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Supply chain integration and barcoding

A case study in Medical Device market

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Supply chain integration och streckkodning

En fallstudie på marknaden för medicinsk utrustning

av

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Supply chain integration and barcoding

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Abstract

Title: Supply chain integration and barcoding, a case study in medical device branch.

Background: Medical device manufacturer are competing in a dynamic and global market. Medical device market is one of the most regulated markets. Recently regulation (EU) 2017/745 is presented. A new medical device database “EUDAMED” will be established soon to integrate several electronic systems to improve and secure information sharing through the medical device market. Medical device manufacturer is operating in a more global market than before with larger information flows. The information availability in a proper quality is needed for the supply chain effective performance.

Method: The author conducted positivist perspective and an inductive approach for this research. Data has been collected through interview with Bactiguard employees.

Conclusion: Establishing collaborative system and find the proper mechanism to increase supply chains of medical devices is highly requested in practice and by regulations as well.

Key-words

Supply chain integration, Medical device, Regulation (EU) 2017/745, barcoding

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Godkänt	Examinator KTH	Handledare KTH
2017-06-26	Jannicke Baalsrud Hauge	Lars-Åke Arvidsson
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	Bactiguard AB	Johan Rugfelt

Sammanfattning

Titel: Supply chain integration och streckkodning, en fallstudie inom medicinteknik bransch.

Bakgrund: Medicinteknisk tillverkare konkurrerar på en dynamisk och global marknad. Medicinteknisk marknad är en av de mest reglerade marknaderna. Nyligen förordningen (EU) 2017/745 presenteras. En ny medicinsk databas "EUDAMED" kommer att inrättas snart för att integrera flera elektroniska system för att förbättra och säkerställa informationsutbyte via marknaden för medicinsk utrustning. Medicinteknisk tillverkare arbetar på en mer global marknad än tidigare med större informationsflöden. Informationens tillgänglighet i rätt kvalitet behövs för att försörjningskedjan ska fungera effektivt.

Metod: Författaren genomförde positivistiskt perspektiv och en induktiv metod för denna forskning. Data har samlats in genom intervju med Bactiguard anställda.

Slutsats: Att upprätta ett samarbetssystem och hitta en lämplig mekanism för att öka försörjningskedjorna för medicintekniska produkter är högt efterfrågade i praktiken och i regelverk också.

Nyckelord

Supply chain integration, Medicintekniska tillverkare, förordningen (EU) 2017/745, streckkoder

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Mohamed Abdo

Stockholm, May 2017

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1 INTRODUCTION

The introduction provides an overview of up-to-date trends in supply chains, and introducing to the reader the main areas of the research. As well the new regulation of medical device market. Problem statement, the research questions, and the delimitations of the research are presented also.

1.1 *Supply chain*

Historically, debates about globalization involved the movement of three main assets: capital, people, and resources (Thomas, 2005).

As well the major tasks of supply chain have been defined (ISC-Europe, 2016) to be the encompass of the following three functions:

- Supply of materials to a manufacturer.
- Manufacturing process.
- Distribution of finished goods through a network of distributors and retailers to a final customer.

(DeAngelis, 2013) debating that managing resources globally through above mentioned functions have been the factor of increasing complexity in Supply chains. It might be not the only factor, but it is the vital one.

Global enterprises are facing a huge amount of uncertainty of information sharing regarding the increased complexity of its supply chains (Shao and Pan, 2009). Moreover, Shoa et al. (2009) are confirming that supply chain integration became an obligation for global enterprises to reduce uncertainty of information and meet customer demands.

From another perspective, Hussain at el. (2010) pointing out that significant connection between integration and visibility in the supply chain, where sustainable information sharing became the key of supply chain performance.

Furthermore, (Jayaraman et al., 2015) mentioned that supply chain data standards – such as SG1[1] - can be defined as unique and universal identification of products and location, which offer the ability to track products to improve system integration to secure a full supply chain visibility from source to end user. The best known of these standards is the barcode (Buyurgan et al., 2011)

In short academic research within supply chain field provides a strong tendency towards the connection between information sharing and the efficiency of supply chain performance in general.

Medical device market is one of the most regulated markets regarding to its direct impact on human life. On early 2017, has The European Parliament introduced REGULATION (EU) 2017/745 which controlling the market of medical devices (Lex, 2017).

Regulation 2017/745 is defining the main objective of a medical supply chain in chapter III article 25 as the achievement of an appropriate level of traceability of medical devices. Furthermore, in chapter I article 44, describing the way to reach a proper level of information sharing is by the creation of a European database on medical devices (EUDAMED) that should integrate different electronic systems to collate and process information. The objectives of the database are to enhance overall transparency, through better access to information and to streamline and facilitate the flow of information (Lex, 2017).

1.2 *The assignor*

> *"Bactiguard is a Swedish med-tech company with a global presence, offering an infection protection solution that prevents healthcare associated infections caused by medical devices. By preventing healthcare associated infections, we reduce the use of antibiotics and thereby the spread of multi-resistant bacteria, which is a growing problem worldwide" (Bactiguard, 2017).*

[1] GS1 is a not-for-profit organization that develops and maintains global standards for business communication.

Bactiguard is competing in the market of medical devices with a unique technology, which will be described on the next chapter. This technology makes Bactiguard categorized under the market of Antimicrobial Coatings for Medical Devices.

The market of Antimicrobial Coatings for Medical Devices had reached $ 0.61 billion in 2015, with expected CAGR[2] growth by 14.2% per year to reach the total of $ 1.17 billion by 2020 (Coatings, 2015). Such a rapid growing market with a new enforced regulation regarding information sharing and integration between different systems needs to be investigated carefully.

1.3 *Problem formulation*

As presented above, the information sharing is the key of supply chain performance likewise the optimal integrated supply chain will be the only one reaches the peak of information sharing. Barcodes are well-known for their efficient aptitude as an information sharing's invention.

