been claimed to measure. Particularly, validity in this study can be justified from the interview (Appendix 2). In the interview, research questions are formulated so that initially it is determined whether there's a need for research (Appendix 2, Question 3). As this is confirmed, specific questions are brought up to get insight into the need and preferences of the product development system studied. Moreover, the interviewee works in management in PAL Finland Oy. Thereby the research is valid and justified.

Moreover, it shall be discussed to what extent the study is reliable and could be applied to a different environment. Firstly, the study has utilized major literature around the theoretical framework, the Stage Gate. The study connects the theory to the case to a high degree, since there are major sources on product development in the medical device industry. The methodology of this study could

be scaled to other cases. However, specific factors such as the company size and industry should be similar, since the study is highly focused on the medical devices industry. Strong emphasis on the industry, particularly findings by Paté-Cornell et al. strengthen the reliability (Paté-Cornell, M. et al. 2009.). Regardless of the case company, the outcome would be similar if the study was repeated in a different environment. Lastly, it is stated that the signed has worked in the company and has gathered tacit knowledge and empirical evidence which support validity and reliability.

4 DISCUSSION

The chapter aims to research primary and secondary sources and analyze them furthermore in a creation of a product development system for PAL Finland Oy. The chapter consists of Phases 1, 2, and 3.

4.1 Phase 1

Phase 1 discusses the need for a product development system for PAL Finland. It is constructed using the primary research and qualitative data on the company, i.e. interview with the company CBDO Jarno Verso (Appendix 1). The validity of the data is strengthened with the empirical evidence and work experience in the company by the signed.

4.1.1 Need for development system for PAL Finland

In an interview with the company representative, CBDO Jarno Verso, it is recognized the product development follows stages in the Stage Gate to a high degree. Initially, the company discovered that there would be a need in the field to solve a specific issue. The need was not only national but moreover global, and no solutions were found in the desk research. In later stages, technical research and feasibility study were organized to justify the further development of Albio. In the final development stages, the shelf life is being tested and an algorithm is being refined. Finally, the product is planned to be launched after a market pilot in spring 2021. (Verso, J. 2021)

The need for a comprehensive product development system stems from the lessons learned in the case of Albio. Firstly, monitoring and controlling of the product development process can be difficult. There are several activities that can be either parallel or nonsimultaneous. Quite often, many parallel activities occur in product development that are in fact interdependent. For example, establishing a quality system runs interdependently with the product development Paté-Cornell, M. et al. 2009.). Verso recognizes, that the company doesn’t use any specific tools which aid in product development. He elaborates that instead

of a specific tool, the projects are executed using the existing knowledge. (Verso, J. 2021)

Secondly, the development timeline is often lengthy in the industry. Delays and setbacks are common in the creation of something entirely new and innovative. Verso elaborates how the development of device chemistry can be a matter of lengthy testing and even a matter of luck (Verso, J. 2021). That's why it's essential to plan systematically in advance, and particularly, to be financially prepared. Having a comprehensive system and understanding of the stages will benefit essential stakeholders in the organization including managers, engineers, and investors (Paté-Cornell, M. et al. 2009.). The project is more organized when the stakeholders can visualize the various activities and decisions that are associated with the medical device development (Paté-Cornell, M. et al. 2009.).

The interview raises two internal challenges related to product development. The knowledge on product development is mainly tacit knowledge, meaning that it exists mainly in the managers' knowledge. Managing knowledge creates multiple advantages in areas such as innovation (NI Business Info. 2021). In the case of Albio product development, however, the knowledge is not shared nor visualized in a way it would benefit the whole organization and different departments.

Verso acknowledges it would be useful to have a tool showing the "big picture" of the project (Verso, J. 2021). Indeed, the need for product development seems to stem more towards the organization and visualization of the project, rather than towards lacking knowledge. Since the company has executed the Albio project similarly to the typical Stage Gate process, it may only need visualization of the big picture and having a system that tracks the processes' flow.

The problems to be solved should thereby be related to the following: managing knowledge in a collaborative manner, and visualizing the project in a single platform. A solution for the problems is discussed further on after phase 2 findings.

4.2 Phase 2

In the medical devices industry, there have been various product development systems used based on the Stage Gate, but only a few comprehensive models are constructed. (Paté-Cornell, M. et al. 2009.) This phase discusses industry research, best practices into product development, and solutions to implement the Stage Gate.

