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New Product Fumbles - Organizing for the Ramp-up Process

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Irene Christensen

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Doctoral School of Business and Management | **PhD Series 13.2018**

CBS COPENHAGEN BUSINESS SCHOOL
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New product fumbles

Organizing for the Ramp-up process

Irene Christensen

Supervisor: Prof. Christer Karlsson

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Doctoral School of Business and Management

Department of Operations Management

Irene Christensen

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Executive summary

This study examines rapid prototyping, also referred to as new production launch, or ramp-up time. A strong emphasis on speed is vital for the success of a product development and market launch. Managers concern themselves with organizing ramp-up activities into arrayed sequences to achieve production launch goals. These sequences are not only regarding prearranged linear milestones, but extensively reviewed and often reorganized complex activities, with the managerial goal of a well-configured productive process.

The need to manage the final phase in product development is evident, because many of the failures leading to product launch delays have multiple root causes, ranging from poorly understood and overly engineered novel technologies to a "throw it over the wall" approach between development functions and inexperienced machine operators, in addition to high complexity levels in quality testing. The study examines these complexities through social theoretical lenses. In doing so, an in-depth qualitative approach has been employed with the aim of addressing the fundamental barriers in the advancement of this managerial field, and the practical complexities in managing this specific part of the development of products. This has been achieved by longitudinally studying a total of eight major development cases at a large Scandinavian manufacturing company over a period of three years. These development projects faced different challenges during the interface between R&D and ramp-up production, resulting in delays in product launch. Drawing on the results of this real-time study, the thesis contributes with (i) a conceptual model for lean management application to the ramp-up process, (ii) the advancement of clinical methodological approach for in-depth studying of the ramp-up management phenomena, (iii) cause and effects of ramp-up activities delays, and (iv) managerial strategies for managing organization-environment interdependencies.

Keywords: Ramp-up management, Longitudinal research, Case study, New Product development, Operations management

Resumé

Denne afhandling undersøger hurtig 'proto-typing', også kaldet ny produktionslancering eller ramp-up tid. I produktudvikling og markedslancering er hastighed afgørende for succes. Hvis produktionslanceringsmål skal indfries må lederne fokusere på at organisere ramp-up aktiviteterne i sekvenser, som ikke kun består af opstilling af lineære milepæle, men som også omfatter en grundig gennemgang og ofte også en omorganisering af komplekse aktiviteter.

Behovet for at styre den afsluttende fase i produktudviklingen er betydningsfuld, hvis fejl og forsinkelser skal undgås. Mange af de fejl, der fører til forsinkelser i produktlanceringen har flere årsager. Disse årsager spænder fra mangelfuld teknologiforståelse og overoptimistisk tiltro til nye teknologier til en tilgang, hvor udviklere "kaster projekter fra sig" uden at forberede dem der skal udføre projekterne ordentligt. Hertil kommer en uheldig kombinationen af uerfarne maskinoperatører og høje kompleksitetsniveauer i kvalitetsprøvning.

Afhandlingen undersøger disse kompleksiteter gennem socialteoretiske briller. Der anvendes en dybdegående kvalitativ tilgang med det formål at overvinde de grundlæggende barrierer inden for dette ledelsesområde og de praktiske kompleksiteter i forvaltningen af denne specifikke del af produktudviklingen.

Undersøgelsen omfatter et treårigt longitudinalt studie af i alt otte udviklingscases i en stor skandinavisk fremstillingsvirksomhed. Udviklingsprojekterne havde alle forskellige udfordringer på grænsefladen mellem R&D og ramp-up produktion, hvilket resulterede i forsinkelser i produktlanceringen.

På baggrund af resultaterne af denne realtids studie bidrager afhandlingen med (i) en konceptuel model til hvordan ledere kan applicere Lean management på ramp-up processen, (ii) en udvikling af klinisk metodologisk tilgang til dybdegående studie af ramp-up ledelse fænomenet, (iii) årsag til og virkninger af ramp-up aktivitetsforsinkelser, samt (iv) ledelsesstrategier til styring af inter-dependenser mellem organisationen og dets omgivelser.

Emneord: Ramp-up management, Longitudinalt studie, Case studie, Ny Productudvikling, Driftsledelse

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This dissertation is affectionately dedicated to my family and friends – here and abroad.

I would like to express my deepest gratitude to my case company with its hundreds of enthusiastic employees around Europe and the rest of the world. They opened their doors and meetings and permitted access across all layers of the organisation that allowed valuable empirical depth of the thesis. I would very much have liked to single out specific colleagues for acknowledgements; however, due to three non-disclosure and confidentiality agreements I signed on my second day of employment, the true identity of the company and its people shall be preserved. I sincerely hope you know who you all are. My gratitude extends particularly to my company supervisors (both of them) for initiating and carrying through our collaboration leading to this dissertation.

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This thesis has been conducted under the keen supervision of my legendary mentor and supervisor, Professor Christer Karlsson. I owe him a special debt of gratitude for firmly believing in developing rare and valuable skills, which has profoundly helped me shape my academic identity into something that resonates. My fairy godmother has undeniably been looking out for me, because I had the best supervisor I could hope for. What I found in my professor was an invigorating brutal honesty, intuitive warmth, and strong leadership. Professor Karlsson gave me the autonomy to teach, review manuscripts, pursue and write about other topics; but the most awe-inspiring, is the confidence and encouragement to try, fail, and get back up.

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Lastly, thank you to Carl Jacob – my *little brown baby with sparkling eyes*.

Gentofte, April 2018.

Irene Christensen

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Structure of the thesis

This dissertation is based on a collection of four individual research papers. Chapter 1 will offer a broad introduction and the research question to the thesis. Furthermore, the chapter will briefly present the methods employed and the empirical field; it will also offer an overview of the collection of the papers and their positioning. A summary of essays 1, 2, 3 and 4 will then present the independent studies. The stand-alone research papers also include these sections, there's minimal overlap. An overview of all four papers is presented in table 1. The first two papers have been published in peer-reviewed academic journals, the third empirical study has been presented at a renowned academic conference and the current version has been further developed for journal submission. Finally, the fourth paper has been presented at the EurOMA conference and the current version is under review in a peer-reviewed journal. The introductory chapter will provide a brief description of the four articles, and will conclude with a summary of the contributions and research synthesis.

1. Introduction

The medical technology industry continues to be one of Europe's most diverse and innovative high-tech sectors, therefore it is a relevant sector to study. It is in many ways, a model European industry, since recent statistics show that 95% of Europe's 25,000 medical technology companies are small and medium-sized enterprises (SMEs). Furthermore, the MedTech industry invests heavily to regularly improve its technologies and come up with ground-breaking innovations, which can be seen through the substantial number of patents filed compared to any other sector. It provides over 575,000 jobs in Europe and delivers a positive trade balance of €15 billion (MedTech Europe, 2015). More than 500,000 medical technologies are currently available and they all share a common purpose: *improving, extending and transforming people's lives*. This industry is considered dynamic and as such a great opportunity to study the ramp-up phenomena and every-day practices at a micro organisational level (ibid). Forecasting conventional measures of success in product development, such as "time-to-market", "product life cycle" or "ramp-up speed", are shrinking, and a fresh view on the design-manufacturing interface is increasingly sought for (Jiang, Kleer, & Piller, 2017).

The purpose of this study is to showcase examples from a field of research and give the reader novel ways of thinking of the management of ramp-up processes.

Researchers and practitioners alike acknowledge the significance of the risks associated with an isolated product development from a corresponding process development. The integration of product and process development is therefore encouraged in organizations, to accommodate contingencies such as late product design changes or fluctuating customer expectations. Strategic capabilities can be built through improved functions in the organization responsible for designing and developing the product. The core phases of a new product development (NPD) project are: concept development, product design, prototype development and testing, process design and development, and finally production ramp-up. The organization must continuously reduce the total development time (time-to-market) as well as the time it takes to achieve an acceptable manufacturing volume, cost and quality (time-to-volume) for the main reason of building strategic capabilities that offer the organization sustained competitive advantage. Although studies have investigated time-to-market, the topic of time to volume has received relatively scant attention. The important difference between time-to-market and time to volume is that the former ends with emanating the commercial production, whereas the latter explicitly includes the period of production ramp-up.

Each new product is transitioned through the ramp-up phase, and depending on the manufacturing strategy set-up, the ramp-up phase is the period during which a manufacturing process makes the transition from zero to full-scale production; in the case of manufacturing-to-order (MtO) or manufacturing-to-stock (MtS). While in the case of engineering-to-order (EtO) there is a high level of customer participation in product development, the ramp-up phase is the process where production is stabilized. The ramp-up for these production strategies must be accomplished at targeted levels of predefined cost and quality measures.

The most important activities of ramp-up consist in scaling up, discovering and removing problems and missed opportunities. This would lead to the production process becomes more scalable. The managerial challenge related to the ramp-up phase is not only the product- and process-related problems, but also the time factor, which poses yet another challenge, because while ramp-up is the initial phase of commercial production, delays can become delays in terms of later return on

the firm's investment and possibly permanently lost sales. It is therefore paramount that the ramp-up phase means reaching full volume as efficiently as possible.

The present thesis argues that there are serious consequences related to the rapid acceleration of production. Fundamentally, managers might be faced with quality problems, and exposing the market to defects and poor reliability during a product's market launch, can permanently ruin the organization's reputation and image. Ramp-up management, being the critical interface between NPD and volume production, has been described and analysed in the literature. The limited amount of peer-reviewed research has been mainly carried out in the automobile, pharmaceutical and software industries. In the following we highlight key empirical insights from our field.

1.1.Ramp-up management as a research field

What we have come to know about the field of ramp-up management is through early studies in a small collection conducted in the late 80's and early 90's, for instance a comparative study conducted in 1987 where the authors identified the gaps in productivity and quality between U.S. manufacturers and their Japanese and European competitors, proving that not only does the design and development of new products play an important role in quality and productivity, but also lead time, engineering productivity and design quality are also significant (Clark, Chew, & Fujimoto, 1987). The authors went further to prove that critical manufacturing activities in the development phase include making prototypes, building tools and dies, pilot production and manufacturing ramp-up; these activities can have a substantial impact on lead time, cost and overall product quality. Clark and Fujimoto (1991) conducted an important study on the global automobile industry. Here the authors positioned pilot production and manufacturing ramp-up as the "tail" of the product development phase. Furthermore, Clark, Chew, and Fujimoto (1992) examined four key stages in a design project's evolution: prototyping, the acquisition of dies, pilot production and ramp-up. In each of these critical design-build-test cycles the "build" is *literally* a manufacturing process.

A frequently cited study that is carried out in the high-tech electronics industry, by Terwiesch, Bohn and Chea (2001) has the objective of gaining a detailed understanding of the production ramp-up process in a hard disk company. Using a longitudinal case study approach, the findings reveal

several organizational patterns that seem to shorten products' ramp-up period. The authors identify a soft handover from pilot production to ramp-up production, where they are running in parallel for an interval rather than a fixed handover contributes to better performance. This is followed by clear organizational responsibilities, together with a high commitment and cross-functional interaction have been proven to foster a smoother transition. Finally, the introduction of product platforms enables companies to leverage previous ramp-up experience for the ramping-up of new products, while ramping down the older model in the same platform. Ball et.al. developed a modelling tool for production ramp-up that demonstrates poor financial adherence as a result from changes in Recurring Costs generated from modifications in the production system and the later difficulties in recovering the backlog. The developed tool proves that this directly impacts ramp-up capability (Ball, Roberts, Natalicchio, & Scorzafave, 2011). Another interesting result is related to product transfer across geographic distance. Here research on communication and coordination in knowledge-intensive environments has long emphasized the importance of collocation of various organizational functions, specifically development and manufacturing. However, the study by Terwiesch et al. (Christian Terwiesch et al., 2001) highlights that the international transfer is able to proceed when using elaborate coordination mechanisms, namely cross-functional and cross-location teams. Within the strategy of mass-customization, managerial objectives are a stable and cost-efficient manufacturing on the one hand and high differentiation on the other. However challenging ramp-up execution might be, two sequential models are proposed in a recent study, high-volume-high-mix and low-volume-high-mix strategies to overcome the challenges (Slamanig & Winkler, 2011).

The structure of the ramp-up process can have major cost- and time-saving potential; it is therefore important to understand how key elements of successful ramp-up management are connected. The ramp-up process is a complex, costly and risky phase in the product life cycle that requires special tools and organizational mechanisms. The way the ramp-up process is structured, organized and managed is of significant importance for many manufacturing organizations, particularly when the ramp-up process is conducted as a cross-border activity.

In exploring the interface between NPD and production, some papers have identified the complexity of ramp-up process characteristics and management (Almgren, 2000; Clark & Fujimoto, 1991; Clawson, 1985; Langowitz, 1988; Wochner, Grunow, Staeblein, & Stolletz, 2016). Upon closer

examination of these papers, a clear characteristic emerges, namely the structural explanation given to the ramp-up concept. Scholars have previously suggested that the focus is on the number of elements identified that affect the ramp-up, which includes the product architecture, the manufacturing capability and the human resource set-up (Heine, Beaujean, & Schmitt, 2016b). Further elements that seem to matter are the product development process and the impact of suppliers and contract manufacturing service providers on the firm's operations. Clearly, the academic field needs to gain more insights into *how* these factors impact the ramp-up performance and *how* they become barriers; i.e. metaphorically speaking, we must look into the arrows and not just the boxes, and address the question of what are the barriers in the way these boxes/factors work?

Recognizing the significance of ramping-up efficiently, various factors may explain why it is important to study and analyse this particular managerial area. The manufacturing process during the ramp-up stage is still poorly understood, and inevitably, much of what is done during the process development does not work properly. Potentially identified issues include: machines break down or are deliberately interrupted to correct errors or to adjust the flow of materials. Set-ups are slow and the planning of the cycle time is uncertain for a number of reasons, such as suppliers are late or have quality problems. Special operations and tools are needed to correct product defects and process oversights, among other factors that impede the desired output.

From the theoretical point of view, it can be suggested that what characterizes the ramp-up concept is the dual broad and contrasting dimensions of institutional affiliation – having the coexistence of both product and process development logic, and manufacturing logic under the same roof. Though there is some confusion about the terminology, generally it is meant to describe a faster cycle time, and the end goal is a more successful process of working together as a team, and in some cases collaborating with the customer. Organizations often tend to collect best practice from many industries and put all the elements together, and the process is directed towards the production of a product or a service. The product owner leads and engages a team with the common understanding of what the customer desires from the product. The feedback results in changing the way in which the organization works and competes in the market.

The current stream of literature is predominantly in the applied sciences area, where the majority of the papers include but are not limited to publications in the International Journal of Advanced Manufacturing Technology, International Journal of Production Research and International Journal of Production Economics, among others. The existing literature concerns itself with industries such as the electronics and automotive industries. Furthermore, the subjects addressed seem to look into learning curves, and production capacity and cost. Our understanding of the ramp-up management phenomenon therefore has many opportunities for further investigations through employing different theoretical lenses. Manufacturing companies have given more attention to the ramp-up process, because outsourcing activities affect the coordination of activities in delivering products to customers. The ramp-up process needs to be faster and more efficient with more well-defined relationships both with pilot production and product and process developments on the one hand, and the volume production that comes after the ramp-up of the production system on the other. This thesis draws on the literature on how to organize the ramp-up process as well as descriptions of best practice of the ramp-up process from the MedTech industry through in-depth longitudinal field studies in a number of different development projects.

The collection of papers that this dissertation comprises contains contributions with managerial explanations on how the elements are constructed, related and/or integrated. Additionally, it is possible to imagine that all these relations have a time dilemma. So given that the focus is on time to volume, then in principle, what is it about the relationship between elements such as product design and time to volume that will hamper time in the context of the ramp-up phase?

The definition guiding this study of the ramp-up is the period when the production process makes the transition from zero to full-volume production, at or near the targeted levels of cost and quality. This is in line with Wheelwright and Clark's definitions (1992): "*In ramp-up the firm starts commercial production at a relatively low level of volume; as the organization develops confidence in its (and its suppliers) abilities to execute production consistently and marketing's abilities to sell the product, the volume increases. At the conclusion of the ramp-up phase, the production system has achieved its target levels of volume, cost, and quality*" (p. 8). Figure 1 illustrates the ramp-up cycle of a typical product (Matta, Tomasella, & Valente, 2008; Scholz-Reiter, Krohne, Leng, & Höhns, 2007; Slamanig & Winkler, 2011).

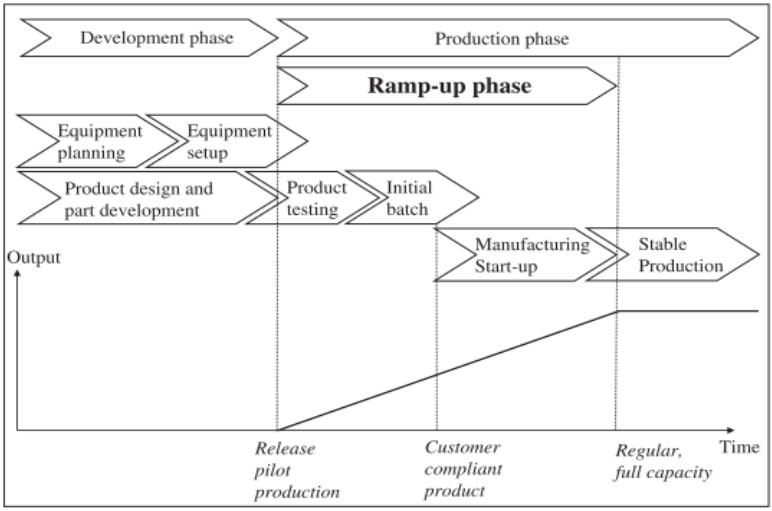

Figure 1 Ramp-up process

Over the last few decades, the focus on decreasing ramp-up time has grown substantially due to the increasingly fast pace of both technology and product life cycles. Up till now, however, the growing significance of ramp-up production activities for manufacturing companies and their growth has been from organisational theory perspectives inadequately addressed. NPD research is well established in the literature (Clark & Fujimoto, 1991; Wheelwright & Clark, 1992). The production and operations management literature addresses mature volume production challenges such as lean manufacturing (Womack & Jones, 1996) and agile manufacturing (Sânchez & Pérez, 2001), but the transition period for ramp-up has received much less attention. Although inter- and intra-firm research is fairly well covered in the general management literature (Choi, Dooley, & Rungtusanatham, 2001; Koulikoff-Souviron & Claye-Puaux, 2013), however important it is in operations management literature, and being the predecessor of cross-functional integration discourse, inter-organisational integration has only been addressed by a limited amount of studies in the operations management field (Gattiker & Carter, 2010). In exploring the relationships in the cases, this thesis digs deeply into the process of ramping-up and its implications in a corporate manufacturing social network setting.

2. Theoretical foundations for ramp-up management studies

Different theoretical foundations can increase research legitimacy, which is "a generalized perception or assumption that the actions of an entity are desirable, proper, or appropriate within some socially constructed system of norms, values, beliefs, and definitions" (Suchman, 1995). Theoretical foundations undergird scientific legitimacy, and they are used for the sake of challenging common sense, "*not only for the direct application but also for encouraging perspective on one's own lived reality and thus facilitating looking upon things in a more all-sided way than is spontaneously the case…*" (Alvesson, 2003b, p. 186).

Arguably, ramp-up management field doesn't reside in its own theory, which can propose a great opportunity to manoeuvre among endless organisational theoretical lenses. Throughout the papers of this dissertation, frameworks are discussed and novel theoretically instituted understandings of challenges in the ramp-up are proposed. This dissertation contributes with insights on how to problematize, comprehend, organize and manage the ramp-up process as an interface part of the NPD and production. In order to investigate these relationships, the organizational theories applied in the papers are knowledge management theory, grounded theory and resource dependence theory. Other organisational theories could also have been applied, such as actor network theory (Callon, 1999; Latour, 1999), which should not be misunderstood as the study of *social* relations of individual human actors. ANT concerns the researcher with studying the heterogeneity of the organisation and on the humans and non-humans actors, which are continuously formed and re-formed in groups.