Hence Bactiguard AB is a pioneer in the field of Antimicrobial Coatings for Medical Devices, and strives to catch the rapid development of this market, as well the fulfillment of new regulation for medical device market 2017/745, therefor this research is focusing on the use of barcodes to optimize the integration and visibility on the supply chain.

1.4 *Research objective and questions*

The objective of this research is to understand and determine the potential of barcoding as an integration element in supply chain from the perspective of regulation 2017/745. The research is aiming to provide a guideline of how to stablish an integrated supply chain based on regulation 2017/745.

This research will try to answer the following question:

- Should supply chains of Medical Devices Manufacturers be integrated?
- Can barcoding systems be developed to be used as integration systems, and not only as tracking systems?

[2] Compound Annual Growth Rate.

1.5 *Delimitation*

This study is detected to Antimicrobial Coatings Medical Devices market, however similar markets in Medical Devices in general with comparable supply chains can be considered.

The study will scope only on the information sharing systems on the medical device supply chain from regulation 2017/745 requirements.

2 Bactiguard AB

This chapter presents the background of the assignor. As well an overview of the field of Antimicrobial coatings of medical devices.

2.1 *Healthcare associated infections (HAI)*

Healthcare associated infections (HAI) also referred to as "nosocomial[3]" or "hospital acquired" infections are acknowledged as the most frequent adverse event in healthcare. Per the World Health Organization (WHO) the prevalence of HAI varies between 5–19% in different countries with an average of over 10% worldwide.

HAI is a leading cause of morbidity and mortality in patients seeking medical care; in fact, it is the third largest cause of death in developed countries. Medical devices, for example catheters, account for over 50% of all HAI cases. Apart from the suffering of the patients, this also causes enormous cost for the healthcare systems across the world (Bactiguard, 2017).

> "*Infection prevention is a crucial element when tackling antimicrobial resistance as it reduces the need for antimicrobials. We will support initiatives that strengthen infection prevention within our countries.*" (Health, 2017)

2.2 *Bactiguard business*

In 2005, Bactiguard was stablished with a vision of combining technology and academia to defined a global standard of care to prevent healthcare associated infections caused by medical devices (bactiguard.se, 2017).

In 2014, Bactiguard is a share listed on Nasdaq Stockholm as a pioneer in the field

[3] nosocomial infection, is an infection that is acquired in a hospital or other health care facility. To emphasize both hospital and nonhospital settings, it is sometimes instead called a health care–associated infection (HAI or HCAI).

of infection protection solutions with a mission (bactiguard.se, 2017):

- To reduce healthcare associated infestations caused by medical devices.
- To minimize the use of antibiotics, which will reduce the spread of multi-resistant bacteria.

Currently Bactiguard has a headquarter in Stockholm, two production facilities in Sweden and Malaysia, around 60 employees worldwide and two business streams (bactiguard.se, 2017):

- License business.
- Product portfolio BIP (Bactiguard Infection Protection), which aiming to prevent nosocomial infections in:
    - The urinary tract by coated indwelling urinary catheters (Foleys).
    - The respiratory tract by coated endotracheal tubes (ETT).
    - The bloodstream by coated central venous catheters (CVC).

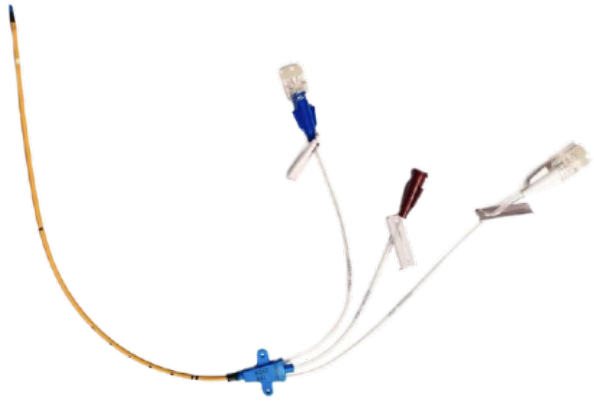

Figure 2:1: central venous catheters – CVC *(bactiguard.se, 2017).*

Figure: 2:1 presents a central venous catheter produced (coated) by Bactiguard Technology.

2.3 *Bactiguard technology*

Even though Bactiguard is quiet recently stablished, but the technology behind it has a long history. Figure 2:2 presents the time line of Bactiguard history (bactiguard.se,

2017):

- 1912: Gustav Dahlén[4], who resolved the critical task of applying thin layers of metals to glass during the development process of the lighthouses. Which further developed by Carl Axel Bergström.
- 1978: Billy Södervall, who is developed the concept of applying thin layers of metal to medical devices to innovate the Bactiguard technology
- 1994: Coated catheters by Bactiguard technology has been approved and registered by FDA[5].

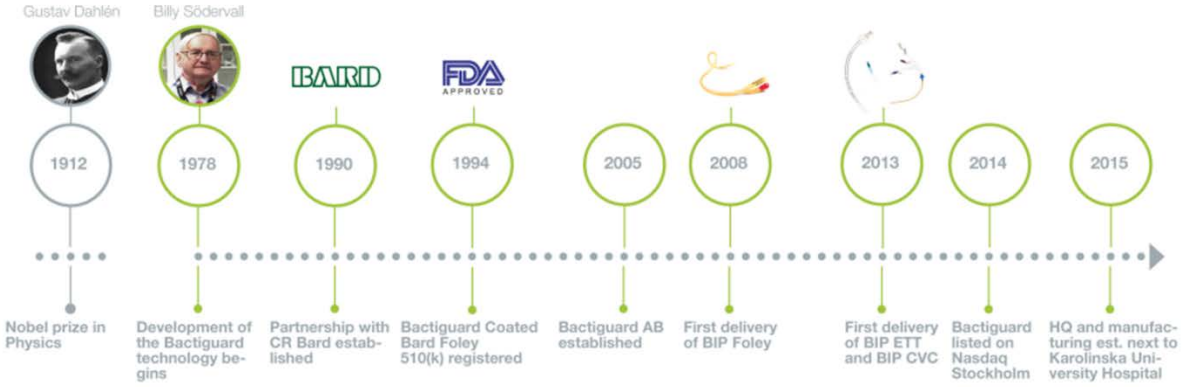

Figure 2:2: Bactiguard history (bactiguard.se, 2017)