4.2.1 Development systems in the Medical devices industry

In their research, Paté-Cornell et al. construct a comprehensive medical device development process representation. This is done by an extensive field study into interviews of experts, regulation, and medical devices' use, lasting from October 2006 to September 2007. The research is highly applicable to PAL Finland Oy and Albio, since the research has been carried out in the same industry, and the authors note that the model applies best to "devices that require some form of clinical data" (Paté-Cornell, M. et al. 2009.) In the case of Albio, clinical data is required to test the product in the field environment, i.e. in the first-aid environment for diagnosis of stroke patients (Verso, J. 2021). Thereby, the research is highly valid for the purposes of this study.

Paté-Cornell et al. give a 5-phase representation of the system which includes 4 gates (Appendix 2). The representation is summarized in the table below.

Phase	Activities
0 - Predevelopment activities	• Exploring and identifying clinical needs • Preliminary market analysis • Fit into company strategy
1 - Initiation	• Market and competitive assessment • Legal/IP analysis • Early risk analysis • Regulatory and clinical path • Financial review • Reimbursement strategy
2 - Formulation	• Feasibility assessment • Voice of customer input • Concepts/prototype analysis • Risk analysis and management • Design for manufacturing • Regulatory & IP strategy
3 – Design & Development	• Verification testing • Validation testing • Risk management & Process validation • Regulatory & clinical • Patent review
4 – Final validation	• Final product specifications • Design and process validation • Sales launch preparation • Quality systems
5 – Product launch and post-launch assessment	• Product launch • Post-launch R&D

Table 2 – Development of Medical Devices (Paté-Cornell, M. et al. 2009.)

The representation by Paté-Cornell et al. relies highly on the foundation of the Stage Gate. However, it has essential elements that are connected to the medical device industry. Factors such as clinical trials are essential for success in the industry. In fact, the clinical impact is “a fundamental characteristic and the most important benchmark” for a successful medical devices company (Kucklick, T. 2013. 414.) Thus, it’s significant that already at the predevelopment activities, there are actual clinical needs identified. Also, clinical validation should be highlighted in every stage towards the market launch. A validated and working product is vital for the success of the market launch. In addition to clinical factors,

the Paté-Cornell et al. representation stresses the importance of industry-specific factors like quality systems. (Paté-Cornell, M. et al. 2009.)

4.2.2 Success drivers in medical device product development

Medical device development is iterative in its nature (Paté-Cornell, M. et al. 2009.). As technology is developed, the product goes back and forth in iterative loops called “build-test-feedback-revise” These iterations are based on different development activities such as a new prototype. Concurrently with the rapid iterations, customer opinion should be sought to continuously improve the product. Thereby, it’s normal that product development does not proceed linearly, instead, various iterations, even in-between stages, raise the success as the project learns from failures. (Cooper 2007, 161.)

Because of the iterative and nonlinear nature, sometimes medical device development can be unexpected. Despite of rigorous procedures that come with systems like the Stage Gate, the project can experience delays from different reasons. Thus, it’s essential to reserve enough time for flexibility and creativity in the project. Particularly, revolutionary product development, such as Albio, benefits from a more flexible timeline. More complexity can be brought by the fact that innovation is often not entirely internal. It may require external collaborations in order to create new technologies. (Paté-Cornell, M. et al. 2009.) Thanks to this nature, projects like Albio are difficult to be estimated in time or resources in advance.

In medical device development, considering regulatory requirements is essential for success. Adhering to requirements can save the project from setbacks in a long run. In the industry, requirements must be approved for instance when a public organization calls for tender. Companies that do not adhere to requirements are highly likely to disqualify. In turn, taking requirements into account from the beginning can create savings in time and money. Thereby, knowledge about the regulatory requirements is essential success driver for medical device companies. (Paté-Cornell, M. et al. 2009.)

In any case, competitive advantage and unique value proposition are the most essential success driver for superior product development. The ability to create one-of-a-kind products that satisfy real customer needs and wants is key for achieving success. This is considered through voice-of-customer analysis, for instance by concept testing, prototype testing and gauging reaction continuously from the customer. Essentially, the customer-driven focus is built into the entire process. (Edgett, Scott J. 2018)

4.2.3 Solutions for implementing the Stage Gate system

There are various methods to implement the Stage Gate system in practice. These vary from heavy automatized software to building the idea-to-launch system from scratch. The table below depicts three common solutions for implementing the Stage Gate system.