As the papers will demonstrate, the researcher has favoured three generally accepted organisational theories of knowledge management, grounded theory and resource dependence theory, because collectively they contribute to the analysis of the ramp-up process and produce significant findings. Resource dependence theory (RDT) can be extended with knowledge management theory, in the sense that both are focused on the technological foundation of the organization, which can be a source of competitive advantage. The difference between these two organizational theories is that while knowledge management is focused inward in the organization, RDT is focused outward towards the environment, therefore the significance of these two lenses applied in the papers lies in

the systematic ways of thinking about and analysing the ramp-up organization and its challenges both within and outside the social network.

Other contextual factors in the ramp-up management studies could also be investigated through another theoretical perspective, namely institutional theory (Voronov, 2015). Here the researcher could look into the multiple logics existing in the professional groups managing the ramp-up processes and realising its goals. Some of the identified common bottlenecks in the organization of the ramp-up process points towards viable organizational mechanisms that remedy these institutional contradictions of both dominant logics of the creative NPD and the efficient manufacturer.

3. Challenges for organizing and enacting ramp-up in companies

As a result of the outsourcing and offshoring strategies of the past few decades, mobilized by cost reduction drivers, development of products and services often start locally, while volume production is carried out at low-cost sites abroad (Larsen, Manning, & Pedersen, 2013). There is a clear division between the local sites and those abroad that perform volume production, however this clarity is not to be found in the case of the ramp-up process. This phase has been proven to involve both scaling up locally, but also transferring knowledge and machinery units to foreign sites, and re-scaling the production to full volume at those sites. This set-up with ramp-up production located in the focal country and most volume production elsewhere is, however, in many cases new and not as formalized as the preferred structure. Therefore, common for manufacturing companies is a process of learning how to optimize and fine-tune the ramp-up process, and the interfaces towards both pilot production and R&D and the volume production.

Technology transfer can be seen in two forms. The first embraces physical items such as tooling, equipment and blueprints. Technology can be embodied in these objects. The second form of technology transfer is the information that should be acquired if the physical equipment is to be utilized successfully. This information relates to analysis of organization and operation, quality control and various other manufacturing procedures.

It is thus critical that manufacturing companies get a better understanding of the elements of the ramp-up process and the implications of the many individual choices, e.g. choice of raw materials,

level of automation and transfer-related activities, as these choices will have a substantial impact on future manufacturing cost.

The research underlying this project has addressed the importance of establishing an overlap between product development and process development by practicing concurrent engineering. Through applying lean principles, such as cross-functional organization, the lead time for the ramp-up process can be reduced. In addition to cross-functional organization, the ramp-up can be facilitated with two foci: 1) reduction of lead time and 2) management of the complexity of ramp-up. Lean principles could therefore be applied for continuous improvements.

The above discussion can lead to synthesising the speed and efficiency of the ramp-up process could be determined by the level of product and process complexities, manufacturing capabilities, product development processes, forecasted outlook and process technologies. This leads to the following research question.

4. Research question

The research questions explored in this thesis is:

- If time compression becomes the key issue, how can it be achieved?
- What factors in the relationship with the ramp-up function hamper time compression?
- Are there interactions between the factors influencing the ramp-up in such a way that they become stumbling blocks to each other?

5. Research Method

To answer the research questions, a detailed study of ramp-up projects was carried out. Here the advantage this dissertation has is the nature of the study set-up: the researcher being embedded in the company with a high level of involvement, affects the case company, and all forms of inquiry into the research field entail interventions (Guest, Bunce, & Johnson, 2006; Jönsson, 2010; Åhlström & Karlsson, 2009). The research motivations and objectives call for analytical in-depth interactive research, for which, at early stages of theory development, clinical research is the most suitable methodology. As Ward-Schofield argued that this type of research does "*not to produce a standard*

set of results that any other careful researcher in the same situation or studying the same situation would have produced. Rather it is to produce a coherent and illuminating description of and perspective on a situation that is based on and consistent with detailed study of the situation." (Ward-Schofield, 1993, p. 202). The project is thus initiated by the manufacturing case company and is based on issues experienced at the organization, ultimately with the purpose of solving them and providing the company with practical managerial tools. Access to the fieldwork is therefore by invitation.

The research aim at every stage is deep, causal understanding of the issues at hand where the researcher undertakes the role of involved helper (Karlsson, Sköld, & Christensen, 2013). Within the overall study of the case company, multiple embedded case studies are conducted that involve collaborations between R&D and pilot production on the development of multiple products, machines and tools. These processes and projects serve as the study's unit of analysis. A mix of single and group interviews has been carried out and analysed, and internal and public documents have also been validated and coded. The choice of qualitative methodology came about, because the research idea is micro-organisational level, it is explorative and therefore qualitative research is suitable. It reduces the possibility of survey studies and enables the discovery of concepts and relationships and elaborative descriptions; this is done in order to develop and test existing theories or create new theories. Moreover, the work process of qualitative research is challenging, interesting and stimulating since it usually involves social interaction with people and earning their trust within the area of study (Merriam, 1998). The aspiration is that this research process can generate useful contributions to the field of ramp-up management. The case studies provide context-dependent knowledge that allows people to engage in expert-level activity – a goal that social science is particularly skilful at accomplishing (Harden & Thomas, 2005; Jönsson, 2010). Current research does a good job at providing practical suggestions on how to choose an appropriate case for study and how to approach its analysis in terms of research design.

The choice of a real-world qualitative research approach was made on the basis that ramp-up management is a discipline that has only been explored to a limited extent in organizational studies. Therefore, according to Glaser and Strauss and others (1967), a qualitative approach is advantageous for explorative purposes (Alvesson, 2003b; Voss, Tsikriktsis, & Frohlich, 2002).

Methodologically, in the clinical approach, evidence is not collected, it is created in hindsight as the discovery process unfolds, which is characteristic of many varieties of process-oriented research. (Christensen, 2016; Karlsson, 2013)

5.1.Empirical field and data collection

As the empirical basis for this thesis, a longitudinal study of a MedTech manufacturer in Europe was conducted. The organizational mechanisms are taken into account for the specific characteristics of the manufacturing company's value chain configuration, because these activities are separated both functionally and geographically. Since 2002, with the aim of transferring and carrying out volume production abroad, the manufacturing company has established its first production site in the EU. Since then, additional production sites have been established in Asia. Today, more than a decade later, 95% of volume production is carried out abroad with a total transfer of more than 500 machines, while the remaining 5% of volume production is carried out locally. Furthermore, two manufacturing sites were established in 2011 at two production units with the intention of maintaining some production activities in Denmark and simultaneously enhancing manufacturing capabilities. The main task of the two ramp-up sites is to take the new products from product development to volume production, i.e. to scale production up from prototypes to pilot production, and finally ramping-up the volume manufacturing process. Another task performed by these sites is identifying potential savings in the existing product portfolio, and by experimenting and redesigning the product or the process, further cost reductions are then harvested.

The fieldwork is conducted at these sites, the so called "*development factory*", which can best be compared to the Toshiba sites studied and analysed by Fruin (1988). The development factory is a factory specialized in developing, ramping-up and launching new products, and transferring machines and learning to volume sites abroad. Among the characteristics distinguishing the development factory from others is the employee-related focus, a high specialization by functions and product area, the centrality of the organization, the strong focus on the company's development of competences and the remarkable feeling of community.

In recent years, the strategy chosen at the case company has focused on applying a semi-automatic production set-up throughout the entire production ramp-up activities, where problems are solved in

order to produce the first saleable products, and the focus is on optimizing and validating machines and the production process. The last phase focuses on stabilizing, ensuring quality standards are met and documenting the process so it can be handed over to the production units abroad. The lead time of the phases will depend on the complexities of the machines and the products configurations.

The overall empirical structure of the thesis is to undertake data collection during the research invitation at multiple sites of the case organisation, both locally and abroad. During a period of three and a half years, the researcher functioned as a trusted observer at daily Gemba morning meetings and at weekly project evaluation meetings. Furthermore, the site director together with a team of ramp-up managers held by-weekly and monthly management meetings to address pressing strategic operational issues that arise from the ongoing projects. The researcher was also an observer at these meetings with notepad as diary tool. The senior management of Supply Chain, R&D and Ramp-up divisions conducted quarterly business updates meetings where access for research observations was also granted. Having pursued qualitative research, the author is aware of not just the uncertainty and flexibility of this particular approach (Lincoln & Denzin, 2003), but also the tension between creativity and rigor (Patton, 2002). To ensure systematic validity of the findings, various steps were taken, and anonymities are granted all through the fieldwork. Working in close collaboration with an assigned company supervisor, helped establishing early sampling groups with two large projects transitioning into critical phases of pilot and ramp-up processes. This sampling was later extended to include numerous other projects that sat the foundation for further empirical analysis. The criteria for eligibility of the projects at the early stages of the study, the sampling of respondents, and the interview protocol were all developed with both school and company supervisors and research assistants.

Throughout the fieldwork, triangulation was greatly applied to respondent selections, interviews, and coding process. Member checking technique (Denzin, Norman K; Lincoln, 2011) was exclusive and unrestrained, because the researcher was becoming a trusted part of the organisation and was present on a daily basis. Follow-ups on data interpretations, and preliminary results from the analysis were therefore possible at all levels of the organisation. As elaborated further in the papers, there are substantial gains to be made in conducting such research of the ramp-up process, experiencing multiple realities and ensuring both valid perspectives and understandings of the fragmented situations during critical phases at the case company. The researcher made active pursuit into social

events participation and establishing close friendships outside of the organisation, which is a strategy that more than anything quickly proved to increase trust and confidence of the participants and the legitimacy of this study.

6. Positioning and relation of papers

Over the course of the research stay, different studies, both conceptual and empirical, have been carried out. This dissertation consists of four papers and they are summarized in the following table.

An earlier version of paper 1 has been presented at the International Competitiveness Management Conference 2015, and the current version is conceptual and was published at the Special Issue on Ramp-up Management in the Journal of Quality Management. Paper 2 is single-authored and covers research methodology perspectives, it was presented during the 2016 Ramp-up management conference in RWTH Aachen University, and later published in Procedia CIRP. The earlier version of papers 3 was presented at the 21st International Product Development Management Conference: Innovation through Engineering, Business & Design, and the current version is planned for journal publication. Paper 4 has been developed from an earlier version presented at the 23rd International Annual EurOMA Conference 2016, and the current version is under journal review. Paper 3 and 4 are empirically founded and employ grounded theoretical lens and resource dependence lens. All papers will be further introduced and explained in the following pages.

Overview of the papers in the thesis

#	Title	*Authors*	*Research perspective*	*Status of the paper*
1	"Lean application to manufacturing ramp-up: a conceptual approach"	Christensen, Irene & Rymaszewska, Anna	Literature review and conceptual model development	Published in the Quality Management Journal – Special issue on Ramp-Up Management
2	"Clinical research – Fieldwork perspective on ramp-up management Studies"	Christensen, Irene	Philosophies of science and methodology for studying the ramp-up process	Published in Elsevier Procedia – CIRP
3	"Contradictions or shared goals? Empirical perspectives on ramp-up management"	Christensen, Irene & Karlsson, Christer	Explorative study of two projects undergoing ramp-up development	Earlier version presented at the 2014 IPDMC conference The current version is being submitted to a journal
4	"The power of intra-organizational coordination in ramp-up execution – a multiple case study"	Christensen, Irene & Karlsson, Christer	Multiple case study of organizational relations formation during two incidents of ramp-up process	Earlier version presented at the 2016 EurOMA conference The current version is under review in Peer-reviewed journal

7. Summary of the papers and their contributions

7.1. Conceptualizing ramp-up management

Essay 1: Lean application to manufacturing ramp-up – A conceptual approach

The important issue of manufacturing ramp-up in connection with lean application is investigated in this paper, as well as organizational learning. The conceptual approach is quite new to the field of ramp-up, thus the importance of the paper can be found in the conceptual clarity affecting the transition of ramp-up studies, from dealing with the application of advanced analytical methods to the analysis of the activities, decisions and responsibilities involved in managing the design, production and delivery of goods and services. Different sources in the literature are compared and the paper presents a synthesis of the meaning that researchers and quality managers attribute to the concepts of ramp-up and lean management. By developing a conceptual model, the paper highlights the discrepancy between existing knowledge amid the community of researchers, and offers opportunities for further studies and contributions. The challenges and the applicability of lean management to manufacturing ramp-up are explained. Here the authors suggest focusing on the need to eliminate, reduce and manage variation in order to become lean. Otherwise, achieving both flow and resource efficiency might not be possible.

Lean application brings a set of tools and techniques to reduce lead times, inventories, set-up times, equipment downtime, scrap, reworking, and other wastes in the pilot and ramp-up production. Managers ought to continue efforts to make the application of lean management in the ramp-up process more accessible, because it has the potential to incorporate leadership, customer focus, process capability and process management in order to achieve process improvements.

The proposed research opportunities in the paper invite subthemes of discrete and continuous manufacturing that could be empirically studied. Research in industrial settings could contribute to manufacturing firms when applying the principles and tools of lean management and Six Sigma, thereby offering an excellent way to improve the productivity and quality of the firm.

7.2. Scientifically studying ramp-up management

Paper 2: Clinical research –Fieldwork perspectives on ramp-up management studies

This paper describes a methodological approach to doing field research. Resonating in the understanding of the logic of problem solving and the production of scientific knowledge, the utilization of a collaborative clinical research perspective is discussed. Novel insights into ramp-up management studies are provided, and an agenda for conducting collaborative clinical research is presented. This ambitious decision to break with "gap spotting" and change the modus operandi in ramp-up management studies is implemented by proposing clinical research as the epistemological base for this area. Furthermore, the paper provides suggestions that clinical research is an inquiry that shares many similarities with process consultancy and action research, and provides mutual value-added contributions and benefits to both the studied organizations and the researcher alike. This methodological choice is a possible way to produce practically applicable management research, and traditionally originates in Scandinavian management studies (see, for instance, Karlsson (2013, 2016)). It is also worth noting the establishment of the "Center for Applied Management Research" at CBS back in 1998 by the late Professor Erik Johnsen. From across the Atlantic, other notable contributions by MIT Sloan professor Edgar Henry Schein in the early 1990s have also laid the foundation for this scientific method.

Furthermore, this paper offers personal reflections and stories of conducting clinical research, as well as specific approaches to extending the epistemological foundation of clinical research as a scientific methodology. More specifically, the paper illustrates the important and multifaceted identity of the researcher in the field study, not only acting as an external observer, but becoming wholeheartedly involved in several ramp-up projects in the organization. Through close collaboration with the host company supervisor and its members, the researcher offers analysis and ongoing research findings and other relevant resources. Subsequently, deep access within the organization was granted, covering multiple layers from the CEO and senior executives to the skilled and non-skilled workers. This level of involvement in ramp-up projects has resulted in a "box seat" status for the researcher to enable him/her to study "under the surface" issues, closely monitor process developments over time and report valuable insights from real-life contexts, while validating the results instantaneously during the project.

Overall, research published in scholarly peer-reviewed journals tends to lean towards, and be in favour of, empirically founded papers, because there is the implicit assumption that fieldwork always produces a positive outcome, i.e. data. On the basis of the researcher's experience with

hindsight, not only has data collection been challenging during a long period of 30 months, but the researcher's identity construct has changed, becoming strengthened or weakened at the host organization, depending on a number of factors; such as the facilitators leading the ramp-up projects. As an example from the study, the mere presence of the researcher is questioned and could even pose a risk in some of the less successfully performing projects, where process changes and re-engineering work are widespread. This example highlights the importance of the researcher's commitment in establishing trust and shared interests early in the process, in addition to maintaining a level of humility and flexibility throughout the fieldwork.

This paper proposes the clinical research method as a progressive way of uncovering other, often hidden root causes to ramp-up process challenges, and as a result, the shortage of influential research needed to expand the area of ramp-up management can be eliminated.

7.3.Empirical analysis on ramp-up management

Essay 3: Contradictions or shared goals? Empirical perspectives on ramp-up management

The primary motivation for this study is to uncover what variables affect production ramp-up and most importantly *how* these effects are manifested. This cause and effect initial study generates a research model on how the issues emerge, develop, grow or terminate over time. The aim is to produce familiarity through describing patterns of effects, such as the lack of root cause analysis in the ramp-up process – too much firefighting, complex and over-engineered first-generation products, insufficient or inaccurate process development and a lack of dependable supplier relations.

Based on grounded theory, the paper explains the direction and extent of causal relationships and change through the generation of hypotheses. Empirically, this paper analyses data from longitudinal research studies conducted by two large projects within a large European organization. The paper sheds light on the characteristics of the barriers affecting the process, such as high variations during the ramp-up, ownership of the project and the managerial commitment to predefined deliverables. The focus is on aspects characterized by asymmetrical uncertainty about deliverables, including overestimating production plant capabilities in terms of speed and flexibility, and underestimating the workload in the ramp-up process and the new product transition from pilot testing to full-scale production.

Essay 4: The power of intra-organizational coordination in ramp-up execution – a multiple case study

The basis for writing the paper is a detailed description of the activities and problems of governance throughout the ramp-up process, which has been done through a resource dependence theoretical lens. The structural complexity of ramp-up processes enabled by cross-functional interactions is examined and the degree of fragmentation in the process planning and execution is analysed. Resource dependence theory is used as the central explanatory framework for intra-organizational and organization-environment interdependencies throughout the planning and execution of the ramp-up activities and milestones.

This study explores inter-firm resource dependencies in production initiation and their influence on the effectiveness of manufacturing ramp-up. Multiple case-based approaches with ethno-methodological studies are applied to pursue the in-depth contextual analysis and cross-case analysis. The final study offers discoveries and exploration of the connections between the inter-firm resource dependence on production initiation and specifically its influence upon the effectiveness of manufacturing ramp-up. Symmetries have been identified, and potential exploitation or opportunistic risks profiles are presented. This paper extends the understanding of ramp-up management in organizational interdependencies from a inter-functional perspective; and from the managerial perspective, the empirical understanding of inter-functional alignment and collaboration conveys the exploitation risks, and offers potential reformulation of strategies concerning the management of ramp-up processes, such as a stockpiling strategy, a levelling strategy, forecasting and scale adjustment strategies, as suggestions so that managers can actively shape dependence relations across the organization.

8. Summary of research contributions

One of the main contributions of this dissertation is creating an awareness of the different contrasting, sometimes conflicting foundations of norms, values, legitimacy and authority that can be found within ramp-up management organisation. Managing ramp-up activities can be achieved from different aspects (quality, time, communication, supply chain management, employee empowerment and training, product specification and bottlenecks). Managers are expected to utilize a variety of strategic choices – including the implementation of lean management practices such as continuous improvement processes, standardization, and internal integration of processes along the supply chain, employee empowerment and bottleneck management.

The ramp-up process runs within, or as, normal production and could disturb it. There can be many alternatives, such as an intermediate experimental plant between the laboratory and the production plant. There is tremendous potential to improve ramp-up performance and reduce the overall time required to achieve volume production. The manufacturing strategy literature conceptualizes a state of "leanness in operations", which can consolidate both the concepts of lean and manufacturing ramp-up, providing a dual perspective.

Managers create and select procedures that mitigate relations in the environment and seek relations that create favourable exchanges. For practitioners, managing environmental fluctuations could follow a set of five proposed strategies. In general, managers can avoid or reduce dependencies and organizations can do so by shaping a dependence relations strategy, scale adjustment strategy and forecasting strategy, among others.

This dissertation is more interested in the advancement and understanding of ramp-up management than in offering specific technical and fixed solutions. Summarizing and bringing the research topics together in this synthesis is beneficial in finding patterns and conclusions, and finally discussing these in relation to existing literature.

The anthology of the papers in this thesis and the research output from the explorative study in the MedTech industry contribute to identifying additional factors that lead to lengthy time-to-volume, and how they have transpired in the context of ramp-up process. Other research outcomes and benefits gained from this thesis are:

- Analyses of and proposals for how operations performance factors impact on ramp-up performance in a manufacturing company

- Throughout the project, unique analyses and proposals for how different strategies for factors such as training and knowledge management, as well as resource management, structures and processes impact on ramp-up performance
- New knowledge on how interdependencies and alliance formations influence the ramp-up process performance and what exploitation risks these formations lead to.