Bactiguard's technology is based on an extremely thin layer of noble metals, which is applied to medical devices and prevents bacteria from colonizing on the surface. The patented coating is a noble metal alloy of gold, silver and palladium where the composition of metals and their different electro potentials create a galvanic effect, referred to as a 'micro current' which prevents bacterial adhesion and biofilm formation as presented in Figure 2:3 (bactiguard.se, 2017).

The coating is firmly attached to the surface of the device, which means that the effect is long lasting. The amount of noble metals is very low and not released in any toxic or pharmacological quantities, which makes the technology both tissue-friendly and safe

[4] Nils Gustaf Dalén was a Swedish Nobel Laureate and industrialist, the founder of the AGA company and inventor of the AGA cooker and the Dalén light.
[5] The Food and Drug Administration is a federal agency of the United States Department of Health and Human Services, one of the United States federal executive departments.

for patients (bactiguard.se, 2017).

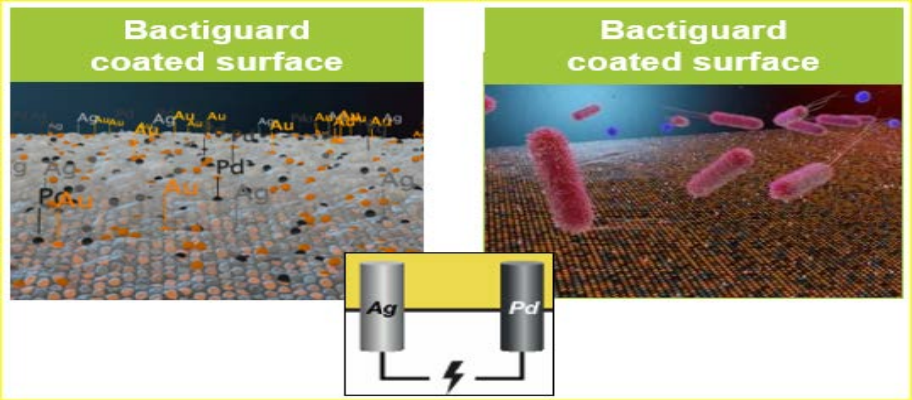

Figure 2:3: Bactiguard technology **(**bactiguard**.se, 2017)**

Bactiguard coated products have been used in clinical practice since 1995 with no reported adverse events related to the coating. Bactiguard provides clinically proven, practical and cost effective solutions for infection control, which in turn contribute to higher patient safety, lower mortality, reduced healthcare costs and less use of antibiotics (bactiguard.se, 2017).

It's appropriate also to illuminate the reader that the author of this research has a practitioner role in Bactiguard organization as a Logistics and Demand Planning Manager, which affected positively the research as reflective practitioner. More details regarding reflective practitioner will be described in next chapter.

3 RESEARCH METHODOLOGY

This chapter describes the applied procedures in the research and validates the approach applied in the research. On the end a summary over methodology will be presented to explain how the reliability and validity of the research may be proven.

Research methodology can be defined as the efficient and intensive ways of collecting data, which obtaining facts that can explain or find answers for a specific research problems (Ghauri, 2010).

It's important when a researcher conducting a study to put efforts into choosing the most relevant and appropriate research methods and procedures. The choose of the method will affect and create a better chance that the purpose of the study is being fulfilled. As well the applied methods should be consistent and consequent for the results to be relevant (Ingeman and Björn, 2009).

3.1 *Scientific perspective*

(Kuhn, 2012) has pointed to the importance of using the term paradigm when we discuss the research methodology, where it describes researcher's major expectations and the way of thinking.

There are two major scientific perspectives:

- **Positivistic perspective**: is mainly a descriptive approach, where it uses the position of recognized theories to describes the integration of knowledge and proven empirical experience (Winterton, 2008).

- **Hermeneutic perspective**: this approach is based on the belief that the world is a creation of mind and contends that interpretations should be given more than descriptions (Walliman, 2006)

(Britta, 2004) argued that logistics research is strongly connected to the positivistic perspective and could benefit from other perspectives as well. Meanwhile (Collis, 2014)

argued that research methodology should be chosen per a research's objective.

As the objective, this research is to understand and determine the potential of barcoding as an integration element in supply chains, which requires to study the links between two major concepts: supply chain integration and global standard adoption. The author believes that positivistic approach will be appropriate for this study where the illustration of the theories proposed and the concepts introduced from a practical point of view, as in applied case study of this research.

3.2 *Scientific approaches*

Two major different approaches of directing a research. These two approaches are inductive and deductive approaches (Ghauri, 2010).

- **Inductive approach** starts by specific observations to broader generalizations and theories. The researcher carries specific observations and measures, and then begins to detect patterns and regularities (Ghauri, 2010).

  The main target is to formulate some tentative hypotheses that can be explored, and finally can develop some general conclusions or theories (Winterton, 2008, Bryman, 2013).

  Inductive methods are most required when the research is investigating a new field where earlier theories are limited. This is one of the main arguments for using inductive reasoning in wider extent regarding the need of the researchers to be unprejudiced (Bryman, 2013).