Solution	Description	Advantage	Disadvantage
1	Purchase software with a fully mapped-out Stage Gate system	-Start implementation fast -High automation	-Software can be costly
2	Use own software to operate the Stage Gate system	-High customization -High adaptability	-May require more time to set up
3	Design the system from scratch	-Can be low cost -High customization	-Needs further development

Table 3 – Common solutions for implementing the Stage Gate system (Cooper 2007, 526.)

Solution 1 involves purchasing a fully mapped-out software to implement the Stage Gate. It is the route for many firms since it allows to start implementing the system fairly quickly. It also allows for automation to a high degree which can make processes more efficient. However, the software itself can be relatively costly, so it should indeed be fully utilized. (Cooper 2007, 526.)

The second solution, Solution 2, uses one's own software to operate the system. The solution benefits from its high adaptability, for it doesn't necessarily require bringing new software into use. Instead, businesses can utilize their working software. However, this option may need more time to set up. (Cooper 2007, 526.) Compared to completely new software, this solution may easily commit the workforce to use it, since the software is familiar to them.

Solution 3 is often used when there is no existing Stage Gate system in place. It involves a time-intensive development phase in which the system is designed for the organization. Through multiple rounds of design and feedback, for instance, gate scorecards are created in collaboration with the whole team. The idea of this solution is to build up and tailor a Stage Gate solution for businesses that haven't used it before. (Cooper 2007, 528.)

4.3 Phase 3

This phase aims to develop the product development system for PAL Finland Oy. The system presented in chapter 4.3 is justified with the qualitative data from Phase 1 and Phase 2.

4.3.1 Discoveries

In Phase 1, it was initially established the company doesn't use any specific tools for product development. In conclusion, the research pointed out two main needs: managing knowledge and project status in a collaborative manner, and visualizing the project in a single platform.

Phase 2, in turn, discovered the model by Paté-Cornell et al. which is intended specifically for medical device companies. Besides, the model discusses success drivers in medical device product development. Finally, various solutions to

implement the product development process were evaluated with their advantages and disadvantages.

4.3.2 Technical solution for PAL Finland Oy

When it comes to PAL Finland Oy, for the purposes of this study, a technical solution to implement the Stage Gate system will be selected. It is essential for the final work of this study and will be discussed consequently.

None of the solutions represented in chapter 4.2.3. are being excluded at first glance. However, concerning the company hasn't had an existing system in place, Solution 3 can be seen as the most potential. It involves tailoring the system for the needs of the company through rounds or stages.

For this case study, Solution 1 could cause a disadvantage, since the Stage Gate system still needs to be implemented in the company. Particularly, this relates to the system itself, since the company doesn't use any product development tool at the moment (Verso, J. 2021). It is risky to take heavy software into use at this point. Certainly, Solution 1 can turn out beneficial later when the system is implemented and needs further development.

Solution 2 would use own software to build up the system. However, the reason not to use this solution can be the same as in Solution 1. Besides, for this study, creating initially a minimum viable product would be most sensible. That is because the study is limited to time, and further development of the system requires a longer time period. Also, since Albio project is currently the only ongoing project in the company, it's most reasonable to implement Solution 3 initially, and involve the company in the further development of the system. Thereby, Solution 3 is selected for the final work.

4.3.3 The final product development system

Finally, the study draws up the final product development system. The system is drawn from scratch, based on the discoveries in the previous chapters. It's

noteworthy, the system built initially is a minimum viable product (MVP), since it will require more time for development to implement the system than this study allows. The product development system for PAL Finland could be summarized as follows:

> *The system is tailored to the medical devices company, based on wide industry research, and the needs of the company i.e. visualizing the project in a single platform and managing project status in a collaborative manner.*

The final work is represented in Appendix 3. It follows the Stage Gate model with an emphasis on industry-specific operations. It is drawn on a Kanban software, Trello, which allows for agile development (Trello, 2021). Trello suits the new system, since the framework is easily editable and shared collaboratively. Each stage is represented by a separate list which includes customizable project cards for different operations. Stages include operations that are essential in the medical devices industry, whereas gates include must-have and should-have checklists. The company may develop the initial system in practice and implement it further.