9. Synthesis

Organizing and managing the ramp-up process is essentially the task of creating a smooth transition between product development and production. In realizing this goal, managerial measures can be adapted to help identify and avoid problems at the early stage of production. Disturbances and unforeseeable events in the process during the ramp-up phase are likely to occur in practice, and these can be in the product or the process. A machine specialist at a ramp-up site puts it metaphorically as follows:

"*Growing up, your body rarely grows at the same rate as your mind. Some mature early, which is preferred, as the changes in your body will seem appropriate when they happen. Then there are the early bloomers that have developed way before the mental side starts to mature. Ramp-up management is about understanding the readiness of those who carry it out. The body (production) needs a mature mind (blue-collar manufacturing employee) to function. I can't stress it enough: education first and then you start thinking about growth.*" Specialist – ramp-up management.

How organizations deal with the difficulties encountered at the start of production has not been adequately investigated from a social scientific point of view, this thesis is a direct response to additional studies into the analysis of effects of process interruptions and defects during the ramp-up process. This thesis takes this task into account and offers a more fundamental disciplinary grounded view, thereby acknowledging the coexistence of two perspectives, that of the developer and that of the manufacturer. There are various detailed conclusions, implications and contributions in the different papers, for instance ramp-up process being portrayed by the imperfect manufacturing process setup, and as such different managerial decision models could be carefully considered.

While there are indications in the literature that an interdisciplinary approach to the development of a new product as well as the cross-functional integration of partners in the value chain leads to the avoidance of problems. There is no investigation into what consequences this

interdisciplinary approach has, when attempting to solve the problems that have occurred and accelerate production initiation. Similarly, to the early integration of the functions involved in the development process, it is possible that this strategy of the affected areas of the ramp-up process can be discovered at a faster rate and addressed, because the knowledge foundation is clearer and the impact of the issues can be better captured and taken into account.

Ramp-ups present challenging management issues in the sense that there is more pressure on planning and control and on organizational design. Companies can experience severe consequences if they do not provide adequate supervision and support during piloting and ramping-up, and if they do not adopt methods to suit the situation. Previous experience and knowledge gained seem to have a significant influence on differences in ramp-up management. Interviews and discussions indicate that there are apparent differences in regard to how previous experience is utilized as input in the process of planning and control and in the organizational design of ramp-up.

Essay 1: Lean application to manufacturing ramp-up: a conceptual approach

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This paper provides a theoretical overview of the concepts of lean and manufacturing ramp-up in an attempt to conceptualize the strategic areas in which lean philosophy and principles can be applied for continuous improvements. The application of lean principles during the final stage of a new product development process, that is, the ramp-up process, is a critical, early enabler of lean manufacturing.

The manufacturing strategy literature conceptualizes a state of "leanness in operations," which can consolidate both the concepts of lean and manufacturing ramp-up, providing a dual perspective. Abstracting from the extant literature, the authors considered the competitiveness of manufacturing companies from two principal perspectives: the leanness of the ramp-up process and the new-value creation of quality managers. While much of the literature fails to acknowledge that the roots of lean actually lie in quality evolution and TQM, there is relatively sparse evidence on the subject of applying the lean philosophy to manufacturing ramp-up, so this study is an attempt to address this gap. This is achieved by providing a comprehensive outline of the two concepts and illustrating the areas in which mutual benefits can be drawn, as well as providing a conceptual framework for future studies in lean application to the manufacturing ramp-up process.

Key words: conceptual framework, lean, manufacturing ramp-up

1. Introduction

The increasing complexity of manufacturing environments and the pressure to deliver new products faster while continuously improving quality requires manufacturing organizations to frequently rethink their operations. Further, quality management practices contribute to operational and financial performance, allowing a firm to achieve a competitive advantage (Kaynak 2003; Lagrosen and Lagrosen 2005).

This paper addresses how to include the application of lean, which is traditionally associated with stable, low variability, and high-volume production, to the process of ramping up production. It examines how lean assists during the transition phase from product development to mature manufacturing. The two concepts of lean and ramp-up are generally associated with dissimilar environments. Lean is seen as particularly applicable to high-volume and low-variability manufacturing, while the ramp-up phase is characterized by its short-term focus, unpredictability, and high complexity. Product developers responsible for the final stages of pilot- and ramp-up production need to constantly develop their process. Process development is typically tracked as

reduced cycle times and reduced time buffers before reaching full-scale production. The success of these process development activities is measured according to predefined cost and quality requirements.

Taking the two concepts of lean and manufacturing ramp-up, the authors' framework centers on an appreciation of the intersubjectivity of embedded knowledge. It views quality management as a medium-level outcome, and time efficiency as a strategy-level outcome. This then is translated into the company's competitiveness. This perspective is broadly influenced by the work of Ferdows and De Meyer (1990), Flynn, Schroeder and Flynn (1999), and Roth and Miller (1990) and Rosenzweig and Easton (2010). The emphasis is on strategic decisions, whereby through structural, infrastructural, and integrative choices, ramp-up managers and manufacturers can acquire and maintain competitive capabilities.

The paper is organized into four sections. The following section provides a theoretical overview of references in the context of manufacturing ramp-up and lean. Following that is a section about lean application areas during the ramp-up, with a particular focus on knowledge and quality management as enablers for lean implementation and thereby ramp-up time reduction. The final section concludes with a conceptual framework and implications for quality managers.

2. The challenging phase of manufacturing ramp-up

The earliest scholarly representation of ramp-up is at the new product level, that is, the launching of production. It begins when the process is scaled up from zero and ends at full-volume production. This agrees with Langowitz's classification of the initial commercial manufacture of a product (Langowitz 1988). Table 1 presents a chronological overview of the most important definitions of a ramp-up process.

These characteristics of manufacturing ramp-up are furthermore outlined by Fleischer, Spath, and Lanza (2003); Scholz-Reiter et al. (2007); and Surbier, Alpan, and Blanco (2014), suggesting that initially managers have a low level of knowledge about the product and processes. Then through a challenging and gradual learning process at low production output with high cycle time and low production capacities, they move to high volume process, with supply chain and product quality, as well as planning reliability.

These characteristics are due to multiple causes, including insufficient product specifications and continuous product changes, which stem from late engineering changes and lack of product maturity. Technical processes such as long setups, unexpected bottlenecks, product manufacturability, and end-product quality, which may result in rework or scrap, are also

complications (Surbier, Alpan, and Blanco 2014). Due to these characteristics, it is extremely difficult to systematize, control, and standardize the ramp-up process. This creates challenges for quality and lean managers in achieving continuous improvement. While there are multiple causes for the lengthy cycle times during ramp-up production, this paper focuses on two of these: quality management and lead time.

3. The context of Lean

The term "lean" originated in the Massachusetts Institute of Technology (MIT) study of Toyota Production Systems. The system described there has been implemented by many major organizations around the world with the intention of reducing costs and improving responsiveness to customer demands. However, Bhamu and Sangwan (2014) point out that lean in different companies varies from a set of tools to an overall change of the organizational mindset. This variance may be due to an evolution in managers' perceptions and understanding of lean from seeing it simply as a means of eliminating manufacturing waste, toward viewing it as a more complex, enterprise-wide method of operating that can incorporate the entire supply chain.

The many definitions of lean indicate that over the years the understanding of the concept has become somewhat blurred. Modig and Åhlström (2012) attempt to provide a universally applicable definition of lean, hence distinguishing between two dissimilar approaches -- resource efficiency and flow efficiency -- and addressing the challenge of combining them. They suggest that a company's ability to combine these concepts is an opportunity for development and building a competitive advantage. Organizations should aim at the most beneficial combination of resource efficiency and flow efficiency, which often necessitates pushing performance frontiers further.

Lean exists at two levels, having both strategic and operational dimensions (Hines, Holweg, and Rich 2004). The term "discrete manufacturing" indicates a focus on isolated measures, such as individual improvement projects using the "lean toolbox." The term "continuous," however, suggests a process-oriented perspective, focusing on the continuous efforts, that is, the philosophy of "lean thinking," or the process of "becoming lean" (Karlsson and Åhlström 1996; Stone 2012).

Based on the review of the literature on lean, one can conclude that the concept of lean is universally applicable and extends into supply chains and even networks of enterprises. The conceptual research presented in this paper builds upon the previous research conducted in the field of lean. The main assumption is that lean principles can also be applied to manufacturing

ramp-up to increase the effectiveness of the process. The remaining sections of this paper are devoted to addressing this assumption in more detail.

4. Lean application to manufacturing ramp-up

The idea that applying lean thinking and principles to manufacturing ramp-up remains scientifically unexplored, although the application of lean beyond standardized and predictable environments is not particularly new. For example, Bowersox, Stank, and Daugherty (1999) address the lean launch strategy in a new product development process. They describe the lean launch strategy from the perspective of the implementation of response-based logistics. The research provides an important input into the wider field of applying lean in less predictable environments; however, to the best of the authors' knowledge, there is not much research that extends lean into the phase of manufacturing ramp-up (Rymaszewska, Christensen, and Karlsson 2015).

To extend lean, not only must the prior concepts be introduced, but a conceptual framework needs to be developed that gives insight about how manufacturing ramp-up can achieve faster time-to-market, along with increased volume and revenue.

While this paper combines two different levels of abstraction, the overall philosophy and principals of lean and the ramp-up process, the scope is necessarily limited. This paper focuses on the aspects of lean that can be easily applied to manufacturing ramp-up, such as waste elimination, moderating variation, and standardization, while also addressing the human factor of operations (employee empowerment), and a broader context of supply chains.

5. Lean manufacturing ramp-up – toward a conceptual framework

Seen in the context of the challenges of the global economy and increasing competitiveness, companies should aim to build their competitive advantage by alternating between trade-offs and pushing their performance frontiers further. There is little evidence that lean tools and techniques such as just in time (JIT), total quality management (TQM), and constraints management have been applied to manufacturing ramp-up. This paper addresses this issue from the theoretical perspective and lays the foundation for the practical application of the combined perspectives.

Table 2 presents the relevant areas where the lean tools and techniques can be applied to the manufacturing ramp-up process. The description provided within the "issues in manufacturing ramp-up" column is focused on explaining the importance of the chosen category to answer the

question “Why?” The “lean implementation guidelines” column explains how the application of lean tools to manufacturing ramp-up could be perceived.

The proposed framework summarized in Table 2 is based on the existing literature (Rymaszewska, Christensen, and Karlsson 2015). In order to enhance the practical applicability of the proposed conceptual framework, a checklist of the issues to be addressed while considering the application of lean to manufacturing ramp-up is proposed in the appendix.

Several enablers of lean application to the ramp-up process exist; however, the following section addresses two of those enablers, namely knowledge and quality management.

Quality Management Value Creation

Strong ties between lean and quality imply that the application of lean tools and techniques to production ramp-up has implications for quality management. Failure to address the quality issues before full-scale production might result in ramp-up being an extended series of fire-fighting events. Early adoption of quality management tools might not only contribute to ensuring the efficiency of ramp-up but also provide considerable potential in the process of creating value to customer and companies. Customer value creation stems from the ability to understand the customer’s perception of value, which often is perceived as a physical product or service offered ahead of the competitor. These attributes are directly related to the growth, cash flow, and profitability of the organization. Products that reach quality targets in considerably shorter time contribute to value creation within companies by ensuring that the ramp-up phase is executed swiftly, and by early detection and elimination of quality-related bottlenecks.

Time Factor and Learning Curves

Time is a crucial factor and a lens through which a successful lean implementation and effective manufacturing ramp-up can be defined. This is especially true in today’s highly competitive and complex business environment, where the pressure for seamless and frequent new product introductions is particularly strong. Time is a competitiveness factor that determines the success of manufacturing ramp-up. Combined with the short-term focused, unpredictable, and fuzzy nature of the ramp-up process, the ramp-up process needs to be revised to increase its effectiveness. The conceptual research presented in this paper proposes the application of lean thinking and principles to the manufacturing ramp-up process**.** Terwiesch and Bohn (2001) outline

the following time-related elements through which the success of a ramp-up process can be defined:

- Time-to-volume (time to reach full production volume)
- Time-to-market (time needed for the development of a new product, while achieving the desired quality level can be seen as a prerequisite of a "market ready" product)
- Time-to-payback (time needed for reaching the initial financial goals)

Time is also an important characteristic in the case of lean. There is a plethora of definitions of lean, however, the importance of time can be observed from the best known time-saving techniques such as JIT delivery, and single-minute exchange of die (SMED). Lean principals are also focused on flow and resource efficiency, which, in the simplest terms, translates into ensuring that the customer receives the right product or service, at the right time, and with the right quality.

Decreasing the time required for reaching the planned volumes is closely connected to the learning processes. Terwiesch and Xu (2004) define learning as a "firm's accumulation of knowledge and its movement along a certain trajectory, called the learning curve." In another study, Terwiesch and Bohn (2001) similarly note that production ramp-up of "poorly understood" processes can be accelerated by putting in place approaches for "deliberate learning through...controlled experiments using the production process as laboratory." The origins of the learning curve date back to the airframe industry and the famous publication by Wright (1936), who on a generic level observed the decrease in the cumulative time or cost per unit with the cumulative number of units produced. Therefore, the general assumption behind the C-shaped learning curve is that the time required to perform a task decreases as a worker gains experience, which implies that the time or cost of performing a task decreases at a constant rate as a cumulative output doubles.

The learning curve can also be expressed as an S-shaped curve, where the y-axis (vertical) expresses the number of products manufactured correctly (free of faults), which increases with the number of units produced (x-axis, horizontal) (Plaza, Ngwenyama, and Rohlf 2010; Jaber and Bonney 2011). Moreover, the learning process can be divided into three generic phases that differ in their steepness, which is a matter of expressing the speed of the process. In the initial phase (prototyping) the number of correct products increases relatively slowly compared to the next stage (zero series) where certain experience has been gathered and, therefore, the number of correctly manufactured units can rapidly increase. The zero series stage is where the learning process proceeds at the greatest rate, which is a consequence of extensive testing and improving.

Both prototyping and zero-series production incur costs for companies; those are necessary steps that can be treated as an investment in the learning process. In the case of Volvo, the zero-series cars are driven by engineers and managers for testing and experimenting, and they are scrapped afterward, thus never getting commercialized, even if no nonconformities are detected (Almgren 2000). This is an example of deliberate learning.

The theory of organizational learning can be perceived as the foundation of the idea of the learning curve. From the perspective of reducing costs, organizations should aim at shortening the time needed for turning new challenging tasks into those performed routinely (Zangwill and Kantor 1998; Plaza, Ngwenyama, and Rohlf 2010; Karlsson 1989).

Almgren (1999) provides a useful understanding of the issue of learning curves and time required for learning processes. According to the author, an organizational learning curve represents learning from experience as well as the benefits from moving from unknown processes to more routine processes. Experience is measured in terms of cumulative production volume or calendar time.

According to Abernathy and Wayne (1974), a learning curve exists when costs are reduced as product volume increases. The authors claim that increasing a company's product volume and market share will additionally bring cost advantages over the competition. However, organizational learning is necessary for a permanent modification in the process to achieve quality, which is referred to as quality learning (Kanji 1996).

Learning will occur at different rates and, therefore, this phenomenon is largely organization specific. Argote and Epple (1990) refer to factors such as organizational forgetting, as well as turnover and transfer of productivity gains in particular. The authors emphasize that a lack of knowledge transfer might severely affect organizational learning, particularly when there are no standard procedures available, and when it is not possible to train employees in a short time. Fioretti (2006) claims that in some cases organizational learning might not occur at all. This is supported by a recent study showing that on one hand, the actors within the organization want to protect their competitive knowledge during the cooperation within the network; however, on the other hand, the distribution of knowledge must be ensured within the network to develop potentials for value co-creation. This has been shown to have a direct impact on increasing competitive restraints; shortened ramp-up phases, product life cycles, and innovation cycles; and augmentation of product lines in manufacturing (Krenz et al. 2015).

6. Conceptual Model

The conceptual framework offers a basis for future researchers to examine different problem-solving strategies in detail. This framework also provides a possible means of integrating lean practices into infrastructural strategic choices that are identified in the ramp-up and quality management literature. In addition, the authors' framework provides a means of organizing research to solve problems within the field of ramp-up process management.

The proposed conceptual framework is then extended with an application checklist intended to be useful for quality management practitioners. The proposed checklist specifically addresses the strategic choices to be considered in the case of lean implementation during manufacturing ramp-up. The checklist has been validated by three independent senior operations managers from the electronic and pharmaceutical industries to ensure its practical applicability (see Figure 1).

7. Conclusions and limitations

This conceptual research paper acknowledges the importance of the manufacturing ramp-up phase and seeks to propose a novel approach to improving the efficiency of the process, based on applying the lean philosophy and its principles to manufacturing ramp-up.

This paper is expected to support the stream of research that assumes a development of lean that reflects the changes in the economic environment such as the growing complexity of operations and pressure for faster product introductions. The paper systematizes the existing theoretical knowledge and, by synthesizing and combining it, the conceptual framework for applying lean philosophy to manufacturing ramp-up. It is expected that the research presented in this paper will lay the foundations for further examination of the so far sparsely researched topic of lean application to manufacturing ramp-up.

A focused literature review both in the field of lean and manufacturing ramp-up is provided, and critical research gaps are identified. This research is focused on providing an overview of the state-of-the-art, highlighting the scarce evidence of lean principles being applied to manufacturing ramp-up processes. The application of lean ideas to manufacturing ramp-up is a potentially promising approach, since it offers extending the scope of lean and addresses the important opportunity to improve the manufacturing ramp-up process, especially in terms of quality and time. Nevertheless, certain obstacles to the applicability of lean to manufacturing ramp-up need to be acknowledged. For instance, the greatest challenge to becoming a lean organization is variation. Here the authors focus on the need to eliminate, reduce, and manage variation in order

to become lean. Otherwise, achieving both flow and resource efficiency will not be possible. On the other hand, the inherent characteristic of the ramp-up process is volume increase and standardization of production methods, which are usually very new to an organization and very difficult to predict; therefore, planning ahead for success is limited. However, organizations might take certain measures and tools in order to moderate the effects of scaling up, starting from lean-related demand smoothing (heijunka), and evolving toward effective organizational learning.

This conceptual research provides a framework for exploring and readdressing the importance of the time factor. The time factor has been discussed in the context of being a determinant of a successful manufacturing ramp-up, as well as the aim of lean philosophy to achieve the same or better results in less time. However, time is also crucial for the idea of learning curves, which are frequently mentioned in the context of manufacturing ramp-up.

The framework is focused on improving the manufacturing ramp-up process by highlighting the areas where mutual benefits can be drawn. Moreover, the areas where the application of lean principles is challenging are also acknowledged and addressed from the broader perspective of variability and learning curves. The contribution of this paper can be described in terms of building a deeper understanding of the concepts of both lean and manufacturing ramp-up. By bringing these ideas closer on a conceptual level, a foundation for further empirical research is provided.

8. Further research

The following directions for further research are proposed. First, additional research into ramp-up factors where lean principles are challenging to apply is needed in order to explore the matter on the conceptual level. Second, the proposed research opportunities in the subthemes of discrete and continuous manufacturing could be empirically validated. Research in the industrial setting could contribute to manufacturing firms, when applying the principles and tools of lean and Six Sigma, thus offering an excellent way to improve the productivity and quality of the firm.

9. Implication for Quality Managers

Lean applications focus on efficiency and aim at offering products and services at the lowest cost and as fast as possible. This information can be used to develop targeted interventions to improve lean ramp-up process; this could start at the senior management level and could be

operationalized within the various departments across the organization to improve flow and efficiency of the ramp-up processes. As an application, lean brings a set of tools and techniques to reduce lead times, inventories, set-up times, equipment downtime, scrap, rework, and other wastes in the pilot and ramp-up factory. Continued efforts are needed to make the application of lean in the ramp-up process more accessible, because it has the potential to incorporate leadership, customer focus, process capability, and process management in order to achieve process improvement. Often companies fail to integrate lean within their process and quality improvement initiatives and, therefore, such companies never achieve the breakthrough results they desire.

Table 1: The chronological overview of the ramp-up definitions.