- **Deductive approach** works from the more general to the more specific. The researcher begins with theories and then narrows that down into more specific hypotheses that can be tested (Ghauri, 2010).

  The research get more constricted when observations have been collected to address the hypotheses. This eventually guides the researcher step by step to reach a conclusion through a logical reasoning (Ghauri, 2010).

In this research, the author has followed the inductive approach. The author efforts are to find patterns where theories can be applicable to understand the connection between information sharing and supply chain integration, and how to narrow the gap of uncertainty of information sharing regarding the increased complexity in the supply chains. Therefore, the research process starts by observations then followed by findings and finally theory building and the outcomes are integrated back into existing knowledge.

Bryman (2013) claims that even though the inductive approach has been regularly used, one of the major areas of criticism has been the influence of theory. Where it might affect the selection of observation group or object, as the study is mainly not based totally on empirics. He claims also that observations cannot solely form the theories, where there is always a limitation of how many observations can be performed and therefore always uncertainty in the results.

3.3 *Research methods*

This section aims to simplify the research methods, as well to streamline the approach of the study to the reader.

3.3.1 Research Type

There are different classifications for research types. The classification is mainly based on the understanding of an existing research on a subject (Björklund, 2003). Björklund (2003) describes some research types that can be relevant to this research:

- **Exploratory study**: This type of study is usually directed when the existing research is insufficient. Normally the researcher strives to gather as much data as possible regarding the research subject.

  Exploratory studies are often used in preliminary investigations. One major goal of this type is to give an evidence to support or controvert a prediction.

- **Descriptive study:** This type is describing and measuring the subject to explain it rather than to investigate it. The key of this type is to reach a deep and extensive understanding of the subject.

- **Normative study**: This types aims to give guidance in a subject.

- **Explanatory study:** which seeks to explain and get deeper understanding.

This research requires on first stages an exploratory study to understand the problem and where the uncertainty of information sharing mainly appears. As well the author needs to understand and determine which theories are relevant for the study.

As described early, the objective of this research is to understand and determine the potential of barcoding as an integration element in the supply chains, which requires to study the links between two major concepts: supply chain integration and global standard adoption, which makes an explanatory study on the late stages is more appropriate to find answers to the study objective.

3.3.2 Case Study

There are mainly four designs of case study (Yin, 2007). Those designs are based on two dimensions:

- **Single or multiple case:**
    - **Single case design**, considers one object to be studied, and targeting to determine the answers of research questions. This design is more suitable if the research seeking to verify a theory or considering an exceptional case.
    - **Multiple case design**, considers to investigate more than one object. This design is more applicable when the researcher is looking to analyze case objects which are connected to each other.
- **Single or multiple units of analysis**
    - **Holistic design**, where the researcher to analyze the outcome of an object as a one unit.
    - **Embedded design**, where the researcher want to analyze one or many objects based on the outcome of the object different units' outcomes.

The combination between those dimensions is depending mainly on how different data collection methods can be used to tackle the research problem (Yin, 2007). (Merriam, 1994) described some advantages of case studies approach, and the most favorable one is the ability to generalize from one context to another. On the other hand, the most tangible restriction is its disability to generalize from a smaller investigated selection to a larger one.

In this research, the embedded – single case design has been implemented. The case study method is being used because it is the most appropriate when the researcher seeks to discuss a descriptive question or an explanatory question as described by Yin (2007). Regarding to the author, the case study will secure the needed empirical data for the research within its real context. As this research is aiming to understand and determine the potential of barcoding as an integration element in supply chains.

While the indeterminate state between the integration and barcoding are not apparently visible, and per Yin (2007) a case study is relevant when the focus of the study is on a contemporary phenomenon, which is the situation in with this research.

3.3.3 Data collection

The term **triangulation** is referring to the use of more than one approach to investigate the research questions, which is helping the researcher to tackle the problem from different angles to increase the visualization of the research problem and provides a more complete picture of the problem (Bryman, 2013).

The author has used the methodological triangulation by gathering information through literature reviews, databases and interviews to enhance the credibility of the research.

Normally data can be collected in two forms primary and secondary data, and that depends on how close collected data of the study subject (Walliman, 2010).

- **Primary data** is including information that obviously collected for the purpose of the research, and should be more reliable with the objectives of the study (Ghauri, 2010).

- **Secondary data** is including information that have been documented in journals, articles and other publications (Walliman, 2010). The importance of literature review in a research is not only helps to find solutions for the research problem, but also present a route that can explain and increase understanding of the problem (Ghauri, 2010).

One of the most common ways of collecting data is interviews (Bryman, 2013). In this research, the author collected primary data by obtaining pre-structured interviews which were conducted in the medical device manufacturing company -Bactiguard - located in the southern part of Stockholm.

The pre-instructed questions were prepared and categorized regarding to the theoretical background of the research and based on the regulation 2017/745 requirements. The structure of the questions was aiming to guide the interview, and to collect the necessary information required for the research. Secondary data was collected in a form of previous literature from articles and journals to assist the author in developing the theoretical basis of this research.

Presenting collected data is determined basically by the purpose of the study (Björklund, 2003). Björklund (2003) further explains that determining factor is which data have been collected, and can be divided to:

- **Quantitative data**, is the data that is more suitable for measuring or can be analyzed numerically. Such data is often gathered by mathematical methods or surveys.

- **Qualitative data**, is the data that can presented in verbal from as interviews or observations.

The major difference between qualitative study and quantitative study is that the first is focusing more on creating understanding about the subject while the second is seeking the explanation of a phenomena in our surrounding world. Though, this big difference the researcher can use a combination of the both (Björklund, 2003).

Interviews has a typical nature of a qualitative research (Bryman, 2013). The author

indicates that information collected by structured interviews in this research mainly qualitative in nature regarding to required information. As well it was difficult to present it quantitatively.