5 FUTURE RESEARCH SUGGESTIONS

5.1 Limitations

The major limitation to this study was limited the timeframe for completing the piece. Eventually, a minimum viable product (MVP) was created. However if there had been unlimited time, the product development system could have been tested in practice in the company and studied further. Besides, as the methodology of this study consisted of qualitative research, the more detailed outcomes could have been delivered with quantitative research. Also, a further interview could have been organized if the product development system was developed to the next stage.

5.2 Suggestions for future research

The product development system drawn up in this study should be taken to use in the company, tested, and developed further. There are numerous factors that could be studied. For instance, the most ideal tool to implement the system in practice could be studied. Besides, the extent to which the structured system creates efficiency could be examined. Gate scorecards should be created. In terms of communication, it could be studied if internal communication becomes effective to a higher degree. When it comes to the medical devices industry, further study could dive into diagnostic devices, since medical devices in itself, consist of various sub-groups.

6 CONCLUSION

This study aimed to create a product development system for PAL Finland Oy. The theoretical framework applied to the case study was The Stage Gate which appeared to be a popular system in the industry, albeit less illustrated through comprehensive process models. Moreover, the study found a product development system that was specifically tailored for the medical devices industry. With the primary research into the company, a system was finally drawn up for the company.

As the final work of this study, the initial system still requires development and testing in the company. Because of being at the MVP stage, multiple rounds of design and feedback is required. However, the final work and the entity of this study compile a key information source for the implementation of Stage Gate approach in PAL Finland. The final work is suited for the needs of the company and acts as a basis for introducing the Stage Gate ideology in practice. It has key elements for any medical devices company to implement new product development and provide a pathway in new product development undertakings.

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Interview with PAL Finland Oy, CBDO Jarno Verso

Introduction Kettunen: Please get familiarized with The Star Gate model with the following article (page 1 & 4-5): The Stage-Gate® Model: An Overview

1 Kettunen: Tell shortly about PAL Finland Oy.
Verso: PAL Finland Oy is founded in 2014 and its main product is blood alcohol meter Albio.

2 K: Tell shortly about Albio.
V: Albio is a new type of blood alcohol meter that makes it possible to measure blood alcohol from a patient under field conditions. It is a quick test that gives an accurate result of the amount of alcohol in the blood in a few seconds. The product is aimed at the needs of first aid, e.g. the diagnosis of an unconscious patient, and the need for the product is specifically based on the needs of first aid.

3 K: Does PAL Finland use any specific models for product development?
V: We do not utilize any specific models. We have had almost similar path in product development like in The Stage Gate model.

4 K: Elaborate product development of Albio and its stages (discover, scope, design, develop, scale up & launch).
V:

Discover – We first started by mapping the market. Is there already a product that would solve the need for first aid (how to measure blood alcohol from an unconscious / traumatic patient when the patient is unable to blow).

Scope – We could not find any existing product so after that we checked the market, i.e. whether there is a demand for the product and whether the market is wide enough (also a global problem, not just Finnish) to start developing the product.

The market was large and promising so next we did a technical study. We explored all possible solutions from existing technologies that we could utilize in our own product development. We browsed through a few different options. Electrochemical measurement or fuel cell analyzer.

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We evaluated both technologies and ended up continuing with electrochemical measurement to the feasibility study, as it was the most economical and viable option in all respects.

The next step was a feasibility study. We did it at VTT. The study widely sought the right types of enzymes and cofactors for electrochemical measurement. As a result of the study, we obtained a preliminary recipe for the development of test strips.

After the feasibility study, we started product development with our partner. A well-known manufacturer from Taiwan who was willing to develop new technology with us was chosen as a partner. At the same time, product design planning and preliminary marketing began.

Product development is now in the final stage where the shelf life of the product under different conditions is tested and the algorithm of the meter is refined more precisely.

The product will probably be launched in March 2021, when the required shelf life of 3 months has been established. In the last stage of product development, the scaling of production has been ensured. The first customers are the so-called. pilot clients who make a medical publication on the use of the product and the benefits of diagnosing and treating stroke patients.