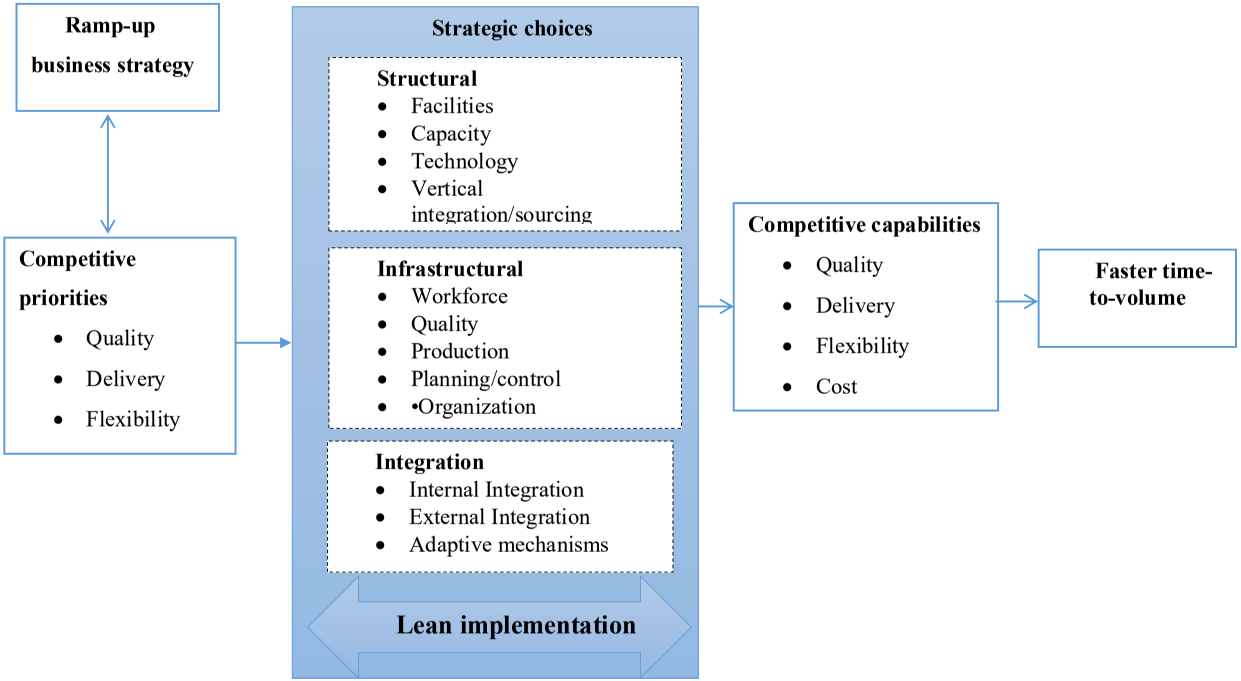
Reference	Definition
Gustmann, Retschlag, and Wolff (1989)	The integration of innovation and industrial production
Wheelwright and Clark (1992)	"In ramp-up the firm starts commercial production at a relatively low level of volume; as the organization develops confidence in its (and its suppliers' abilities to execute production consistently and marketing's abilities to sell the product, the volume increases. At the conclusion of the ramp-up phase, the production system has achieved its target levels of volume, cost, and quality."
Almgren (1999)	During the production ramp-up, predefined indicators of cost and quality indicators are achieved.
Terwiesch and Bohn (2001)	The period following the product development phase during which a manufacturing process makes its transition from zero to full-scale production at targeted levels of cost and quality.
Romberg and Haas (2005)	Starts at the same time as the initiation of new product development; the reason is that the planning must take place before the actual execution.
Schuh, Stölzle, and Straube (2008)	The time span of the product creation of a firm. Ramp-up begins after product development with a first production run during which the product is manufactured on zero-series machinery and ends when full-scale production is reached.

Table 2 The framework for applying lean to manufacturing ramp-up

	Issues in manufacturing ramp-up	**Lean implementation guidelines**
Quality	An important determinant of a product's "market readiness." The desired level of quality should be reached in the shortest possible time. Simultaneously, the drive toward introducing a product fast often compromises the quality.	Promote a sense of continuous improvement among the production employees and encourage them to actively propose different types of experiments to reduce variations in the production process, which may cause deviation in product performance.
Time	Accelerating the speed of work to shorten cycle time and reduce time buffers during the ramp-up process increases the likelihood of human error and equipment failure.	Achieving the same or better results in less time lies at the core of lean thinking. Elimination of wasteful activities and focus on creating and delivering value to customers.
Communication	Lack of communication is one of the central reasons for the failure of manufacturing ramp-up.	Standardize communication and information flow with the help of lean techniques such as Obeya meetings, together with flattening the organizational structure and overcoming barriers in communication.
Supply chains	Successful application of lean to manufacturing ramp-up might in certain cases be dependent upon	Lean tools implementation to manufacturing ramp-up results in supply chain members' awareness of their roles. Hence, before any actions are

	how a supply chain performs as a whole.	undertaken, managers need to ensure that the leanness spreads throughout a complete supply chain.
Responsibility, empowerment, training	The effective ramp-up can be achieved by assigning responsibility for certain actions, which helps improve the speed of the decision-making process.	Lean implementation happens at the shop floor; empowerment of the line workers is achieved through training and assigning clear responsibility.
Product Specifications	Detailed and well-circulated product specifications might contribute to eliminating problems caused by unclear instructions.	Using standardized documents for product specifications and work instructions. The learning process should be embedded for continuous improvement and steady elimination of variability.
Bottlenecks	Process bottlenecks negatively impact the effectiveness of the ramp-up performance and, at the same time, are difficult to predict.	Lean aims at the elimination of bottlenecks and ensures swift and even flow as well as resource efficiency. This is achieved by systematic identification of wasteful activities and eliminating them.

Figure 1: A holistic view of ramp-up manufacturing strategy: Conceptual model of lean implementation



Appendix

Variables of ramp-up strategic choices to make (= measures)	
Competitive priorities Quality: capability of doing things right Dependability: capability of doings things on time/when promised Speed: capability of doing things fast; short cycle and lead times Flexibility: capability of changing what is done: volumes, product mix, or to new products or services Cost: capability of producing goods and services at relatively low costs	**Competitive capabilities** Qualifiers: capability of being considered for tender Order winners: capabilities that make buyers choose or have preference for product or service Orders: capabilities of reaching deals
Integration factors Industry: Structure, technologies, development Suppliers: structure, bargaining power Customers: structure, bargaining power Rivalry: numbers, sizes, development Size: actual volumes, relative size Resources: physical, human, externally available	**Ramp-up strategies** Competitive role: not doing wrong, best practice, lean implementation, strategic factor, advantage Objectives priority: trade-off choices in quality, dependability, speed, flexibility, and cost Processes: workshop, batch, mass, flow Resources: plant, equipment, staff Organization: forms and managerial processes

Technologies: areas, levels, closeness to front, externally available Dynamic capabilities: capabilities of developing and changing the above ones	Systems: capacity and process planning, quality control, maintenance Improvement: rationalization, continuous improvement programs

Essay 2: Clinical research - Fieldwork perspectives on Ramp-up management Studies

Abstract

This paper is about the logic of problem solving and the production of scientific knowledge through the utilisation of clinical research perspective. Ramp-up effectiveness, productivity, efficiency and organizational excellence are topics that continue to engage research and will continue doing so for years to come. This paper seeks to provide insights into ramp-up management studies through providing an agenda for conducting collaborative clinical research and extend this area by proposing how clinical research could be designed and executed in the Ramp- up management setting.

1. Introduction and motivation

Social researchers and in particular - management researchers call for alternative and novel methods in studying strategies for organizational effectiveness and thus achieving evidence-based-research. Clinical research method bridges between two disciplines: the applied sciences and the social sciences. The ultimate purpose is to develop knowledge that can maximize the effectiveness of practice.

This research strategy call for different methodology research designs, for instance Cheng and McKinley (1983) claim that in prescription-driven research, the independent variables should be applicable and that research should always focus on overall organizational performance as dependent variable (Cheng & McKinley, 1983, p. 98).

This paper provides suggestions that clinical research is an inquiry - while time consuming and requires intensive interactions with the studied organizations and their members - shares many similarities with process consultancy, providing mutual value-added contribution and benefits to both the studied organizations and the researcher alike. The explicit discussion presented in this paper could benefit and encourage aspiring or even active researchers to make scientific progress in ramp-up studies as a spun-out and recognized management field. The primary aim of this paper is thus to offer insights into and guidelines for conducting clinical research and the second aim is to suggest that ramp-up management studies can be created through a deeper and more robust research process, well embedded in the understanding of how basic scientific discovery is achieved and knowledge is created.

The launching of a third international conference on the topic of ramp-up management says something about the journey of maturity the topic is currently undergoing. It can be said that the conference creates visibility of what the field is and where it is going and this methodological focused paper is strongly suited for this purpose.

1.1. Background

To advance ramp-up management studies, a growing number of scholars are engaged in empirical and conceptual studies. (See for instance (Brauner et al., 2016; Christensen & Rymaszewska, 2016; Heine et al., 2016b; Lefakis, 2016)). In the previous years some scholars have investigated this area although briefly, most notably Terwiesch with some contributions made in the early 2000 (C Terwiesch & Xu, 2004) addressing ramp-up production before changing to healthcare and innovation management. Other noticeable ramp-up management contributions can be found in (Gopal, Goyal, Netessine, & Reindorp, 2013; Gross, 2014). Nonetheless, this research topic remains adequately represented throughout conference proceedings, dissertations and working papers (Almgren, 1999a; Alsoussi, 2015; Pufall, Fransoo, de Jong, & de Kok, 2012; Laurène Surbier, 2010). Whether these sources have strong academic contribution is highly questionable. For instance and to a great surprise to the author, a closer examination of two dissertations (Alsoussi, 2015; Laurène Surbier, 2010) reveal that their respective authors use the terms *methodology* and *method* interchangeably or having different meanings.

Other studies reveal serious and numerous deep flaws. For instance a working paper (Pufall et al., 2012) on ramp-up performance - cited 3 times according to Google Scholar - presents a time series analysis despite the fact that the paper fails to produce any narrative of leading or lagging effects from the available data. Furthermore, that very same data is treated as normally distributed with constant variance, although some data are truncated and some are binary. This should by no means be seen as a standalone single case but rather a commonly deeply flawed misuse of statistical measures in many scientific disciplines (Siegfried, 2014). According to Jeff Leek "*The problem is not that people use P-values poorly it is that the vast majority of data analysis is not performed by people properly trained to perform data analysis*"(Wasserstein & Lazar, 2016).

There is therefore an essential need to reconsider viable strategies for positioning and advancing ramp-up studies as a solid and recognised management field with robust emphasis on *management* at its extensive level. This focus has numerous potential benefits for contributions through research methodology for ramp-up management, and this paper takes on this task through defining and illustrating particular benefits and challenges of conducting clinical management research.

2. Research strategy – Clinical research

The epistemological aspects of any social science researcher are almost infinite in varieties in acquiring knowledge. We are set to ask what the problem is in the management of the Ramp-up process and venture on a study. The formulation of the research question is essential because it is linked to a number of theoretical and methodological choices. The research strategy becomes the methodological connection between the research philosophy and the following strategy in data collection methods and analyses (Denzin, Norman K; Lincoln, 2011).

Clinical research is defined by Cohen & Manion as "*a small-scale intervention in the functioning of the real world and a close examination of the effects of such an intervention*"(Cohen, Manion, & Morrison, 2013), this research strategy is a choice that - based on research objectives - guides the researcher's work and determines the approach taken. In the case of clinical research the objectives are directed towards acting, intervening and solving immediate practical problems with functional applications and theory testing which might direct practice (Karlsson, 2013; Portney & Watkins, 2015).

This strategy is in contrast with basic research, where the researcher is directed towards the acquisition of new knowledge, motivated by intellectual curiosity, with limited or no reference to the potential practical use of the results.

3. Scientific knowledge production

Academic studies are reflected in two important characteristics or traditions – how we see the nature of the world, i.e. ontology and how knowledge of this nature is acquired, i.e. epistemology. The majority of the management researches – though not always explicitly mentioned in scholarly publications, are imbedded within three perspectives – realism, phenomenology and constructivism:

- The perspective of realism is based on the fundamental assumption that reality exist in a specific and in principal unambiguous manner. Realities are "out there" independently of the researcher's knowledge of it. From this perspective the intention of the researcher is to capture the phenomenon of interest and to describe them in a settled manner and as accurately, clearly and objectively as possible (Justesen & Mik-Meyer, 2012). One objective might be to identify

and explain cause-and-effect relationships between different phenomena which in this context are often defined as variables.

- The other perspective is of phenomenology; which focuses instead of subjective actions, especially with regard to the meaning given to active actions. The researcher's objective in this perspective is not to identify and explain causal relationships but to interpret, understand and typify subjective universes of meaning.(Justesen & Mik-Meyer, 2012)
- The assumption that reality is continuously constructed through social processes and interactions fits within the constructivist approach. Through this perspective the job of the researcher is an attempt to capture the complexity that characterized the phenomena that interest him/her and describe it (Justesen & Mik-Meyer, 2012; Newman & Hitchcock, 2011).

Other concepts and philosophies presented in figure 1 include the instrumentalist perspective where the goal appears to be identical with that of the clinical research method; namely helping predict events and solve problems through scientific theories as instruments; though I will argue that not only a research problem but also a practical problem is attempted solved through theory. Thus the instrumentalist's epistemic stance while still rejecting the scientific realism – tend to merge closer to the truth and move closer to foundationalism concept. This is in line with what Manfred Kets de Vries and Edgar Schein agree on, namely that the clinical approach both scholars use is more empirical than that of the positivist statistical approach; not only is the clinical approach more empirical in getting closer to the data, but the acknowledgement by both scholars that all the activities conducted are an intervention, and thereby data generating (Manfred F. R. Kets de Vries, 2000).

Although foundationalism can be seen as a version of instrumentalism, here science is believed to evolve towards truth and rejecting any statement of reality by unobservable entities (Lakatos, 1976). The research within the foundationalism perspective emphasizes on data-gathering where scientific knowledge is developed inductively.

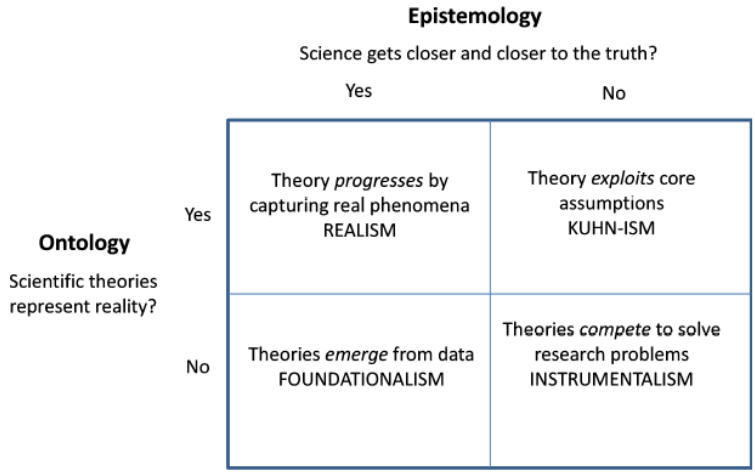


Figure 1 Matrix of Philosophy of Science Approaches and Associated Logics of Action (Kilduff, Mehra, & Dunn, 2011)

3.1. Objectivity and Subjectivity in Clinical research

Whilst on the notion of managing subjectivity, in the traditional sense the realist scientific research concerns itself with minimizing it altogether, as well as any contextual element; the ideal knowledge is therefore objective in the sense that is concerned with reflecting the object of the study as accurately as possible; therefore, it can be said that ontology takes superiority over epistemology. This is obviously in strong contrast with both phenomenology and constructivism, both of which contemplate the notion of subjectivity to be the condition of the study process but neither can or should be ignored.

The critical point of the social scientist when applying clinical research approach is being close to the data source, because one cannot understand a social system construct - regardless of the levels be it individual, departmental, or at the overall organizational level - without becoming involved with it, even trying to influence it and change it. According to Schein being able to help people has far more appeal than sitting in a laboratory or massaging numbers.(E. Schein, 2000). Oftentimes researchers try to maintain an illusion of objectivity, which in standard practice usually means detachment. Though the moment an epistemic researcher – clinical in particular enters an organization, he/she disturbs the system. According to Kets de Vries, instead of fighting that

result, he suggests to use the data that comes with it. *Not taking account of the clinical dimension — the fantasies that people project on you, and your own fantasies in this interpersonal playing field — leads to an impoverishment of the research effort. The natural science model tends to linger on in the social sciences.* (E. Schein, 2000, p. 17). Thus it can be perceived that knowledge construction from clinical inquiry is a result of the researcher *not* stepping outside and pretending to see 'everything from nowhere' but being an integral part of the study. (Haraway, 1988)

3.2. Developing research questions

Different kinds of knowledge emerge when posing 'how' and 'why' research questions. The 'how' questions lead to project description that focus on context, while 'why' questions typically seek to identify general causal patterns (realism) that apply to more than just a specific context (Justesen & Mik-Meyer, 2012). The 'how' research question is more likely to be answered by the use of more exploratory approach in reaching an understanding of the phenomena (constructivism or phenomenology); this approach involves less structured interviews, focus groups, documents studies or participant observation. In contrast, the 'why' research issue can be addressed by analysing valuable data that is generated through the use of structured interview guide or structured observation. (See table 2 for more detailed explanation).

Much of the existing ramp-up management research published in OR journals begins with hypothesis or an outcome assumption which is in line with quantitative inquiry, whereas qualitative research starts with initial question or academic curiosity which Carpenter & Creswell further elaborate on by pointing out that the qualitative questions are 'evolving' processes. (Carpenter & Creswel, 2007). Other scholars (Marshall & Rossman, 1999) distinguish research questions with different functions or research outcome: exploratory, explanatory, descriptive, and emancipatory. See table 1 for detailed summery.

Purpose of the study	**General research questions**
Exploratory To investigate little-understood phenomena. To identify or discover important categories of meaning. To generate hypotheses for further research	What is happening in this social setting? What are the patterns, meanings of categories for the participants? How are these patterns linked with one another?

Explanatory To explain the patterns related to the phenomenon in question. To identify plausible relationships shaping the phenomenon	What events, beliefs, attitudes, or policies shape this phenomenon? How do these forces interact to result in the phenomenon?
Descriptive To document and describe the phenomenon of interest	What are the relevant actions, events, beliefs, attitudes, and social structures and processes occurring in this phenomenon?
Emancipatory To create opportunities and the will to engage in social action	How do participants problematize their circumstances and take positive social action?

Table 1 Matching Research Questions and Purpose (Marshall & Rossman, 1999)

Table 2. Implications of Philosophies of Science for Organizing (Kilduff et al., 2011)

Key focus areas	**Realist**	**Foundationalist**	**Instrumentalist**
Characteristic goal and logic of action	Discover fundamental structure of the universe through pure research	Find hidden patterns in data through induction	Truth-independent *problem solving*
Types of knowledge produced	Scientific breakthroughs, irrespective of commercial implications	Unanticipated discovery of patterns in data from which new theory can be formulated	Pragmatic solutions to theoretically defined problems
Indicators of progress	Causal expression of relationships among theoretical terms; verification of causal relations among terms	Unexpected but replicable correlations indicative of new discoveries; counterintuitive derivations from first principles	Greater number of important problems solved
Characteristic method	Mathematical model building	Data mining	Those that are considered historically and socially legitimate
Illustrative organizing	Self-governing community	Cadre of experts	Cross-field, focused collaboration

4. How to conduct clinical research

Conducting clinical research can best be described by Suddaby's grounded theory perspective, which states that it's "*most suited to efforts to understand the process by which actors construct meaning out of intersubjective experience*" (Suddaby, 2006, p. 634). Throughout extended studies of Ramp-up management over a period of two and a half years, the researcher learned most from working with their company colleagues and interacting with their supervisor about the organization. During the first 14-16 months daily involvement is expected and encouraged with the project divisions responsible for conducting the myriad of activities related to the preparation, planning and Ramp-up project management, which makes the researcher realize what initiating production mean in the distinction between theory and organizational realities. It expanded the researcher's skills as an ethnographic investigator and has the potentials of teaching the researcher the ins-and-outs of active listening, understanding, and identification of organizational life themes. It also gives the researcher a microscope through which to observe individual and organizational change process (Manfred F. R. Kets de Vries, 2000).