3.3.4 Data analyzing

During collection of data via qualitative research, the ideas and guesses can misdirect the researcher to other areas. The process of analyzing information needs to be recursive and dynamic process (Merriam, 1994). In this research, collected data has been analyzed continuously, and intensive analysis took place when the collection of data is completed. The data has been organized and gathered to make the intensive analysis more efficient.

In this research, all interviews have been transcribed and the interview guide can be found in the attached Appendix. Through the study, the analysis process was continuously developed as each interview has been reflected on the results and compared them with excited theories and concepts per the qualitative analysis approach. Irrelevant information for the study was sorted out after the data collection to allow the description of the case to facilitate the cross-case analysis.

3.4 *Reflective practitioner*

Reflection in-action is described as the exchange between practice and research which improves the practitioner's capacity for reflection, where researcher can develop benefits from the theory and the methods of analysis in the process of reflection-in-action (Schön, 1995).

Schön (1995) categorizes researcher/practitioner partnership till two:

- Consultant: where the researcher is a consultant to the practitioner and the research is an instruction for the practitioner.
- Reflective practitioner: where the practitioner is taking the privilege of exchanging roles between researcher role and practitioner role.

The author has followed the second form, as he exchanged the roles between

researcher role and professional role. This dual role as practitioner with research interests, by performing 'reflection-in-action' helped him to analysis the case from a broader perspective and carry out an opportunity for social interaction, mutual learning and objective knowledge.

3.5 *Validity and reliability*

The most common used tests to determine the integrity of a case study researches are (Yin, 2007):

- **Construct validity** is debating the identification of accurate operational measure (Yin, 2007).

In this research, the construct validity has been obtained by securing information from multiple sources. As well the transcribed interviews were e-mailed to each of the interviewees to be confirmed and avoid any possibility of misunderstanding.

- **Internal validity**, is debating the causality reasoning between two variables (Ghauri, 2010). Yin (2007) argues also that internal validity is a concern for explanatory case studies.

In this research, the interview questions have been e-mailed to the interviewees in advance to give them a sufficient time to prepare robust answers as well to avoid any misunderstanding can misled the research. As well collected information has been vilified through secondary sources.

The author avoided any personal assumptions since the empirical information were analyzed based on theory to arrive at the conclusions.

- **External validity,** refers to the ability of generalization the research findings to elsewhere the studied subject (Yin, 2007).

It is common on qualitative studies to use the term transferability to reflect the external validity, where other researchers based on the context of the study and its methods can validate it (Trochim, 2007).

In this research, the context of the study and its process have been descried in details to rationalize for other researcher the possibility of determining whether the study is transferable or not. On the other hand, the research can be applicable for other medical device manufacturing companies that have a similar supply chain as studied subject.

- **Reliability**, refers to the stability of the measures where other researcher can reach the same conclusions and findings if they apply the same procedures of original study (Yin, 2007)

In this research, the methodology of analysis is presented carefully as well the conceptual framework of theories to ensure that reproduction of the study will have negligible bias and deception.

3.6 *Research process*

As explained above, this research will mainly consist of:

- Positivistic perspective, which is highly connected to logistics studies, and is more appropriate to illustrate theories and concepts related to the case study.
- Inductive approach, which will assist the researcher to conclude from the case study the applicable patterns of theories and concepts.
- Both exploratory and explanatory study types, which the exploratory type will be used to understand the problem and to determine the relevant theories and concepts. While the explanatory type explains the findings and answers to the study objective.
- Embedded – single case design is implemented, which is the one of the appropriate designs to secure the needed empirical data for the research within its real context.
- Methodological triangulation is used to collect information through literature reviews, databases and interviews to enhance the credibility of the research.
- Qualitative approach is the nature of the this research.

On the initial exploratory stages of this research, a literature study carried on to certify a good approach to the research and to get an overview of the existing theories and concepts. Scientific journals and articles were the basic platform to collect the information. These platforms were found in well recognized databases to ensure high reliability. Key words that were used when searching the databases were: “barcoding”, “information sharing” and “supply chain integration”. Supply chain integration is relatively a new concept which made available books are very limited.

Once again on explanatory stages, after analyzing interviews, another literature study has been carried to supplementary spread the knowledge of the relevant objects and to help analyzing the out-comes of collected data.

The interviews have been used also, on the exploratory stages, to determine the current situation at the company and to locate the challenges of the current problems in the case study. The interviews questions were only pre-structured to avoid personal opinions which may affect the final analysis. As well several persons were interviewed by standardized questionnaire with open questions to secure the validity of the research.

In the later stages on explanatory stages, after intensive analysis, a discussion and the results of the research are presented.

4 THEORETICAL CONCEPTS AND FRAMEWORKS

This chapter aims to describe the available literature in the field of supply chain and medical device regulation 2017/745. This chapter ends with a framework of concepts that are applied in the research and its connection to the research objective.

4.1 *Value supply chain*

Since 1985, and the concept of value supply chain has been introduced by Michael Porter (Schary, 2001). Porter present a framework where the output of different supply chain processes such as; inbound- and outbound logistics, operations, sales and services, can deliver value both internally inside the enterprise and externally to end user (Schary, 2001). Schary (2001) also confirms that further research into the field of value supply chain has been extended to include other processes than only above mentioned processes, such as product development and customer relations.

Logistics processes as well product development processes and customer relation processes, are parallel flows which should be also considered to create the value supply chain. In short, to enable the value to reach the end user, so the three flows should be aligned together even if they are working separately inside the organization.

4.2 *Supply chain management*

Above explanation of value supply chain where all flows should be aligned together, has a valuable impact on the concept of supply chain management. Consequently, the supply chain management will not only include managing logistics processes but also managing of the cooperation within and between other flows (Choi, 2014).