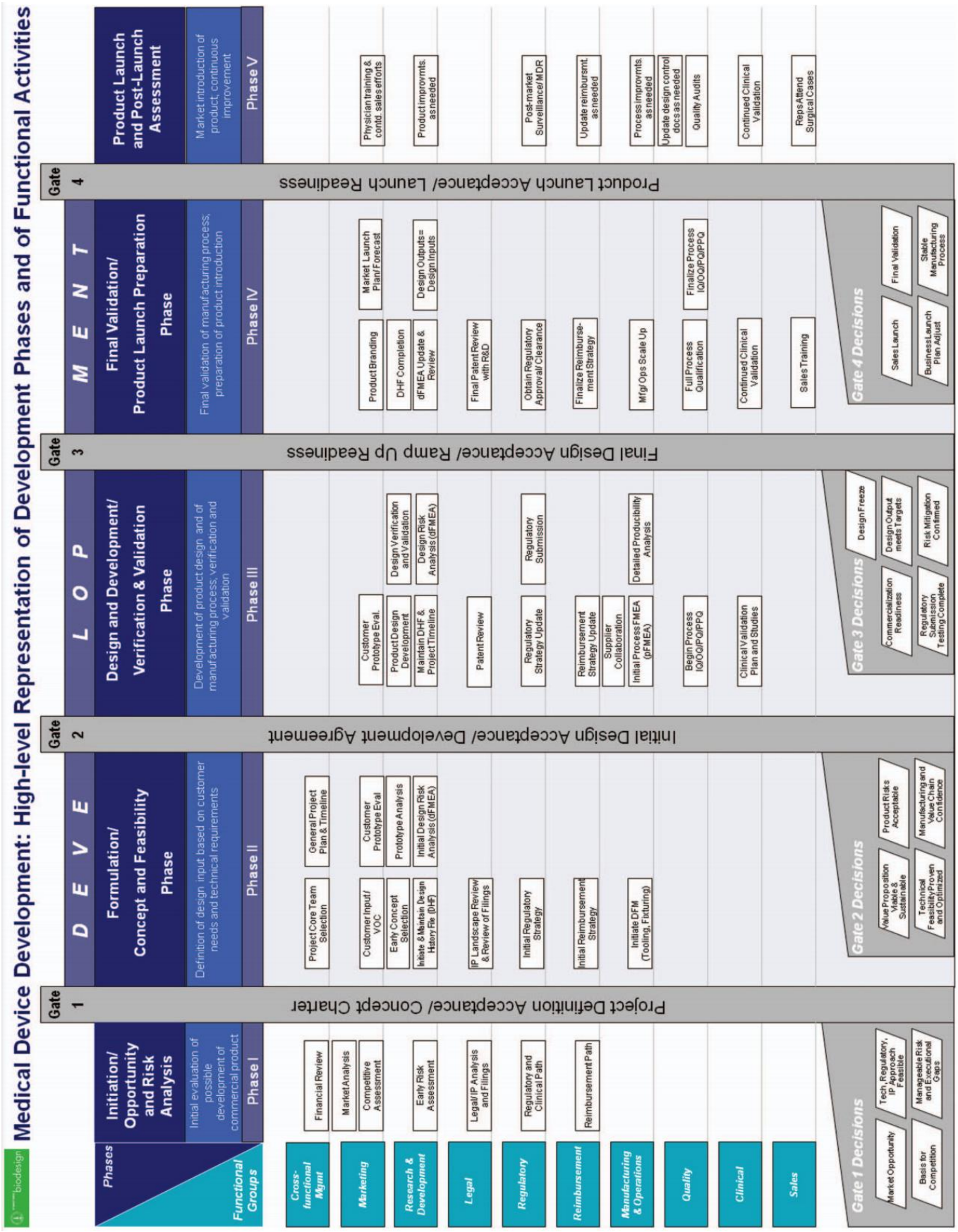
5 K: Which areas of product development have been especially challenging for development of Albio? How? (Possibly elaborate faced challenges)

V: The development of chemistry has been the most challenging, of course this has been known from the beginning. Either we get it invented quickly with luck or we have a long way to go through successes, insights and learning.

6 K: Could product development of Albio benefit from utilizing a tool such as The Stage Gate? What benefit do you see? (e.g. scorecards)

V: We have already had a similar practice in place, although there is no concrete tool to look at the big picture. Some sort of transparent tool that shows the big picture would be useful in monitoring the product development process.

Medical device development system (Paté-Cornell, M. et al. 2009)



Product development system for PAL Finland Oy