The clinical researcher has to deal with many levels in the organizational system, each with its own theoretical lenses and explanation model. It is advised that when conducting an intervention, it is paramount to pay close attention to the power network, because any suggestions of process modifications, resulting from some form of organizational analysis must be extended to the key players or a change agent identified in the organization involved. (E. Schein, 2000; Schwartz, de Vries, & Miller, 1985).

Researchers attempted occasionally to change organizations starting at the middle- or lower-management levels, though quickly discovered that while it's sometimes possible, it's usually more complicated and time consuming.(Manfred F. R. Kets de Vries, 2000)

Numerous projects are studied during their Ramp-up process development in the organization; this is part of an ongoing effort in trying to distinguish successful from unsuccessful process performances. In doing so, the researcher relates the behavior of the blue collar employee with the behavior of the skilled workers, and that of the manager and supplier groups, and how those influence the organization. The researcher makes note on their forms of interactions. Some issues appeared during the researcher's presence in formal meetings, GtG, and less formal settings such as Friday's joint breakfast gatherings, Christmas and annual parties etc.

The given identity of the researcher in the organization is dynamic, in the sense that what the expectations that the various actors had of him/her during their early visits, are not the same 30 months later. The researcher reflects on the manufacturing site and office layouts, the lunch seating preferences different groups had and what the significance of that was? He/she wonders about the major cultural values of the people who had been with the company for 10 or 25 year+. What kind of organizational culture and values were they now experiencing? Questions are asked about employees' hopes for the future, perceptions of recent structural changes, etc. As a result, in a short amount of time, he/she ultimately receives a wealth of insights — a substantial part of it is non-verbal and should be noted during or immediately after it occurred in a log. As the researcher reflects on the impressions he/she has of people and situations, many associations can be triggered. The researcher's task then becomes withdrawing back to the university and conducting some thematic analysis with the goal of identifying the major themes that permeated the Ramp-up organizational units.

4.1. Challenges when conducting clinical research

As clinical researchers we have a systemic view and perceive people in context. We often find ourselves in situations where people in our studied companies approach us with unrealistic expectations. According to Edgar Schein, the hardest part of the clinical researcher's work is 'to see beyond individual dynamics into group and systemic dynamics'. Furthermore, there are two ways the organization perceives an invited clinical researcher and neither of which is attractive:

Fundamentally speaking, one group of people perceives the researcher as the Messiah and expects him/her to have an instantaneous magical problem solving recipe to their lengthy Ramp-up time-span, i.e. 'the problem' you've been invited to unravel.

The other group escape altogether and they appear to be scared, and suspicious of the presence of the researcher, perhaps even look at the researcher's computer screen while passing by and ask into what's being written down on the pad. At some point refuse to talk to the researcher completely, because they inform the resrearcher that they suspect him/her for being a spy for the senior management team. Why else senior executives take precious time out of their busy calendar to sit with the researcher, show him/her around the production site and join his/her table during lunch breaks. In a way this raises a different yet another problem.

It has been proven that having a broader view is a valuable capability. As researchers, we can come to terms with the situational dictates and pressures put on, expressed and most probably felt

by the studied organizational members (Maanen, 2011). It is paramount to always try to take these challenges seriously and demystify our presence in the organization. For instance, the author leaves her glasses at home and uses contact-lenses instead, in addition to wearing flat shoes and minimal make-up; it is encouraged to remember as many names as possible and interact with people from different layers in the organization; ask about their day, the jubilee of one of their colleagues or their plans with their families for the holidays.

This strategy is beneficial because it breaks down the barriers; build up trust which helps the researcher gain access to essential data about Ramp-up challenges for sufficient analysis.

5. The value of theory in clinical research

The role of theory in conducting clinical research is paramount. In clinical research we use theory to generalize beyond the specific situation and to make predictions about what should happen in other similar situations. The validity of these forecasts can be tested through triangulation.

Depending on how we choose theory in conducting clinical research, it can serve several purposes: it can summarize the knowledge and give meaning to isolated empirical findings, it can provide framework for the phenomena studied and it is also used to explain observable events by showing how variables are related; though *not* according to how well they represent 'actual' causal processes. This allows the researcher to predict what might occur giving a set of specific circumstances. (Laudan, 1978; Portney & Watkins, 2015). Schein, however has a different perception of the value of theory: he believes that as clinical researchers, we ought to be able to explore the revealed data without recourse to any particular formal theory or model, to let the data lead the researcher, so to speak (E. H. Schein, 1987). This statement seems to suggest that there are fewer rules and procedures for clinical research to follow, though subsequently more work to be done.

6. Dissemination of and contribution of clinical work

The refocus of ramp-up management as a managerial field must have an impact on the research methodologies chosen by new as well as established researchers alike. The field has a strong relationship to the practical world and it is neither identifiable with innovation management nor with operations management, but it should be approached as a single standalone in between these two fields. It cannot be explained and theorized by purely deductive approaches; because the

human behavior should not be ignored neither should the social dynamics existing in the organization with direct effects on normative modeling be dismissed.

The studied organization, its participating employees and the academic setting provided basis for this paper and in return the researcher offers deeper and viable understanding of the clinical research approach and more insights into knowledge co-creating within Ramp-up management. For the scholarly community, this paper provides new directions for ramp-up management research, strengthens the clinical research method through providing a comprehensive foundation within the philosophy of science and for empirical work and dissemination.

The scholarly literature has oftentimes sharp, outdated and unproductive separation between methods – being either qualitative or quantitative, and this view is still prevalent (Flyvbjerg, 2006). Instead social science should steer away from being a methodology driven and instead focuses on being problem driven in the sense that it employs these methods that's for any given scientific curiosity best help answers the research question at hand. Often times a combination of qualitative and quantitative methods will do the task best.

Essay 3: Contradictions or shared goals? Empirical perspectives on ramp-up management

Abstract

Many industries focus more and more on improving their productivity traditionally defined as the amount produced related to one of the resources used. Shortening time-to-volume has been widely investigated as one of numerous manufacturing improvement initiatives. Shortening the time for development of new products and ramping-up faster in particular has not seen the same focus as source of productivity improvement goals. Based on grounded theory methods, two large cases within a MedTech company are examined, and relationships affecting the ramp-up process are analysed. Ramp-ups are performed for each new product and it is the time-to- volume and includes the tail of New Product Development. A prototype makes the transition from zero to full-scale production at expected levels of quality and cost during the development period and includes several important activities, scaling production, experimenting, discovering, eliminating problems, and uncovering potential opportunities to make the production process more stable.

This phase is characterized by a high complexity level of the production system. Some companies address the challenges by a combination of semi-automatic processes during the ramp-up production, thus achieving the necessary combination of flexibility and efficiency needed to succeed in optimizing the production process. This model makes it possible to retain manufacturing locally and offer low prices at the same time. To some extent, manufacturing in these cases could be viewed as an industrial example, which demonstrates that manufacturing locally may be competitive.

Keywords: NPD, RAMP-UP MANAGEMENT, PRODUCTION PROCESS, LONGITUDINAL FIELD RESEARCH

1. Introduction

The swift and efficiency with which new products are developed and introduced into large-volume production is an important influence on competitiveness in manufacturing (Hatch & Mowery, 1998). The assumed failures of many organizations to manage product development effectively have been frequently cited as a critical contributor to deteriorating firm competitiveness (Dertouzos, Lester, & Solow, 1988). Many industries experience the pressure from strong competitors, investors and technology progresses calling for shorter product lifecycle. Ramping-up new products quicker is essential when considering the cost of R&D, supply chain, distribution and marketing of every new product making a transition into full-scale production. In addition to great potential harvesting first-mover advantages (Franco, Sarkar, Agarwal, & Echambadi, 2009), successful Ramp-up reduces time to payback and improves accounting measures such as return on investments (ROI) and return on assets (ROA). Additionally, lower variable cost is achieved through lower level of material scrap and better utilization of idle time.

The premise of this paper is that managing the tail of New Product Development (NPD), that being the interface between NPD and the full scale production is important; not only how this phase is carefully executed effects the success of the throughput time, but also it also signifies greatly the efficiency and productivity of the firm.

1.1. *A Model of ramp-up process characteristics – a disciplinary significance*

Early research focuses on the ramp-up process from a NPD perspective (Eppinger & Ulrich, 2015; Marquis, 1969; Wheelwright & Clark, 1992), but most literature stems from operations research and manufacturing perspectives (Becker, Stolletz, Stablein, & Stäblein, 2016; Byun, 2016; Kremsmayr, Dronhofer, Mitterer, & Ramsauer, 2016; Linder, Anand, Falk, & Schmitt, 2016).

However heterogeneous these two disciplinary perspectives are, they offer interesting and insightful studies into the ramp-up process. In fact, there are institutional differences between them, that might often be contradictory, which affects the way the ramp-up management concept is studied. This paper suggests that ramp-up field not only having a functional engineering role but also social and managerial dimensions, because having such a holistic construct of the field permits for an illustration of dynamics of social science in the pursuit of engineers as either subordinates or decision-makers.

While the ramp-up process can be illustrated as the interface between NPD and production,

without differentiating its disciplinary affiliation, this paper aims for an encompassed affiliation and addressing this tension through an empirical field study. How the ramp-up process is managed and executed will influence successful machine stabilization and the generation of valuable knowledge at the ramp-up sites; both the product and process technology will have to be developed and adjusted during the phase of ramp-up.

1.2. *A review of related literature*

New product is the launching of production from when the process is scaled up from zero to full-volume production, fulfilling some predefined indicators of cost and quality. This definition of Wheelwright and Clark (1992): "*In ramp-up the firm starts commercial production at a relatively low level of volume; as the organization develops confidence in its (and its suppliers' abilities to execute production consistently and marketing's abilities to sell the product, the volume increases. At the conclusion of the ramp-up phase, the production system has achieved its target levels of volume, cost, and quality*." (Wheelwright & Clark, 1992, p. 8).

There is a prevailing lack of agreement on the terminologies assigned to classifying the ramp-up phase, which could further diversify the field of research. Carefully examining the related literature, our discoveries reveal a range of expressions employed to labelling the activities that occur during this phase. Ramp-up has been referred to as 'manufacturing scale-up' from NPD perspectives (Meyer, 2007), 'product launch' is the phase where the product debuts for production in a manufacturing plant (Gopal et al., 2013). 'Initial commercial manufacturing'(Langowitz, 1988), 'production launch' (Gross, 2014; Neumann & Medbo, 2016; L Surbier, Alpan, & Blanco, 2010), 'R&D/production interface' (Säfsten, Lakemond, Johansson, & Magnusson, 2006), 'rapid prototyping' (Sommer, Hedegaard, Dukovska-Popovska, & Steger-Jensen, 2015), and 'new-product introduction' (Cantamessa & Valentini, 2000), which should not be misinterpreted as 'market launch'(Robert G Cooper, 1988), because through four experiments, the paper deals with initial manufacturing capacity planning and strategizing for fluctuating demands. Clark and Fujimoto (1991) provided a detailed empirical analysis of product development processes from the automotive industry, their impact on product development performance and their divergent use across multiple regions. Clark and Fujimoto referred to this practice they called "*integrated problem solving*"; by observing companies targeting short time- to-market combined intensive knowledge transfer with processes overlap, which came to be referred to as concurrent engineering. In exploring the critical interface between NPD and mass production, some papers have identified the complexity of Ramp-up management (Clark & Fujimoto, 1991; Clawson, 1985; Langowitz,

1988; Pisano & Wheelwright, 1995). Although there are studies from different industries, the limited number of research has been carried out in the automobile industry, and is mostly focused on defining the constructs, describing the observed patterns of empirical evidence and referring to earlier literature. While construct definitions are important, they are insufficient in ensuring the understanding of the unique functional relationships among concepts of ramp-up (Thomas, Cuervo-Cazurra, & Brannen, 2011).

When addressing the productivity phenomena, previous studies tend to focus on full- scale production processes. For instance, the study of Lieberman (1990) showed that improving productivity is possible through more efficient labour utilization. Another study by MacDuffie, Sethuraman and Fisher (1996) demonstrated the negative effect found in increased complexity of parts in production and manufacturing productivity. A higher variability in automotive options has a negative impact on productivity (Fisher & Ittner, 1999). When analysing volume flexibility a recent study shows that production can occur at above/below capacity when responding to realized demand (Goyal & Netessine, 2011). Furthermore, launching product at a flexibility manufacturing setting, might recover lost productivity (ibid). A recent study from 64 automobile plants in the United States over a ten-year period shows that even severe weather conditions hamper plant productivity (Cachon, Gallino, & Olivares, 2011). Clark and Fujimoto (1991) demonstrated that introduction of new products to the normal factory operations results in productivity drop during the ramp-up phase. In their study, they state that the initial production "*…is often a period of confusion. Productivity dives, the defect rates soar, scrap and rework mount, machines break down, lines stop, and engineers and supervisors run to fix problems"* (Clark & Fujimoto, 1991, p. 198). Roger Schmenner's recent paper on productivity (2015) highlights the critical role of effective operations management, and proposes the theory of Swift Even Flow as a framework for dealing with productivity issues. Throughout this paper, he presents a pantheon of innovators in operations management and specifies only two factors essential in gaining productivity: (1) reducing variation, and here variation of quantities, quality and timing. (2) to reduce the throughput time as much as possible. Schmenner suggests that companies should aim at eliminating *the nonvalue- added aspects of production, which is where the cost and inefficiencies lie* (Schmenner, 2015, p. 345).

The cohesions of this body of literature is the identified elements that seem to matter in studying the ramp-up process, such as the product development process and the contingencies manufacturing firms are operating under.

This paper is set to identify the barriers towards the operations of the ramp-up process and

identifying how these barriers are manifested. In principal, what is it about the relationship between barriers that such as product design and time-to-volume that will prolong the time span of the process. It is important to expand the existing knowledge with a managerial explanation on how these elements are related and/or integrated.

1.3. *Research aim and scope*

This study focuses on new product and process development projects within a single company. This study contributes to the literature on innovation management which reports on innovation at the level of a specific industry or an entire company (Krishnan & Ulrich, 2001). This paper is a direct response to the call for additional studies into the analysis of effects of process interruptions and defects during the ramp-up process, made recently by Glock and Grosse (2015). It is important to understand the approach of the study being that of concurrent knowledge development within the participating company and the academic setting in a parallel setup throughout the research period: the case company focuses on problem-solving issues while getting help from the researcher. The researcher is then looking at the issues while acquiring observations and other data from the company. Thereby, what emerge out of this set-up are the following research questions: (1) What are the patterns and barriers shaping ramp-up flow in the case organization? (2) How are these barriers affecting the process handover from R&D and Engineering to production plants? The findings from the current study will generate hypothesis intended for future studies.

2. Methodology

2.1. Epistemological assumptions, reflections & research design

Before making any decisions about a preferred methodological approach, one is first to analyse not a research topic but own scientific assumptions, since methodological choices are largely informed by ontological and epistemological choices of the researcher: *...research problems are not neutral. How we frame a research problem will inevitably reflect a commitment (explicit or implicit) to a particular model of how the world works* (Silverman, 2015).

Nevertheless, we – the practicing researchers are often influenced by and look to worldview perspectives from a "community of scholars" perspective (D. L. Morgan, 2007, p. 53). According to the author, paradigms can be viewed as the "typical" solution to issues and they may represent shared beliefs of a research field. Scholarly communities work using such ideas as shared identity,

common research issues, social networks, knowledge formation and informal groupings. There are both advantages and disadvantages with such practice, for instance Rogers (2003) refers to students of innovation being notoriously predisposed to a "pro-innovation bias". Other scholars recognize innovation biases, frankly stating that: "*"The act of innovating is still heavily laden with positive value. Innovativeness, like efficiency, is a characteristic we want social organisms to possess. Unlike the ideas of progress and growth, which have long since been casualties of a new consciousness, innovation, especially when seen as more than purely technological change, is still associated with improvement*."(Downs & Mohr, 1976).

Carefully recognizing these challenges, the selected cases for this study contribute to the understanding of the processes, mechanisms, life cycles, the meaning of time, changes, progresses and development in organizations. In studying these phenomena, the selected research design is longitudinal (Langley, Smallman, Tsoukas, & Van de Ven, 2013; Pettigrew, 1990; Van de Ven, 1992). Kondratieff was one of the first scholars to acknowledge the need for studying phenomena over time, elaborating that *"The reasons for this attitude are to be found first in the nature itself of economic phenomena, which are always changing, perpetually in a state of flux. As a result, the static conception, however perfect in itself, is unable to give a complete explanation of economic realities and to satisfy our craving for their scientific analysis and understanding. In addition, with the general rise in the level of culture and technique, the pace of economic development tends to increase, and the changes acquire a growing importance.* (Kondratieff, 1925, p. 575).

In response to the limitations in the literature on the ramp-up process management, the empirical study offers profound exploratory insights into two large projects within a Danish manufacturing company, and the philosophical assumption behind the exploratory design allows the researcher to work as a constructivist during the beginning of the study. At this stage, the approach is inductive and the researcher tries to understand NPD and production processes from the company informants' point of views. In gaining a deeper understanding into their practices, all forms of inquiry into the case company entail intervention (Åhlström & Karlsson, 2009). It's imperative to recognize "*how the phenomenon works*" and how people live, work and act in relation to it in their daily life (Silverman, 2015). With regards to trustworthiness and validity accustomed from assessing positivistic studies (Ahrens & Chapman, 2006), longitudinal real-time study can increase internal validity by enabling the researcher to track cause and effect (Leonard-Barton, 1990).

2.2. Prototypical version of exploratory research design

The key characteristic of longitudinal research design is that the data define what happened to the research units across a series of time. Menard (2008) describes four basic designs for longitudinal research: total population designs, repeated cross-sectional designs, revolving panel designs, and longitudinal panel designs. The most commonly used longitudinal research designs are repeated cross-sectional studies and trend, prospective longitudinal studies or the panel and retrospective longitudinal studies, event history or duration data.

This study is approaching longitudinal research methods as an umbrella encompassing qualitative data collection through ethno-methodological and clinical research design (Miller & Friesen, 1982). Most scholars agree on the drawback of longitudinal study: being extensive time and resources consumption compared with a deductive study with yield immediate results from a survey (Burgelman, 2011). The inductive researcher however spends great amount of time and effort on aligning expectations by the host company, and on fostering and maintaining relationship with the informants; while simultaneously spending time on the actual data-gathering (Leonard-Barton, 1990).

2.3. Research model and purpose of exploratory design

The data underlying this study emerge from a longitudinal research study conducted in a large Danish MedTech manufacturer. Within the longitudinal field study, an explorative study approach is carried out at the case company's R&D, pilot and ramp-up facilities. The author followed several products during three phases: before, during and after production ramp-up. This approach allows the researcher a particular type of access, it helps the researcher get close to processes and experiment, because the setting can be influenced and the case company tries to experiment with the views of the researcher; however, limited the researcher can experiment.

The primary motivation for this study design is to uncover what variables affect production ramp-up and most importantly *how* they do so. The goal is a theoretical contribution by carefully explaining the logical relationships among ramp-up management concepts. This first initial study generates a research model on how do the issues emerge, develop, grow or terminate over time. The aim is producing familiarity through describing patterns of effects; and secondly, to explain the direction and extent of causal relationships and change through hypotheses suggestions (Streb, 2010).

Davies (2006) argued that the distinctive feature of the exploratory study is that "*exploration constitutes a distinct form of discovery*", this is fundamentally different from both: the broad

characteristic of exploratory social science research as simply investigation, and the narrow classification that exploration is innovation (p.111). The general approach to data collection in this research method leads to '*a rhetoric of generation*' according to Glaser and Strauss (Glaser & Strauss, 1967, p. 18), where the purpose is discovery; thus the motivation is the development of theory from data in a process of constant discovery.