Despite the material flows, the supply chain management should mainly manage the information flows from supplier to end user and eliminate any cross limitations that can reduce or affect the value to end user (Gibson et al., 2005). Gibson et al. (2005) further defined that supply chain management is a collaborative concept which coordinate and integrate a network of flows to accomplish a mutual goal. In the same line

Hussain et al. (2010) are pointing to a new paradigm of supply chain management, where maximizing the overall generated value of all flows, rather than the profit generated only of supply chain processes.

(Rodney and Daniel, 2001) are directing the main task of supply chain management towards the collaboration between enterprises. Finally, Shao et al. (2009) are explaining that supply chain collaboration is standing along two fundamental characteristics: integration and visibility.

4.2.1 Supply chain integration

Hussain et al. (2010) have coherent that supply chain integration can be defined as a network of dynamic supply chains linked with a system which merge all firms to increase the value of every chain. The author of this research is using this definition as the definition of supply chain integration.

Recent research has approved that integration is the major factor that affecting supply chain's performance (Shao and Pan, 2009). Empirical findings verified a robust association between performance and the level of integration. Supply chain integration encompasses internal and external integration. The internal integration is an obligation to reach the external integration (Frohlich and Westbrook, 2001).

In summary, supply chain integration can be considered as a system linking dynamic supply chains to a mutual value by increasing the performance of the supply chain management and internal integration is an obligation to achieve the external integration.

4.2.2 Supply chain visibility

The other characteristic of a collaborative supply chain is visibility. Goh et al. (2009) agreed that supply chain visibility can be defined as the availability and accessibility of relevant information to a supply chain player about the entities involved in the supply chain for better decision support.

Many researchers who have approached the issue have proved that increased visibility will improve the performance of the supply chain (Stanley et al., 2007). Stanley et al. (2007) demonstrated tangibly that the exchange of high-quality information as part

of an improvement initiative does lead to significant improvements in the overall performance of the supply chain. On the other hand, (Lee, 2016) confirmed that the lack of accurate information can cause certain negative consequences such as the 'bullwhip-effect' in supply chains.

In summary, supply chain visibility is the availability and accessibility of high-quality information to support decision makers and avoid certain negative consequences.

4.3 *Information sharing*

(Stanley et al., 2009) approved that key enabler for improving performance with a more process based organization was originally information technology. This explains the vital role of information sharing in both supply chain integration and supply chain visibility.

Furthermore, (Mahadevan, 2010) has concluded that integration cannot be complete without a tight collaboration between the entities of the supply chain, and he focused in in information sharing, organizational linkage, and coordination mechanism across distinct firms or organizational units. Additionally, (Khan et al., 2016) determined that key information across organizational boundaries is increasingly viewed as essential criteria to the competitiveness of the supply chain.

In summary, information sharing is a vital component in both supply chain integration and supply chain visibility. Moreover, it became a critical component of the new medical device regulations 2017/745.

4.4 *Medical devices regulations (EU) 2017/745*

Medical device market is one of the most regulated markets regarding to its direct impact on human life. On early 2017, The European Parliament and the European Council have introduced REGULATION (EU) 2017/745 which controlling the market of medical devices (Lex, 2017).

This Regulation mainly aims to ensure the smooth functioning, and sets high standards of quality and safety of medical devices market, taking as a base a high level of protection of health for patients and users, and considering the small- and medium-sized

enterprises that are active in this sector (Lex, 2017).

Key elements of the existing regulatory approach, such as the supervision of notified bodies, conformity assessment procedures, clinical investigations and clinical evaluation, vigilance and market surveillance should be significantly reinforced, whilst provisions ensuring transparency and traceability regarding medical devices should be introduced, to improve health and safety (Lex, 2017).

REGULATION (EU) 2017/745, defines the key aspect in fulfilling the objectives of this regulation is the creation of a European database on medical devices (EUDAMED) that should integrate different electronic systems to collate and process information regarding devices on the market. *EUDAMED: A new European database* on medical devices that will collate and process information regarding: devices on the market and the relevant economic operators (e.g. manufacturers), certain aspects of conformity assessment, notified bodies, certificates, clinical investigations, vigilance and market surveillance. Much of the information on the database is to be made accessible to the public and the European Commission is tasked with setting it up by spring 2020 (TaylorWessing, 2017).

EUDAMED database will integrate two new major electronic systems that have a significant impact on supply chains of medical devices, and are mainly connected the objective of this research are:

- ***UDI: A new Unique Device Identification*** system that would improve traceability of devices (Lex, 2017).

- ***The electronic system on vigilance and post-market surveillance:*** A system that would improve post-market vigilance of devices (Lex, 2017).

The objectives of the database are to enhance overall transparency, including through better access to information for the public and healthcare professionals, to avoid multiple reporting requirements, to enhance coordination between different partners in supply chain and to streamline and facilitate the flow of information between them (Lex, 2017).

In summary, the value of EUDAMED database is the smooth functioning, and sets high standards of quality and safety of medical devices market by integrating different electronic systems such as UDI system and the electronic system on post-market

surveillance to enhance coordination between different partners in supply chain.

Previously, a brief introduction regarding the new required electronic information systems that has a significant impact on medical device supply chains from the perspective of regulation 2017/745. Similarly, it will be also appropriate to introduce briefly the only technology of information sharing on the field of supply chains from also the perspective of regulation 2017/745.

4.5 *Automatic identification and data capture ('AIDC')*

Regulation 2017/745 describes AIDC as the technology used to automatically capture data. AIDC technologies include barcodes, smart cards, biometrics and RFID. The Basic UDI-DI is the primary identifier of a device model. Furthermore regulation 2017/745 is defining the Device Identification (DI) as the assigned level of the device unit of use, which is the main key for records in the UDI database (Lex, 2017).

Historically, barcodes have been developed as a data identification standards, which can be read by optical scanners called barcode readers or scanned from an image (Youssef and Salem, 2007). Youssef and Salem (2007) explained that development is mainly made to serve the needs of industrial products regarding movement traceability and inventory control purposes. Barcodes are widely used to implement standard systems.

Consequently, Steinfeld et al. (2011) conducted that a standard system identification is developed by an open community that uses public communication platforms and software to collect data, which is the situation of the new database "EUDAMAED".

Standards in supply chain are viewed as a resource and a coordination mechanism which can help improve operational compatibility and connectivity, efficiency and effectiveness of inter-organizational supply chains due to clear and unambiguous communication between partners (Nathalie et al., 2006).

Nathalie et al. (2006) reports about a lack of studies on supply chain standards as compared to standards in technology development, which might be the reason behind considering barcoding systems are the dominant of information sharing technology in the field of supply chain.

4.6 *Traceability vs. integration*

Two different terminology that will be used frequently through this research: Traceability and integration. There is always a confusion in recent literature as often there is a swapped between the concepts of integration and traceability.

Traceability can be defined as the ability to identify the origin of an item or group of items, through records, upstream in the supply chain (Schwägele, 2005).

While integration, as described above, is a network of dynamic supply chains linked with a system which merge all firms to increase the value of every chain (Hussain and Mohammad Othman, 2010).

Above mentioned definitions are the considered definitions for traceability and integration through this research.

4.7 *Research framework*

The purpose of this section is to develop an analysis model that will be used to answer the research questions with considering also that research objective is to understand and determine the potential of barcoding as an integration element in supply chains from the perspective of regulation 2017/745.

The components of the model are commonly mentioned in literature and are discussed below.

4.7.1 Supply chain integration in medical device market

EUDAMED will be established as one of the new platforms within medical device market, targeting the value of a high level of protection of health for patients and users. Such value needs a high level of performance and accuracy on decision making.

Earlier research in supply chain performance showed that integration levels between all partners, internally and externally, should be streamlined to an optimal level to reach the requested levels of performance and accuracy.

The author is aiming to provide a guideline of how to stablish an integrated supply chain based on regulation 2017/745.

4.7.2 Barcoding as integration system

A new set of standardization will be settled and should be combined with a new Unique Device Identification (UDI) system that would improve post-market vigilance and traceability of devices. A tool that can carry such information is barcodes.

The author is aiming to explore the possibility of barcoding system to be developed from only traceability system to an integration system.

5 EMPIRICAL FINDINGS AND ANALYSIS

This chapter is presenting the empirical information and the findings based on interviews conducted with different departments at Bactiguard. Finally, a summary of challenges that are facing Bactiguard to optimize its supply chain integration.

5.1 *Core business*

As described in chapter 3, Bactiguard technology is based on an extremely thin layer of noble metals, which is applied to medical devices and prevents bacteria from colonizing on the surface. Therefor the core business of Bactiguard is the coating process of medical devices with a thin layer of noble metal alloy.

The medical devices where Bactiguard is applying the coating process are:

- **BIP Foley:** a coated indwelling urinary catheter.
- **BIP ETT:** a coated endotracheal tube.
- **BIP CVC:** a coated central venous catheter.

The production of noble metal alloy, which is called concentrate is taking place in Sweden, while the coating process of medical devices are taking place in:

- **Malaysia**, for BIP Foleys production.
- **Sweden**, for BIP ETT and BIP CVC production

5.2 *Supply chain*

Bactiguard supply chain extend from the purchasing of raw materials and external services from different suppliers, passing through production process (coating process) to distributing the final coated and sterilized product to several distributers worldwide.

Suppliers that are connected directly to the production process in Bactiguard are classified to:

- **Raw Material supplier**, which can be divided to:
    - ***Uncoated medical device***, such as catheters and tubing. These materials are mainly produced of latex or silicone. Suppliers are in China and Malaysia.
    - ***Chemicals***, which are used in noble metal alloy production and other concentrate used during coating process. Suppliers are in EU.
- **Packaging material supplier**, who provides materials used in packaging of Bactiguard final products after value added process (coating process) such as sterile barriers, labels and premium boxes. Suppliers are in EU.
- **External service supplier**, which mainly is the sterilization process that takes place after coating process. Suppliers are in EU and Malaysia.

Bactiguard is presented in more than 50 countries worldwide with a sales team who communicating the value of Bactiguard protection infection products. Meanwhile distribution strategy of final products is applying a chain of distributers to make the final product available to end user.

5.3 *Quality control*

All incoming materials are controlled by trained personal at Bactiguard labs. Essential documents such as certificate of conformity and certificate of analysis with product information should be provided also by suppliers.

During production process several tests should be performed to secure that coating process is firmly implemented and valid for clinical uses. Each produced item has a record of approved test results and certified for distribution to end-users after sterilization.

Sterilization process is outsourced to an international supplier. The supplier provides a sterilization certificate per quality agreement and regulated standards.

5.4 *Information sharing*

Bactiguard uses an Enterprise Resource Planning system (ERP) called Jeeves to handle the transactions and activities of supply chain as purchasing, production, distribution and inventory.

The ERP-system is designed to include basic information regarding both raw materials and final products such as trade name, device model, product description, clinical size and reference number. As well standard production processes.

The information of incoming materials, such as LOT number, production date and expire date are mainly interred to the system manually. Likewise, production information of final products is mainly interred to the system manually. Main users of ERP-system are only Logistics department and Finance department to manage sales, purchasing, production and inventory.

While other departments use a web-based system called intranet to communicate between each other and to upload documents and records of quality control, clinical studies, clinical evaluations, production release and post-market surveilles. Internal and external information are exchanged mainly by e-mails, and most of Bactiguard employee are missing proper access to ERP-system.