3. Method

The constitutive epistemological stance from which the analysis derives is that of a structuralist researcher, and language is positioned as means by which humans establish their social realities (Foucault, 1972). The data was collected and analysed trough Grounded Theory approach (Glaser & Strauss, 1967), because meaning is primarily derived from interpretations, and thus important to explore and clarify meanings by applying the most appropriate data analysis method. The problem with driving meaning from expressions by the respondents is that their words might often have multiple meanings, as well as ambiguous meanings (Agar, 1990). Grounded theory as developed by Barney Glaser and Anselm Strauss (Glaser & Strauss, 1967), is an approach used by researchers to analyse, interpret and explain meanings of a phenomenon constructed between social actors (Charmaz, 2006; Glaser & Strauss, 1967; Suddaby, 2006). Thus, grounded theory is employed in this paper as an analytical procedure to drive meaning and generate concepts from the qualitative dataset attained from the various sources such as observations and interviews.

Throughout the fieldwork, the method has primarily been observation and routinely 'shadowing' following employees in different settings in their work (Czarniawska-Joerges, 2007) as well as conducting semi-structured 1:1 interviews and focus groups. This method allows for access to all relevant knowledge and not just second hand knowledge collected from the internal company intranet databases. The researcher has the opportunity to experiment in real-time and follow the argument as they unfold in practice. Since the researcher gains high level of access, one can get into the heterogeneity, or simplicity of ways from which we can think about issues and concerns in the organization. This is particularly helpful because the researcher can understand the nature of the production process and draws on the likelihood of increased closeness to the managerial struggles to launch new products over the course of time. The advantage of such approach is getting closer to the real dilemmas of the case company, while simultaneously being aware of the risk of becoming an advocate or a critic rather than an observer. The account of how to collect the data is central, it is therefore important to specify and disclose the fact that the role of

the researcher is interventionist. Therefore, the researcher has kept a diary as a tool, because the research must make self-reflections throughout the field work (Nadin & Cassell, 2006). At the host company, the role of the researcher is to follow processes that are already there or are planned, there are also intentions of the researcher to fuel new processes.

3.1. *Research approach and population*

The purpose of step one is to answer the research questions defining the variables determining the ramp-up flow in the selected cases. This was achieved by asking participants to describe their experiences being involved in this part of the NPD as well as the ramp-up processes. The top management took on the role of a facilitator for field access across the different units in the organization, as well as co-developers during the pre-study; the goal here was to articulate more accurate research questions, which had to evolve beyond the obvious issues originally identified by the company.

A research protocol was also developed covering the procedures and the general rules on whom and from which manufacturing sites or business units' different information are to be pursued, what are the underlying contexts in which the questions are embedded, and why is the context interesting to the general reader. (Ahrens & Chapman, 2006; Qu & Dumay, 2011; Voss et al., 2002).

Different members at different levels of the organization have taken part in the study; employees with affiliations to different departments in the organization at various levels provided valuable insights into the two cases. 14 men and 9 women from diverse positions, seniority, and ages participated in the study. The participants ranged from non-skilled workers often hourly employed to high-level managers, and seniority from two months to 31 years. The participants' ages ranged between 18-to 56 years. They included individuals from R&D, Pilot production, Volume production sites, Quality and Engineering business units, Marketing and procurement. Two strategic management members took part in this study as well and functioning as "sponsors" with sufficient seniority to 'open doors', they functioned as "key informants" possessing high level of knowledge on the studied projects.

With the attempt of avoiding the risk of subjectivity and bias, multiple viewpoints were actively pursued. The case company manufactures and distributes several million products in medicine related businesses all over the globe. The company primarily operates in Europe and the Americas, and has product development divisions located in three cities in Denmark where the

fieldwork was conducted.

3.2. *Data collection and coding*

The data sorting process was conducted according to the grounded theory approach, which calls for a process of three stages – open-, axial- and selective coding (Saunders & Bezzina, 2015; Strauss & Corbin, 1998). In the first step, we conducted open coding process, and involved disaggregating the data into conceptual units with specific labels. The categorization of the collected data enabled the researcher to identify themes and concepts derived from the data. According to Strauss and Corbin, there are three principal ways to generate names for concepts. Either the researchers can utilise terms that emerge from the data analysis, or themes can be derived from the terms expressed by the participants. Another option is establishing these concepts that have been identified in the literature (Saunders & Bezzina, 2015). However, Strauss and Corbin (1998) advice against the latter, because the reader might interpret themes with similar naming to share the same meaning (ibid.). Thus, in this paper, the codes and categories are derived from a combination of the researchers' analysis of the data and the terms expressed by informants. Axial coding is the second step in the analysis process, and it refers to the process of identifying conceptual relationships between established categories and subcategories (Strauss & Corbin, 1998)

The field work can be classified as getting to know people in their own working environments, gain their trust, and maybe go to even further as committing ourselves to long- term relationships; this is similar to how van Maanen (2011) puts it, we are "*part spy, part voyeur, part fan, part member"*. As a request by the host company, multiple NDA and confidentiality agreements were signed at the very beginning of the process, and all informants were granted anonymity. This type of participant observation as a conduct implies *"immersion in the research setting, with the objective of sharing in peoples' lives while attempting to learn their symbolic world"* (Delbridge & Kirkpatrick, 1994, p. 37). We have developed an interview protocol, where the interview questions were considered to help the interviewees ponder (Alvesson, 2003b; Hermanowicz, 2002) on ramp-up process development and major incidents that affects the process either positively or negatively. Further details on methodological protocol overview for this inductive case study are summarised in table 2.

The case company has undergone some organizational changes, therefore the first questions were asked so that participants with relevant seniority think about those changes and how -if any- they had effects on their own positions first, followed by effects on NPD process then and now.

The respondents were then asked to think of some of the more complex projects they were involved in, in terms of expected performance versus actual performance, and what factors were determining the course of events seen from their perspectives. The next questions were on functional activities in the development process with the purpose of identifying that functions entered the different phases of product and process developments, and how the organization incorporated cross-functional integration - if any. The next questions required the respondents to reflect on current tools and software used for ramp-up stabilization and optimization. Data collection was also effective during full day's workshops regarding preliminary production planning of a 2-3 years' time span. Other workshops concerned new product unit integrations and capacity planning. The data was also collected during daily plant performance updates, with participants from different divisions in the organization; weekly project board and monthly department meetings generated significant amount of valuable data. Additionally, informal interviews were conducted at planned social events, such as daily lunch breaks, Friday morning joint breakfasts, October fest and annual parties. It is also significant to highlight the different approaches this study applies throughout data collection, as Alvesson highlights "*When elites are being studied, it is normally in the form of interviews where they themselves control the situation and produce their own versions of the world. Workplace ethnographies are carried out among blue collar workers, not executives.*"(Alvesson, 2003b, p. 179).

Observational field notes, plant tours, minutes from meetings, diaries, email correspondence, newsletters, pictures and interview transcripts are all forms of collected data, reviewed and coded. This process allows data to be *"segregated, grouped, regrouped and relinked in order to consolidate meaning and explanation"* (Grbich, 2007, p. 21). The intention is to categorize similar data into clusters that share the same characteristics. Furthermore, routinely coding of the empirical data has been actively pursued during fieldwork (Silverman, 2001, p. 293); this has been particularly beneficial in developing and crystallizing the interview protocol from preliminary questions into refined inquiries with terminologies and acronyms related to those already used within the case company (Alvesson, 2003a).

3.3. *Data analysis & Synthesis*

All the events have yield data that was noted either immediately on the spot or soon thereafter. We implemented systematic data sorting and analysis based on events, where the strategy in this section is to address rival explanations. The findings were transcribed and read and frequently

accruing words and phrases were marked, other concepts that were crucial or central were also highlighted. Particular attention was also paid to the actions taken by respondents. This manual process was followed by mind mapping of coded incidents using Nvivo 11 Pro software.

The following section is a presentation and analysis of two projects (Alfa & Beta) that were closely monitored over the course of 28 months. The careful selection of these two projects in particular has been carried out with both the host company and the authors, because they represent a research opportunity which was an extreme case of paradoxes regarding the project performances and managerial struggles. The time of the initial fieldwork, these two held the highest number of development and quality issues and represented the lowest productivity levels in the entire organization; while simultaneously, marketing forecasts indicated extreme market launch potentials and high revenue generation in the European and North American markets.

On the overall strategy level, the company announced upon official occasions that it would be putting an increased emphasis on the R&D projects, and they shall continue serving the company with the launch of numerous products in the coming years. R&D department focuses on improving the development processes and complementing the internal capabilities combined with a robust network of internal and external partners. These initiatives have been reducing product and process development times, in addition to having enabled the company to launch new products and product improvements at a regular basis. (Source: company CFO quarterly announcements).

4. Findings and Analysis

The major issue considered in this paper is in the context of the case company, what variables determine a lengthy transition from zero to full-scale production process. This process is categorized as dynamic and complex and the research questions are analysed in the context of two real-life NPD projects Alpha & Beta. Among the findings, we discovered recurring emphasis on the contradictory nature characterizing the ramp-up process for machines built to handle many variations. A senior director says:

"We ran into various difficulties and very characteristic this one machine, so when we run into difficulties, then it's hard to get geared up (to full speed) *again. And we have not really reached here after maintenance is that* (the machine) *gets run again. And again, it is this contradictory that we work with. We have worked to run many variants and output because that is the demand, so we will not have stability in the process. And, it is in fact what has also become our requirements in the future with this Machine; it is that it is built to run even more variants."* The irregularities

discovered occurring in the ramp-up phase of the product development originate in the multiple contradictory objectives on the site, being the flexibility in conducting multiple activities on the machine, while ramping-up products for new market launch.

4.1. Ownership and commitment during ramp-up process

The ramp-up team's project owner is ultimately responsible for delivering predefined ramp-up performance goals to the business. Taking on the ownership of the project under vague conditions, where the problems are complex, solutions are unknown, adding unclearly defined scope is deemed unfavourable by a fretted senior manager: "*as long as we do not have the design in place. We do not know anything or anything for the pilot phase at all. We have no idea how the foil material behaves when it comes up in greater width. Of course, we have indications, but we have nothing tested. By saying that we go ahead and make a committed ramp-up plan, is something I do not buy into… But with that uncommitted ramp-up plan, which I also wrote you about, and where I wrote to* (two Managing Directors)*. We commit to nothing, even before that, you must have the machine commissioning team in place first and tell me what their deliverables are? What can this (*machine*) do when we process a PQ (*Production qualification milestone*). Because that is what we build further on. And before that is achieved, we cannot commit ourselves to anything. But it is one thing if not even the commissioning responsible doesn't even know what the hell we produce on it."* The managing directors draw on previous experience where even literal replication of activities result in varying degrees of success of ramp-up project performances.

4.2. Alpha Project

This project consists of developing and ramping-up an exclusive first generation product, designed for a single use after which is disposed as recyclable waste. The consumer is provided with the short-term convenience, the maximum level of functionality, built-in features, without the trade-off from the competing and award-winning product design.

Due to the many integrated components, the majority of the respondents categorized product A as an "overly engineered" product, resulting into extensive development and complex ramp-up processes. The manufacturing launch of this product is a complex assembly process of numerous components, causing frequent plant production line-breakdowns and high levels of material scrap. Some components of the product are already familiar in the existing product portfolio and plant; however, the assembly production process itself has not been seen before. Furthermore, the supplier is unfamiliar with the long-term raw material demands, though daily and weekly knowledge

exchange on on-time delivery status has been less challenging, with the support of shared interface software concerning inventory overview.

4.3. Beta Project

Similar to the above-described project, the second project also consisted of developing and ramping-up a unique first generation one-use product, spanning over 24 variations in sizes and shapes. The company had no prior knowledge or experience in production process, raw material handling or quality testing techniques. Furthermore, the product development was swift and some milestones in the stage gate model were intentionally disregarded due to persistent forecasting outlooks. (The internal reference to this particular project is the "*get fat fast*"). The plant is categorized as a pilot machine and therefore delivered incomplete and unsuited for full-scale production. In addressing this challenge, regularly machine interruptions are conducted for performance enhancements and additions of functions and software were built-in, resulting in even higher level of material waste and productivity decline for an extended period.

Both Alpha and Beta plants are typically long (20m+) single integrated assembly lines operated by a mix of non-skilled and skilled assembly workers, mechanical and electrical engineering support functions for the daily operation and maintenance of plants, machinery, and automation and control systems. The observed working schedule is divided into 3 shifts with the duration of 8hours each. Quality testing is central and mandatory for each product-lot before being released for distribution, so that the product is in accordance with regulatory protocols such as Food and Drug Administration (FDA) and European Medicines Agency (EMA) - regulations. While ramping-up, quality-testing methods for both Alpha and Beta products are unstandardized, complex and uncoordinated, adding further delays in the process. The R&D business unit and the production sites are all located in different geographical locations, making organizational interaction during the development and ramp-up process lacking or lopsided, therefore the involvement from the production specialists was classified as ill-timed creating negative implications on the production performance at the launch milestone.

4.4. Major results emerging after data coding and analysis

Following table 1, the critical findings that emerged from the data coding and analysis are summarized and discussed in section 5.

Theme	Sample findings
Pattern recognition of the Ramp-up process	Factors affecting the process: • Lack of production flexibility to accommodate experimentation and plant interruptions • No timely involvement of different functions • Numerous and complex software used for ramp-up process stabilization an optimization (E.g. Lotus Notes, Enterprise One, SharePoint and TrackWise). • Lack of resource and capacity overview • Lack of root cause analysis in the ramp-up process – to much firefighting • Complex and over-engineered first generation products • Insufficient or inaccurate process development • Lack of dependable suppliers
Prior knowledge an experience	Organizational characteristics of current state: • Lack of internalized knowledge • Missing standardized database-storage for knowledge gained from past projects
Early involvement in NPD	Factors affecting early participation • Unknown or unclear agendas • Asymmetrical product and process Development speed (too slow / too fast)

Table 1: Presentation of results after data coding and analysis

5. Discussion

Little is known about the ramp-up production phase and this study is a small contribution in shedding light on the importance of this process. It is characterized by asymmetrical uncertainty with overestimating production plant capabilities in terms of speed, flexibility, and underestimating the workload at the launch face of new product transition from pilot testing to full-scale production.

A couple of factors seem to relate to uncertainty and unexpected, sometimes not even tried to be foreseen, events. Not being ready to do what is supposed to be done in the ramp-up process and not having planned for it, are factors that occur repeatedly. There can be many explanations for this but not seeing ramp-up as a specific phase and process can be one, and lack of cross-functional integration and overlapping of development phases may be another major explanation. Building on the recent award winning study by Gopal et al. (Gopal et al., 2013) on *Product Launches and Plant Productivity in the North American Automotive Industry*, our study also shows that it is challenging to achieve flexibility during production launch or ramp-up faces. The findings of this study support Morgan and Liker's study (2006) explaining roots to waste during ramp-up process:

1. Slack time in the development schedule
2. Re-making of product design due to unanticipated errors and oversights in the prototypes; and
3. Over-engineering which are build-in features, durability and performance levels

6. Conclusions and managerial implications

The study set out to explore issues in production ramp-up as a link between product development and full-scale production. They can be summarized and grouped as follows.

The ramp-up process risks getting the same attention as product development and production; it just comes in between. There are product development engineers and production engineers but no ramp-up engineers. It is one of those handovers in the development process but not given as much attendance as for example from concept to product development or from product to process development but it involves the same issues of cross-functional organization and overlapping activities.

An effect of ramp-up not having its own position is that it does not get its own resources. It applies to staff but also to facilities. One consequence may be that ramp-up is run within or as normal production and disturbing it. There can be many alternatives to this such as an intermediate

experimental plant between the laboratory and the production plant.

The perspective to ramp-up may also be a problem, manifested in such a construct of seeing the process as a problem solving approach and not as an integrated product and process development phase, where product and process technologies are further advanced to higher maturity.

7. Limitations & further research

This study has focused on aspects of NPD processes and particularly the transition into manufacturing setup at a single company. As with all research, it is important to recognize limitations of this paper. The use of case study, albeit explorative, of necessity limits the generalizability of the findings. Yet the confidential case offers insights about the phenomena and invites to new research territory (Patton, 2002). The second limitation is the empirical data representing only a small selection of the experiences of the respondents.

Future studies could develop and design a detailed instrument with psychometric properties, addressing correlation between the variables identified in this paper.

The emerging hypotheses are therefore the following:

1: The dimensions of an optimized ramp-up process correlate positively with cross-functional integration.

2: The dimensions of an optimized ramp-up process correlate positively with product flexibility and organizational learning.

3: The dimensions of an optimized ramp-up process accounts for more variance than the right resources and competencies.

Appendix - Interview protocol

M/F, age?

Can you describe your function at (company X)?

How long have you held your current position and how long have you been with (Co. X)

Do you conduct employee supervision? How many?

Back in 2002, the production strategy indicated moving volume production abroad and the Danish factories should focus on developing products and processes.

- Describe for me what happened back then
- How have you been involved in this process?
- What changed? How did that affect your work?

Previous operations strategy (source) stated that the ramp-up production process should be located close to volume production, i.e. elsewhere in the world. Nevertheless, the current situation is different.

- Why was that strategy revised?
- From your experience, what does the ramp-up production process consist of?

Have the new organization evolved in the direction you had expected at the start of the project?

- In what areas is it gone differently (if any)?

How do you see the current ramp-up production sites functioning, with the interfaces between NPD in R&D business unit and volume plants?

- What works well?
- What challenges or barriers do you face from your position?
- (For Sr. Managers) Do you get any feedback from your employees who have been involved in the production, process development on what works really well, and what could be improved?
    - Can you give an example?

With regards to the experience and knowledge gained during the ramp-up process

- Who is responsible for the documentation?
- When is documentation required?

Management strategy states that ramp-up plants must help reducing production

complications that exist in the development phase today and be quicker at ramp new products up

- In your opinion, how do you believe that can be done?

Describe for me the transfer process of volume production to the international sites

- How do you ensure that volume production factory receives all relevant information?

The company uses different software, including Lotus Notes, Enterprise One, SharePoint and TrackWise for stabilization and optimization the ramp-up processes

- How does that affect plant productivity when extracting data from different systems in the production launch?

How does the company evaluate performance?

- How does this along with your total performance

Would it be beneficial to involve production specialists earlier in the development projects?

- If yes: elaborate
- If no: Why not?

Any final remarks you want to add?

Table 2 - Methodological protocol overview for inductive study. (Inspired by Sousa, 2000)

Context area	Unit of measurement	Questions	Field procedures / Sources of information
Business environment	Plant	Key characteristics of the business environment	Interviews & background information on the industry
Rate of New Product introduction	Plant	Consequences of the introduction of new products to manufacturing	Interviews, observational field notes & product procedures
Rate of process change	Plant	The rate of change in the process cause by the introduction of product customization, engineering or new market forecasts	Interviews & direct observations during plant tours
Degree of standardisation	Dominant process	• Degree of standardization of process procedures • Level of detail of manufacturing work procedures • Existing of written operating procedures available to the workers on the assembly floor	Interviews & direct observations during plant tours
Nature of quality issues	Dominant process	• Most frequent causes of quality issues (design related, materials, or manufacturing process and equipment) • Most frequent quality issues in the main assembly line during production launch	Interviews
Overall manufacturing performance	Plant	• Evolution of operations performance over the last 3 years (inventory, lead times, on-time delivery, productivity, flexibility and cost • Strong / weak areas of production performance	Interviews

Essay 4: The power of intra-organisational dependencies in Ramp-up management - a multiple case study

Abstract

The structural complexity of ramp-up processes enabled by inter-functional interactions is examined and the degree of fragmentation in the process planning and execution is analysed. While fast product development with early prototyping and reduction of both cycle time and lead-time are major concerns, there is little research on ramp-up management. Drawing on resource dependence theory (RDT) as a central explanatory framework for intra-organisational and organisation-environment interdependencies, we provide a thorough analysis of the planning and execution of the ramp-up activities and milestones. This in depth study explores inter-firm resource dependencies in production initiation and its influence on the effectiveness of manufacturing ramp-up.

Keywords: Ramp-up management, Resource Dependence Theory, Case Study

1. Introduction and overview

Inter-organisational relations are of high importance in operations management with focus on the formation of alliances from suppliers through the production system and to customers. Deployment of operation system will involve collaboration among external parties such as suppliers and customers as well as internal organisational functions such as product development, procurement, marketing, and distribution. A prominent study by Handfield et.al. (1997, p. 312) concluded by posing a number of questions for future research, one of them is: *"How can environmental engineers influence members of the value chain to adopt strategic environmental initiatives when they do not consider the environment as 'part of my job'?*" the literature has been negligent regarding this significant aspect of the inter-functional integration. There is a seemingly great need for mitigating the complexities of organisational relations, and studying the process of their impacts. While there is considerably little research on inter-organisational issues, there is even less on amidst navigating the processes. The current paper addresses the operational phase of transitioning from new product development to full-scale production; here existing literature identifies issues on both manufacturability and assemblability but little on the scale up and the nature of interactions between R&D developers and ramp-up engineers during the ramp-up process of a given product.

Managing both incremental and radical innovations have been extensively studied; however, we know little about the organisational conditions for managing relationships, power imbalance, and dependencies within and outside the central organisational unit responsible for initiating production and ramping it up to full volume

The contributions of this manuscript are three folds: (1) extending the understanding of ramp-up management in the organisational interdependencies from an inter-functional perspective; and (2), empirical understanding of how the inter-functional alignment and collaboration conveys the exploitation risks. (3) Offering qualitatively grounded propositions for strategies affecting the ramp-up process to help overcome the barriers to the implementations of changes to the product or process.

The remainder of the paper is organised in the following manner: After this introduction, we briefly review the literature on ramp-up management. We offer a network graph illustration of central keywords clusters identified in the literature. Then follows the theoretical foundation where we introduce RDT as the lens for understanding the intra-organisational formation in executing the ramp-up process. Section three covers methodological approach for the research,

the setting, the empirical findings, and the procedures used in the analysis. The following analysis is the main body of the paper, followed by discussion and conclusion, and finally contribution.

2. The nature of ramp-up management research

Over the years, the vast majority of academic publications on ramp-up management perceive the ramp-up paraphernalia as a patently problem-solving tail end of development. At this stage, technology is transferred from informational representation to a physical component such as a prototype, and back to the informational stage for further modifications and rework. This interface is characterised by the collaborative efforts of engineers, designers, and developers in realising a set of predefined objectives at the shop-floor level. And while some objectives are achievable, others lead to a '*problem-solving-cycles'* as highlighted by Clark, Chew, and Fujimoto in their study on pilot production and ramp-up processes (1992, p. 180). The authors pointed out that these cycles consist of three activities: design-build-test and the frequency of the cycles is dependent on the resources and capabilities of the organisation. Indeed, some problems and critical events occurring during the ramp-up process might actually be solved by referring to existing knowledge gained from previous experiences (Fjällström, Säfsten, Harlin, Stahre, & Johan, 2009; Levitt & March, 1988).

However, when investigated from a behavioural theory perspective, problems related to specific component changes during the pilot and ramp-up processes are dealt with through an ad hock and improvisational problem-solving approach (Gross, 2014). Modifications and rework of the product or tools required for meeting customer expectations are inherently engineering change orders (Loch & Terwiesch, 1999), which are drivers for lead time and cost. Ramp-up activities continue including the design-build-test cycles, with additional managerial tasks of acceleration to full volume production and commercialisation (Wheelwright, 1988), all while dealing with the symptoms of bad quality, high cost and slow product launch. The rise of problems being a market-driven feature modification, the required managerial approval, and finally the implementation can take several weeks, several months, and, in extreme cases, even years despite strong time pressure (Ibid). Other publications have highlighted problem areas related to machinery and equipment, personnel, and material supply, thus causing capacity losses during the ramp-up process (Almgren, 1999b). Perhaps the earliest description of the nature of initiating production, stabilizing it and then scaling-up is summarized by the work of Richard T. Clawson's paper on controlling the manufacturing start-up: "*... Managers develop concepts, fill positions, shape plans*

into definable tasks, everything looks wonderful… The team's job is simply to implement the master plan. Managers begin to delegate authority, hold status meetings, and smile a lot. Some even start calculating their bonuses, and why shouldn't they? Everything is rosy. The plan couldn't fail. Or could it? ...No one knows it, but the program is in jeopardy. The problems haven't surfaced, but they are there, waiting to emerge at just the wrong time."(Clawson, 1985). The author argues that countless unpredicted variations and problems plague the production ramp-up - referred to as start-ups with rampant cost, schedule and configurations goals before the first unit is finalized, and the confidence of experienced production managers with proven records of accomplishment, might in fact hamper production. The study proves that flexibility in the managerial style and new sets of procedures are more preferred over a mere systematic variation of the same controls (ibid).

Another research conducted by Winkler et al. (2007) looks into the stages of the ramp-up process and offers to split the phase into two stages: (1) preparation, (2) run-up, where the preparation phase is then split into two phases: start-up and pilot production.

In an another study within the high-tech industry, Bohn and Terwiesch (1999) examine the economics of yield-driven manufacturing processes, they state in their paper that "*the key driving force behind ramp-up is usually learning of various kinds. Machine downtime decreases as causes are identified and fixed. Bottlenecks are detected and circumvented. More workers are trained for the labor-intensive production steps".* Alternative solutions might fit in the case of newness of the issues or when similar problems have never occurred before.

Organisational structure is added as a root cause for the problems occurring during the ramp-up activities by Putnam (1985) who argues that traditional functional organisations are obsolete and calls for bringing manufacturing engineering, quality engineering, and test engineering earlier in the design process for the purpose of "*high-quality trouble-free production*" when integrating these functions. The definition of the problem and thereafter the attempt of solving it, is not appropriately rigorously dealt with in many organisations (Spradlin, 2016). Dismissing the rigor, organisations might waste valuable resources and missed opportunities in realising their production launch.

When executing the process of ramping up, organisations deal with uncertainty in developing new products, collaboration among agents that is much too often taken for granted, challenges when acquiring knowledge and joining forces across networks. Ramp-up management is therefore characterised by the multi-disciplinary (Basse, Schmitt, Gartzen, & Schmitt, 2014; Laurène

Surbier, Alpan, & Blankco, 2014) and it is the process of iteration, which in this paper is a continuous interplay between the theory and empirical insights.

2.1. Theoretical overview and resource dependence perspective

The ramp-up management publications have foundations in several theories, for instance game-based approach (Brauner et al., 2016), behavioural theory (Gross, 2014), queuing theory (Winkler et al., 2007), benchmarking theory where a holistic view of ramp-up management is examined (Schuh, Desoi, & Tücks, 2005) and strategic management perspective (Heine, Beaujean, & Schmitt, 2016a). We also found knowledge management theory applied in (Fjällström et al., 2009) who demonstrate how actors adapt their preference within the organisation as they perform their tasks. The knowledge management is focused on creating experiences aiming at retaining and transferring expertise within the organisation, by forging relations that facilitate the knowledge sharing behaviour among different actors.

Two complementary organisational theories are Resource dependence theory and knowledge management theory, they both emphasise the technological foundation of the organisation, which can be bridged to gain independence and control within the network. The two theories differ however, in the sense that while organisational learning is focused inward, we found RDT is focused outward towards the environment (Pfeffer & Salancik, 1978). The significance of these two lenses lays therefore in the systematic ways of thinking and analysing the organisation, its challenges and constrains both within and outside its own environment.

The key idea behind the RDT is the assumption that the organisational actor does not control all the relevant resources that he/she needs (Pfeffer & Salancik, 2003, p. 2), however the actor manages through relations building with other actors, essentially leading to acquiring access to resources. The association between the actors is an exchange relation, and one actor is dependent on the resources owned by the other actor who is a representative as a source of power. Power is defined by Emerson to be explicitly treated as an attribute of a relation rather than a person and "*empirically it is manifest only if A makes a demand, and only if this demand runs counter to B's desires (resistance to be overcome). Any operational definition must make reference to change in the conduct of B attributable to demands made by A".* (Emerson, 1962).

Another reason for selecting RDT as the theoretical framework in this paper is because it is frequently referred to as a theory in its own right (Hillman, 2009), and becoming "*one of the most influential theories in organisational theory and strategic management"* (Hillman, 2009, p. 1404).

It is in fact perceived as an overarching perspective, which integrates a theory of the environment and a theory of power to make forecasting about a variety of organisational responses and management of its environment (Aldrich, 2013). Some scholars argue that while some organisations may be *motivated*, they may not always be *capable* of taking actions in managing external dependencies (Casciaro & Piskorski, 2004).

An explanation of the construct of interdependence is significant, because the concept of relations discussed throughout this paper is founded on is a group-group relation, where the social relation is subject to mutual dependence between the groups. The interdependence is operationalized and consists of two constructs: power imbalance (PI) and mutual dependence (MD) and they both differ in types of impact on constraint absorption model, both in an independent and in an interactive way (Emerson, 1962). PI captures the difference in the power of each actor over the other, and MD captures the existence of mutual dependencies regardless of whether the two actors' dependencies are balanced or imbalanced. (Casciaro & Piskorski, 2005, p. 170). Previous empirical studies have looked at the combined impact of the two constructs, though not tested them separately.

The research done by Casciaro and Piskorski (2005) proved that both PI and MD constructs can have contradictory effects on the organisation's ability to reduce dependencies. Another study of US automotive manufacturers and their suppliers (Gulati & Sytch, 2007) concludes that the mutual dependence proves to have positive effects, in the sense that it enhanced the performance of procurement relationships for manufacturers. This is obviously in contrast with the logic of value appropriation, in which the stronger actors get a bigger share of the pie at the expense of the weaker ones. The study shows that while manufacturer's dependence advantage weakens, its performance and supplier's power advantage has no significant effect on the performance (Gulati & Sytch, 2007).

In an attempt to get around the issues inherent in the organisation of ramp-up, utilising theoretical lenses are important, because theory provides a framework and structure for the analysis. Furthermore, utilising theoretical lenses provide an efficient method for fieldwork and development, because an integrated body of knowledge can only be pursued efficiently if integrated theory is developed through consistent theory-building methodologies, and it also offers clear explanation for the pragmatic world (Wacker, 1998, p. 363).

3. Methods

3.1. Research setting: the field work

The source for empirical inputs for this study is multiple projects within a publicly listed Medical Technology organisation located in Europe. This industry is particularly interesting, because it files more patents than any other sector and invests extensively in breakthrough innovations (MedTech Europe, 2015). Given these characteristics, the focal organisation must contend with its ramp-up process complexities, because it embeds aggressive product launch strategies that are based on increasingly shorter product development time, and consequently swift ramp-up processes. The maximised field access was granted to the researchers by the senior management of the MedTech Company and six different projects were considered and subsequently selected based on their representation of the polar extremes of innovation novelty, incremental versus radical. The critical step in polar case selections is in view of their significantly difference in their operations practices within the same manufacturing site (Jugdev & LaFramboise, 2012). The projects have been divided into three undergoing major changes, and three minor technology and process changes during their ramp-up phases. The development projects were studied exhaustively in one single setting with the involvement of fragmented groups of informants in the company over a three years' period.

3.2. Research approach

The underlying epistemology orientation guiding this study is inherently constructivist as "*the key philosophical assumption upon which all types of qualitative research are based on is the view that reality is constructed by individuals interacting with their social worlds*" (Merriam, 1998, p. 6). Hence, the researchers' view of "*reality is not an objective entity; rather, there are multiple interpretations of reality*" (Merriam, 1998, p. 22).

The qualitative multiple case study design is favoured because it unfolds the ramp-up unit's dependencies in its real world settings (Flynn et al., 1990; Meredith, 1998). The case research strategy is deliberately chosen, because the dissimilar and polar contexts enrich and provide a comprehensive view of the studied relationships in the ongoing projects (Jugdev & LaFramboise, 2012). Along these lines, we ensure strong findings, in-depth contextual and cross case analysis by applying multiple case-based with ethno-methodological approach. Following Eisenhardt (1989) multiple sources of evidence are employed, where qualitative data, observations, interviews, and internal company documentation such as contractual agreements are combined.

These sources are selected for exploring the complexities of the sub-processes. The combination of these methodological approaches is actively sought for, because it provides improved possibilities for triangulation (Pieter-Jan Bezemer, 2014).

For the sampling, the selection of multiple cases has increased external validity and helped resist observer bias. Our use of multiple cases creates more robust and testable theory for theory building purpose (Eisenhardt, 1989; Eisenhardt & Graebner, 2007).

3.3. Data coding process

The conducted interviews were exploratory and open-ended with the intention of clarifying the nature and the dynamics of the ramp-up unit's relationships and interactions with the involved departments. The product and process developments are organised according to the traditional approach from Cooper (2014) using the Stage-Gate-Model as illustrated in figure 1, Gate evaluation reports were analysed in-depth, which unveiled the power imbalance and mutual dependences across departmental collaboration, selection, involvement, and elimination of resources. The resources are not only the physical materials, but also the technological, such as knowledge and expertise. The governance is closely studied, as well as project life cycles, process and design changes, and operations progress and improvements during the projects. These phenomena and the relatively short time span of ramp-up events become evident through a multi-case research design. Details about the respondents' affiliations are found in appendix 1.

The data coding strategy was executed using Qualitative Data Analysis Software (QDAS) for ruling out validity threats (Siccama & Penna, 2008). Specifically, NVivo 11 played a powerful role in systematically processing transcribed open-ended interviews at different levels in the organization. Furthermore, observations, participant logs and internal company documentation were collected and coded. Initially, the researchers and assistants worked disjointedly developing initial codes to mirror "categories" of data gathered and verified with the company informants as core "issues". Through the review of the data, additional codes were identified that were general causes and effects of the ramp-up project advancements. Later, as the projects progressed, the researchers differentiated working in a constant comparison manner, where identical codes merged and others arranged in hierarchal structures. This process further strengthen validation in the data.

The unique opportunity of accessing real organisational setting and collecting data, permits the researchers new insights into the problem (Farquhar, 2012). For both datasets, the same rigor and thoroughness is applied using QDAS and they are critically treated in terms of quality and their

overall contribution (Farquhar, 2012, p. 77). The strategy employed for verifying the authenticity of the dataset is to apply different line of questioning in the interviews. Hence, the goal is to examine the possibility of any divergences in the datasets, as well as in the findings.

In our data coding we used "*a comparison of a pattern of observed outcomes with some pattern of expected values derived from a given theory*" (Bitektine, 2008, p. 162). The selected cases address the alignment of complex ramp-up manufacturing process changes with the intra-firm resource governance formation and central ramp-up manufacturing performance in the context of resource dependencies. All six cases are coded in relations to the polar novelty of both the product and the process technologies as perceived in the ramp-up management department. Forming a dyad as presented in the findings chapter - three cases are classified as radical and three as incremental. Furthermore, inter-departmental involvement is coded as inter-functional integration with the ramp-up business unit is coded in two polar values, identified as high and low involvements.

The central concern is the focal ramp-up organisational unit members and their multiple resource dependencies with other organisations in their environment, making the unit of analysis the intra-organisational relationships of dependence manifested in the organisation.

4. Empirical findings

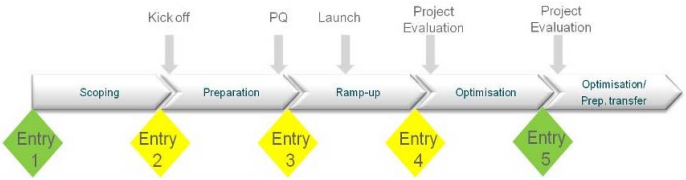
From the higher-level coding conducted through the building of the analyses, we organise partially emerging meta-conditions and conceptually clustered findings, together with inductive causal networks. Our discoveries highlight that there is strong strategic emphasis on ensuring the direction of the product development being fully aligned with the sales ambitions. This is particularly demonstrated by several mandatory formal stakeholder meetings with Global Team (GT) and the company's Commercial Leadership Group prior to Gate 0. At the time of Gate 0, a Project Manager is appointed and has the overall responsibility for the project progress until the project is closed at Gate 5. In collaboration with line management, the project manager identifies the project team and the competences needed to drive the project forward within the agreed project scope and development time. At the gate decision points, the projects are governed by senior management represented by the CEO Business forum consisting of: the CEO, CFO, Global Manager, Senior Vice President, R&D Senior Vice President, Operations Senior Vice President, and Sales Senior Vice Presidents. The role of these gatekeepers is to make strategic decisions based on the Gate reports and the discussions at the Gate meetings.

Between the Gate meetings, the projects are governed by the Innovation Steering Group (ISG) and equivalent locally functioning steering groups. On the daily basis, the project progress is supported by the Innovation Trios formed by Global Management, R&D and Operations management respectively. The project governance structure and detailed areas of responsibility are presented in appendix 2.

The data findings further demonstrate that different types of intra-organisational formations are observed at the focal ramp-up organisational setting that adjusting and coping with resource dependencies, while considering the implications from the novelty of the product/process.

The studied cases and their overall project tasks are organized as stages as seen in figure 2 and table 1. The production processes are categorized as Continuous, meaning that they operates 3x8 hour per day to evade high machine shutdown costs. The process is repetitive, meaning that the site produces in large lots. Initiating with an intermittent setup, where the machines produce in small lots to sales forecasts, and customer specifications. The formalized project stages are broken down and are seen in figure 2: scoping, preparation, ramp-up and finally optimization and preparation for machine transfer to volume sites in foreign countries.

Figure 1: Ramp-up process overview



All the development stages are performed and evaluated with the direct involvement of project management. This includes close collaboration with suppliers, logistics management, procurement, quality management, validation management, employee health and safety management, and human resource management. Furthermore, we found that the formation of intra-organisational relationships and interdependencies occurs during the pre-ramp-up project planning, continues throughout each milestone entry point, and after the project performance evaluations.

These relationships are formed by the objectives at the concept development stage, which are to explore and identify ideas and concepts fulfilling the project scope and to recommend concept(s) with documented principles and functionality for Gate 1. Once the project manager has been appointed from the ramp-up site, the scoping phase begins. A project agreement containing KPIs and an overall project plan is then prepared. The Scoping phase ends at entry 2, where the management of the ramp-up site must decide on the project with the related documentation for ramp-up project agreement, project plan, learning curve KPIs and launch plan. The preparation phase can then begin and the steady initial production being prepared.

For the preparation phase, KPIs are available for preparation, a launch plan and a learning curve, which is an excel document for collecting production statistics of the ramp-up process. As production progresses, the learning curve will show the number of products produced per. hour, how efficiently the plant has been operating, and how much scrap there has been. Prior to project start, the documentation will be completed with pre-defined production objectives. Furthermore, based on forecasted data for the agreed upon KPIs, the management can keep track of what is planned. The project managers and his/her members use these numbers to assess whether the ramp-up project is running as planned or there is need for more attention towards reducing the amount of scrap or making the production process more stable.

The project leader presents the project for the project team and other involved employees at the kick-off meeting. Shortly after, the production site is then prepared for allocating floor space and developing blueprints of where the machine (s) will be stationed. Together with the machine suppliers, skilled workers and machine commissioning engineers help set up the machine at the site. It is also during the preparation phase that the validation of the machine begins. The preparation phase ends when the process qualification (PQ) is approved by the ISG management. The PQ is the last of many validation tests and is used to demonstrate that it is possible to produce the products in a sufficiently uniform quality for Food and Drug Agency (FDA) and the European Medicines agencies (EMA) approvals. Once it is completed and the result has been approved, then market launch can be fulfilled.

At entry 3, the ramp-up site management approves the ramp-up phase's KPIs, the corresponding learning curve and launch plan. After ISG management approval is granted, the ramp-up phase starts. This is when the production is scaled up and stock is rigorously built before launching the product to multiple large markets around the globe. The ramp-up site must be prepared for continuous production, as in the previous stages. Finally, during the ramp-up phase, KPIs are defined more precisely for the following optimization phase. Prior to entry 4, the ramp-

up site management evaluates and approves for the finalisation of the ramp-up phase, including accepting unresolved issues that might be perceived less important for the volume production management abroad.

Cases	**Alpha**	**Beta**	**Gamma**	**Delta**	**Epsilon**	**Zeta**
Type	Product	Product	Machine	Machine	Product parts	Product parts
Volume	3-5 mio/Qtly	1-1,5 mio/Qtly	1	1	1	1
Technology Novelty	1st generation product	1st generation product	Pilot machine	2nd generation machine	1st generation tools	Familiar components
Highest management	COO	COO	Site director	Head of engineering	Site director	Site director

Table 1: Overview of case demographics.

Having established the overall project development process, our case specific findings highlight that for a period of more than 6 months of our data gathering, the projects Alpha, Delta, and Epsilon were operating without an assigned operations program manager. This decision was made in agreement between the heads of R&D department, Quality & Engineering department and the ramp-up site. The senior operations management together with the innovation steering group was under the belief that "*these projects were fairly straight forward, because not all new machines and tools had to be commissioned*." When the operations management realized that there was a need for a dedicated operations program manager, resources were scares and none of the qualified and knowledgeable program managers were available to lead these projects. Furthermore, the innovation value stream (IVS) project manager was reassigned to a different project just before market launch, because his injection moulding expertise was urgently needed in a different department in the organisation. This swift decision left these projects even more vulnerable and without leadership. The innovation steering group assigned a newly employed project manager from a new section within the R&D organisation; however, his *appointment and expertise level did not stand a chance of picking up on the project.* [Sr. operations director]. The three remaining projects Beta, Gamma, and Zeta had no such radical organisational interventions,

and the product and process modifications needed were incremental of nature with dedicated resources.

In the following section, the project stages are examined individually, in addition to detailed inputs provided by the project team members. This approach is more effective in identifying and systematically organising the dependencies occurred according to activities and milestones.

Furthermore, organisational ownership is identified and is presented in appendix 2 of the last stage, namely ramp-up. The *scoping*, *preparation* and *ramp-up stages* of the studied projects has been coded according to obstacles faced throughout the activities mandated by the process. The stages are also characterized by fragmented activity ownerships with consequential complications.

Stage	Obstacles/issues	Central findings/Original quotes
Scoping	1. Unclearly defined process 2. No authorization of role, task & mandate 3. Dependency on other functions for providing 'intake criteria and understanding of the performance requirements 4. Unclearly defined project agreement and risk profile 5. Unbalanced involvement of management in the overall IVS planning	(1-2) *"The company typically handles the task* [resource] *allocation through peer training, co-location and job rotation. On the other hand, the company is inferior at systematically involving managers from the ramp-up projects, so that this knowledge can be recycled in subsequent projects"* *"The design and process freeze* [decision activity] *first came by gate 2 and 3. Therefore, it came whenever. We did not have anything, so the project plans were completely put out of balance."* (Quality and Engineering director) (3-4) *"Given that* [project] *development is very unpredictable* [activity], *there are just huge risks, but they* [Project managers] *said *we are prepared to handle them*. We run high-risk profiles on our projects and if we fail, we will take it from there.* […] *many times, it is because we have failed a validation or design verification. We have just done these projects and so the team has been working 24/7 and now they are back on track"* (Sr. Ops director) (5) "*Another thing that has happened during the development is that the ramp-up managers began to come earlier into development projects so the site can better contribute with production knowledge, but that's case by case and depends on the IVS project manager*" (Ramp-up site director)
Preparation	1. Unclearly defined process 2. Project planning un-prioritized and dependency on local participation 3. Planning isn't detailed enough and is long term focused	(1-3) "*Normally you prepare documentation* [for FDA & EMA approvals] *at gate 1, and by gate 2, you have the same documentation but more refined.* […] *The case concerning these projects was to make the final version right away. We had to be a lot faster with the documentation, but we also had to finish developing the product quickly. It took about 1½ years to reach gate 3, all while the machine takes 1½-2 years to be built. That means machine builders and engineers should actually start production and build the machine without knowing what product it was for."* (Validation manager)

	4. Dependence on clearer defined roles and responsibilities 5. Dependence on inputs from other functional areas on quality and timely delivery 6. Lack of or outdated basic knowledge in relation to the quality management systems	(4) *"You can say that R&D and the ramp-up site belong in their own silos, and in my experience, there are generally serious challenges in the transition between the different silos. The ramp-up site managers have not been* [involved] *in the process of development but they are now at a stage where you can have a clearer framework for what ramp-up management must and can, and what should be in place for the development projects when the operational part of the ramp-up begins."* (Ramp-up Site director) (5) *"When running* [the preparation phase] *concurrently, then you are very dependent on the other* [organizational] *party, that they actually deliver at the exact same pace* […] *but that's what we were struck by, because we control maybe only the first part or some of the second part also."* "*And the problem is, we must of course be better, and what happens if we are not at a given time live up to that? Does the project continue towards the same launch* [date] *or do you start to talk about consequences? Because we do not have so much flexibility in our pipeline*" (Sr. Ops Director) (6) *"We have a proprietary system that is used; a database that serves as an advanced to-do list. It is not all relevant knowledge that is registered in the* [quality management] *system, nor would it be entirely suitable for receiving all information. It is not our experience that data from the system will be used subsequently. It requires a tremendous commitment to put information in and maintain the system*" (Quality and validation manager)

Ramp-up	1. Communication difficulties 2. Lack of training feedback 3. Not enough focus on Root Cause Analysis throughout the process 4. Low problem-solving and superficial analysis and lack of proactivity when facing problems 5. Low autonomy among skilled technicians 6. No communication or clarification of problems 7. Dependence on employees' engagement	(1-3) "*All of us are either moving into a problem on the way out of a problem, or right in the middle of a problem. The only thing worse than the problems is to relive the same old problems again and again because we have failed to solve them correctly the first time."* (GMP -*Good Manufacturing Practice*- Manager) (4) *"When there has been a late change in the product, then the process we thought we should have has consequently changed, and we will have to change the machine* [construct]. *Moreover, not all those things have been fun neither for development, nor for the engineers or the sites that should receive* [the project] *because we constantly had to change along the way. It has been incredibly messy"* (Project Manager) (5-7) *"Due to the product issues, we had during the ramp-up the Project Manager and I, we actually went up* [to Sr. directors] *and asked if we could get half a year's extension* [on market launch]. *Their answer was NO. We knew we had a problem, we could not solve it within the given time, but we were told that we should launch. So, the process just had to be with reduced volume and reduced countries. We stayed with October 1st, but we did not get out to the countries we planned for. We launched only in Switzerland and Norway, which are the two smallest countries."* (Machine commissioning manager) (7) *If you go back historically and look at the site for example and you compare day, evening and night shift* [performances]. *The day-shift worked 37 hours, evening shift 34 and night shift worked 34 hours. The night shift conducted ramp-up production* [outputs], *equivalent to day- and evening-shifts combined. Then you ask, "How can it be?" What we are talking about production here, right? Well, it was always during the daytime that there was external* [functions] *who just needed to optimize something. All those things happened during the daytime, right? The evening team, that's the shift that nobody likes to be on. To put it blankly. Because you* [operators] are *supposed to come to work at 3 o'clock and*

	you were off at 23 o'clock. And you should do that 5 days a week. That's not the coolest, right? […] *The engagement was lower as well. Where the night shifters, there were many people who enjoyed it and who were engaged because you were not disturbed.* (Sr. core operator)

Table 2: Coded illustrations and evidences of the power imbalance and resource dependence in different project stages.

The relationship between the members of the ramp-up organisational unit with other functional areas is contingent with the degree of changes made to the product and process while in the ramp-up stages. Through a close examination of all six cases, we use RDT in identifying and comparing the number of resources, activities, and collaborative commitments and agreements needed.

We discovered that radical changes made to the product and the process increase the ramp-up unit's dependency on the resources and expertise of new technologies, material, and process from other functions in the company. However, with small incremental changes, a higher inter-functional integration strategy is less likely to lead to power imbalance and external control over the ramp-up organisation. Based on our findings we propose the following theoretical propositions:

1. The effects of PI and MD between the ramp-up organisational unit and the various organisational functions are influenced by the degree of novelty of the innovation changes.
2. The more radical changes made to the product/process, the higher degree of ramp-up department dependence on inter-functional involvement.
3. PI between the ramp-up organisational unit and its functional integration is moderated by the strategic choices made in the rest of the organisation.

We focus on how the structure of the relationships dictates the dependencies, which now will be analysed and discussed.

5. How to apply RDT to ramp-up dependencies

The point of departure that will help illustrate the theoretical perspectives of the collected data is based on the propositions; we attempt to study the collaborating effects in polar degree of changes in the product and process. This is achieved within the ramp-up organisational unit, and the functional integration on their dyadic relationships, as illustrated in figure 2.

We focus on the dimensions of joined actions and commitment expressed and demonstrated to realise the overall deliverables of the projects. These efforts together with allocated resources would make it critical and therefore link them to the process output. We disregard the continuous nature of the process changes, and only assume two polar classifications – radical changes and incremental changes. We focus on the dyadic collaboration and management during the ramp-up activities, such as design, cost control, and quality improvement.

Functional collaboration could involve developing bilateral solutions to overcome operational problems. It is probable that the effect of dual dependence on a ramp-up process performance will

be facilitated by the degree of mutual actions two or more functions undertake (Gulati & Sytch, 2007). Different functions throughout the ramp-up process could become pre-disposed to carrying out mutually coordinated activities and could develop greater overlap in their strategic goals, in part because they face fewer structural obstacles to the joint pursuit of such goals (ibid).

The aim is to explore the contingencies found in the mutual dependence and the power imbalance among the actors. We then analyse the data collected, transcribed, and coded from key informants. Casciaro and M. Piskorski (2005) suggest employing the difference between each party's dependence on the other as power imbalance in a dyad, and the sum of each actor's dependence as mutual dependence. We have explored this suggestion by assigning the value (1) to incremental changes in the product/process's dependency on inter-functional involvement, and the value (2) to radical or novel changes and its -higher- dependency on the inter-functional integration.

In the course of analysing the practices of ramp-up business unit and the managers involved, it became increasingly evident that understanding the dynamics of inevitable modifications in the product or the process at this stage, leads to substantial consequences. In particular, viewing the changes throughout the phase of ramp-up differently significantly overlooks their impact and how these changes lead to shifting exploitations risks.

The different configurations are presented in the following table, '*Configuration 1'* represents the PI between the radical and the low involvement of cross-functional units, valued at 1, which is the difference between their dependencies on each other (2 – 1 = 1). Their MD is on the other hand the sum of their joint dependencies (2 + 1 = 3).

Power imbalance and mutual dependence are simultaneously dealt with the purpose of producing a theoretically sound representation of the power-dependence structure as seen in table 1. This is done because the goal is to address the three propositions and identify potential exploitation risks embedded in these relationships. We took note on each party's dependence profile as power imbalance in figure 2, configuration of PI and MD.

'C*onfiguration 1*' for instance, the PI value is 1, which is the difference between the dependencies of the functional integration level and its dependence on innovation being a radical (See figure 3 for overview).

Product and Process changes at the Ramp-up business unit level			Functional integration	
			Low	High
	Incremental	Dependence on the other 1	1 Configuration:3 PI: 0 MD: 2	2 Configuration:4 PI: 1 MD: 3
	Radical	2	Configuration:1 PI: 1 MD: 3	Configuration:2 PI: 0 MD: 4

Figure 2 – Degree of changes and functional integration effects on Power Imbalance (PI) and Mutual Dependence (MD)

Configuration	*Degree of changes*	*Functional integration*	*Power imbalance*	*Mutual dependence*	*Exploitation risk*
1	*Radical*	*Low*	*Asymmetrical*	*Moderate*	*High*
2	*Radical*	*High*	*Symmetrical*	*High*	*Low*
3	*Incremental*	*Low*	*Symmetrical*	*Low*	*Low*
4	*Incremental*	*High*	*Asymmetrical*	*Moderate*	*High*

Table 3 – Control effects of product/process changes, functional involvement on the effects of power imbalance and mutual dependence on exploitation (Casciaro & Piskorski, 2005).

In taking a closer look at table 3, the developed theoretical model serves to illustrate how the configurations of degree of changes in the product or the process and degree of functional integration will affect the power imbalance and mutual dependence, which will consequently influence the exploitation risk profile. The classifications presented in table 3 are that of power imbalance and mutual dependence simply corresponding to the values in the boxes in Figure 2. Therefore, configuration 1, power is imbalanced because the radical changes in the product or the process lead to high dependency of the ramp-up business unit on the functional integration, simply because of the significant novelty of the product or the process requires commitment and expertise from other actors. Whereas, the functional integration is less dependent on the ramp-up organisational unit because of its low concern for resource allocation.

In configuration 4, there are also asymmetrical power relations. However, here the disadvantage is within the functional integration, which makes it more dependent on the ramp-up organisational unit dealing with minor incremental changes. These changes make the business unit less dependent on resources from the organisation due to the familiarity with the changes made to the product or the process.

In configuration 2 and 3, power is symmetric and balanced because in configuration 2, both the ramp-up unit and the inter-functional integration are equally dependent on each other, and in configuration 3 they are both equally low dependent on each other. The dyadic relationship as seen in table 3 between the degree of changes and the dependencies and power imbalance result in different combinations of exploitation risks.

6. Discussion and Conclusion

This section extends on illustrating the extended understanding of polar changes in the projects undergoing the final development phases by elaborating on the value of the power and dependency guidelines. As these were introduced to add a strategic dimension to the ramp-up milestones, the following discussion continues how the extended consequences of changes contributes to strategically managing intra-organisational resource collaborations. Finally, we offer directions for future research

From the findings, a strong explanation of intra-organisations relationships is provided, although based on a small number of cases. The motivation for this study is to offer an explicit theoretical realisation of power as a fundamentally a dyadic phenomenon, which allows the

managers to capture the organisations' motivation and ability to predict, plan and stabilize the procurement of resources given changes in the product or the process at the phase of ramp-up.

Furthermore, the results of this study show how the degree of changes in the product design or the process and the strategy of the functional integration moderate the impact of mutual dependence and power imbalance. As the changes to the product or the process become more radical the ramp-up business unit's dependence on its inter-functional team members' increases which in turn, strengthen the managerial efforts to construct relations across departments, through for instance co-development strategies. By contrast, the smaller the incremental changes induced, the more reduced the ramp-up unit's dependence is on functions from other departments.

This study demonstrates different combinations between the degrees of changes made to the product or the process at the ramp-up stage combined with fragmented inter-functional involvements; result in several configurations of power imbalance and mutual dependence. The paper theorises that dyads with PI is asymmetrical with high level of exploitation because of the unequal power and high or moderate level of mutual dependence.

A theoretical distinction between power imbalance and interdependence is presented. RDT addresses this by posing the general question of how and why a more powerful organisation would enter balancing processes with a dependent organisation, and thus give up its's power and the advantageous exchange conditions it harnesses (Casciaro & Piskorski, 2005).

7. Contribution and relevance

The effective manufacturing ramp-up processes, expressed in terms of time-to-volume, time-to-market and time-to-quality, are essential, yet often overlooked elements of a successful product introduction. The relevance of this study is the innovative approach in looking at intra-firm collaboration during this stage of product development and production. The benefit of this research comes from considering the wider intra-organisational influence and the significance of the changes throughout the ramp-up process.

This paper examines the complexity of the ramp-up organisational dependencies including the interactions across different functions and analyses the degree of fragmentation in the process planning and execution. Resource dependence theory is used as a central explanatory framework for the formation of inter-organisational interdependencies throughout the planning and execution of the ramp-up activities and milestones (Pfeffer & Salancik, 2003). The study highlights and explores the connections between the inter-firm resource dependence during production initiation

and specifically its influence upon the effectiveness of manufacturing ramp-up. Symmetries that have been identified, in addition to potential exploitation or opportunistic risks can be found.

Further work can be done with the aim of examining how knowledge and relationship factors grow and interact in joint innovation projects between organisations. The findings of the research presented in this paper relate to both theory development and managerial implications.

7.1. Contribution to the literature

Resource dependence theory is applied to the phenomenon of production launch and problem solving. Albeit neither manufacturing ramp-up, nor the RDT framework are particularly new research topics, the combined scientific evidence on the process is rather scarce. Empirical studies on ramp-up management is largely focused on automotive and hardware industries and the current state of literature, as well as the identified challenges of manufacturing ramp-up cases in the MedTech industry, serves as a justification for this research.

This paper addresses the challenges of the manufacturing ramp-up's inter-organisational dependencies and focuses on the empirical analysis thereof, in the context of inter-functional involvement. The research has been carried out by studying organisational mitigation during the execution of six ramp-up projects.

The argument put forth in this study, is to better understand reliance and power balance among functional managers and fragmented project participants in executing the critical phase of ramping-up, we must distinguish between the degrees of changes, which we have demonstrated through operationalising RDT. To manage the organisation's resource dependence in the environment, the RDT explains the organisational process models. We have also demonstrated that managers create and select procedures that mitigate relations in the environment and seek relations that create favourable exchanges.

The difficulties of managing ramp-up process occur when the manager has multiple objectives, the question becomes how does he transform the process from a complicated and in principle describable process into a complex system? Given that the ramp-up manager cannot identify all the objectives, the assumption is therefore the consequential managerial effects.

We look at managerial opportunity, engagement and effort, in order to understand how ramp-up process can be linked to its wider network. Rather than looking at the process as an

optimization pursuit, it transfers to a researchable purpose of how different types of interest can be aligned.

7.2. Managerial strategies for dealing with dependence

This study explored a number of issues that address the way a ramp-up engineer or manager conducts him/herself through the complexities of organisation's resource dependence in the environment. In this way, The RDT explained the organisational process models. This study has also showed that managers create and select procedures that mitigate relations in the environment and seek relations that create favourable exchanges.

The closure of this paper is derived by an influential book chapter by Voss et.al. (2016) who in section 5.9.3 propose hypothesis generation as the aim and the output of case research. We follow these guidelines and propose the following five strategies, which might help reconfigure pre-existing assumptions, avoid or reduce the dependencies within and outside the organisation:

1. Stockpiling strategy: this is concerned with controlling the inputs and the outputs released to the volume manufacturing sites, which can be seen as a passive response. The challenge is that ramp-up production significantly depends on inter-functional involvement, but that an expert resource is not always available.
2. Levelling strategy: it is concerned with controlling the input-output ratio, which can be seen as an active involvement by reaching out into the environment and providing the organisation with inputs about ramp-up production capacity requirements.
3. Forecasting strategy: If environmental fluctuations cannot be managed by stockpiling or levelling, the ramp-up function might have to adapt by anticipating or forecasting volume production launch or market launch and how the changes made to the product or process should not result in further delays.
4. Scale adjustments strategy: This does not jeopardize the core of the ramp-up production site, but rather it manages its size.
5. Shaping dependence relations strategy: This choice can be achieved through bridging actions, which can be done through negotiations with other organisations, exchanging resources with them, pooling resources across them, or by performing mergers and absorbing another firm in its own entirety.

Appendix 1

Data Sources –March 2013 and October 2016		
Source	**Frequencies**	**Total**
Interviewees		
• CEO		2
• Executive VP, Global Operations		5
• VP Pilot, Ramp-up & Machine Transfer	*Every 4-5 weeks*	28
• Project managers		22
• Product Development managers		6
• Supply Chain Managers		3
• Machine and raw material Suppliers		1
Archival records • Strategy presentations & white papers • Contractual agreements with suppliers • Meeting minutes		
Observations		
• Strategy meetings	*Quarterly*	8
• Board of directors' meetings	*Every 4-6 weeks*	25
• Core group meetings	*Weekly*	30
• Observations in office (4-6 hours/day)	*Sporadic*	141
• Social events	*Annually*	5

The total number of interviewees is 67; Archival records totalled 58, and observations 209

Appendix 2

Main planned actions - Project Stage: Ramp-up		
Activities details	**Activity/milestone**	**Activities ownership**
Various employee health and safety assessment activities	Activity	Employee health and safety management
1. Stop time analysis 2. Standard Work 3. 6S 4. Scrap analysis 5. Root Cause	Activity	Lean management
Handover between launch and production support	Activity	Logistics management
1. Project risk assessment 2. Monitoring of Production Output during Ramp-Up 3. Six Sigma 4. Weekly reporting 5. Ramp-Up Project Agreement 6. Project GTG 7. Resource plan 8. Project plan 9. Sign off meeting (Entry 3 Preparation => Ramp-Up phase) 10. Open Change Requests (CR) 11. Training of operators/skill workers 12. Training in product understanding (Quality) 13. Evaluate production flow 14. Project Evaluation	Activity	Project Management
Ramp-up Production Launch	**Milestone**	Project Management
Project Evaluation (Entry 4)		
Project Evaluation (Entry 5)		

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