One of important operations during production process of final product is labeling operation. Labels containing vital information of the final product. Beside basic information, it contains also LOT number, production- and expire date, sterilization status, storage conditions.

Labeling process in Bactiguard uses a software called Bartender, and data entry to labeling system are also managed manually. No barcodes or any other automatic identification and data capture system is applied on labels. Bartender is not connected to the ERP-system, but the potential to be integrated with ERP-system is planned to take place soon.

Apparently, there is three software systems that are implemented in Bactiguard for information sharing in daily basis. A lack of integration between systems internally. As

well main communications with external partners, suppliers and distributers, are taking place via e-mail.

5.5 *Regulations*

Bactiguard is a legal manufacturer of medical devices within EU which follows ISO 13485 and MDD.

Bactiguard products are CE marketed and approved per directive 93/42/EEC. Recently regulation 2017/745 has been presented and will replace previous directives with a transmission period of one to three years ends on May 26th 2020.

Regulation 2017/745 has impact on all Bactiguard departments, specially the implementation of EUDAMED system, and UDI system. As this new regulation and systems has been presented recently so many employee of Bactiguard are not familiar with them yet.

EUDAMED system is not created yet, but the European Parliament has set a commission of professionals from different fields related to medical devices and supply chains to design and standardize the information that should be communicated to the EUDAMED system. The determined lead time of establishing EUDAMED system is 18 months.

The criteria of the EUDAMED system are described in details at the published regulation 2017/745. It's certain that EUDAMED system will be an open system for medical device industry worldwide. Bactiguard management team has proactively established a team from different departments including; logistics, production, quality, product design, regulatory and post-market to plan the integration with EUDAMED based on recently published regulation with attention to identify the principles of integration internally.

UDI-system is also a new system that will be enforced by regulation 2017/745, but on the contrary of EUDAMED system, the UDI-system will be an open system for tracking medical device with an international scope. Regulation 2017/745 is describing UDI-system to be an international system and should can be integrated with other systems

worldwide. In addition, the electronic system on vigilance and post-market surveillance to improve post-market vigilance of devices should be stablished as well to fulfill the requirements of regulation 2917/745.

5.6 *Challenges*

To summarize and analyze the findings of data collection through interviews and by practitioner reflection regarding the challenges that are facing Bactiguard to optimize supply chain integration, below challenges are defined:

- **Global networks**; Bactiguard is engaged in a global environment and both suppliers and distributers, who are presenting respectively up- and downstream of Bactiguard supply chain, are in different locations worldwide.
    - **Suppliers network**: Most critical suppliers of Bactiguard have a critical information, that are vital for production process. Uncertainty or delay of information sharing can take place, which affects negatively discussion making process, and in worst case can harm final product availability or visibility in the market. This challenge will harm the traceability concept, which is the main value of EUDAMED database.
    - **Distributers network**: Top ten distributers of Bactiguard are in the Far- and Middle East regions. Despite the geographical challenges to secure end-users demands, the gap of information sharing and sometime even poor traceability of final products can affect negatively product availability in the market and in worst case – such as recall process - can a defected product harm end user (a patient). This challenge might deficient the performance of electronic system on vigilance and post-market surveillance.
- **Information sharing:** Working environment in Bactiguard is very friendly, and communication between different departments is informal. Information are available and are communicated mainly via e-mails, meetings and phone calls, but the main challenge is the quality of shared information between departments. The lack or even the delay of proper information can affect badly discussion-making process. As well various information platforms and occasionally the limited

availability of relevant data, creates unnecessarily bottle-necks.

- **Information platforms:** There are three applicable platforms in Bactiguard to store data, which are: ERP-system (Jeeves), intranet and Bartender (for labeling operation). In practice, there is no integration between the three platforms, but integration possibilities are not limited. The integration gap between the platforms decreases the mechanism of information sharing, which consequently, increases the lack of information quality and eventually delimitate the supply chain visibility.

- **Regulation 2017/745;** the new regulation enforces Bactiguard, and all other medical device manufacturer within EU, to establish a standard platform of communication within the supply chain. As well other internal departments that had a minimum integration with supply chain previously such as post-market surveillance or clinical investigation should be integrated in one system (EUDAMED). This approach of integration creates a massive necessity of finding a new mechanism of information sharing internally and externally.

6 DISCUSSION AND THEORETICAL CONTRIBUTION

This chapter reflects how empirical findings and theoretical concepts have affected the understanding of challenges in case study.

6.1 *Supply chain integration*

One of this research question is: Should supply chains of Medical Devices Manufacturers be integrated? Figure 6:1 is a chart developed by the author to describe the connection of related theories in supply chain field to fundamental concepts such as value and performance from the perspective of regulation 2017/745. Discussion regarding theoretical contribution has been developed as following.

EUDAMED will be established as one of the new platforms within medical device market, targeting the value of a high level of protection of health for patients and users.

The concept of value supply chain has been developed to be the gathering of different processes towards one mutual goal (Schary, 2001, Choi, 2014). Gibson (2005) and Shoa (2009) have confirmed that the key challenge of collaboration in supply chain networks is to eliminate cross limitation between all entities in the supply chain. Case study has showed that Bactiguard are facing a challenge of eliminating cross limitation between internal and external entities.

The challenge of cooperation between global networks is not unique for Bactiguard. Hussien et al. (2010) described supply chain integration as a dynamic chain linked with a system to merge the overall value. There is no doubt that all partners in Bactiguard supply chain is seeking the overall value, but standard system that can accumulate them together is still not established. The need of a standard system to integrate supply chains has been a global need.

Regulation 2017/745 have pointed out the importance of vigilance of medical device flows. Equally academic research presented by Goh et al. (2009), defines visibility as the availability and accessibility of information for better decision accuracy. Both medical device regulation and supply chain research seeks a quality flow of information

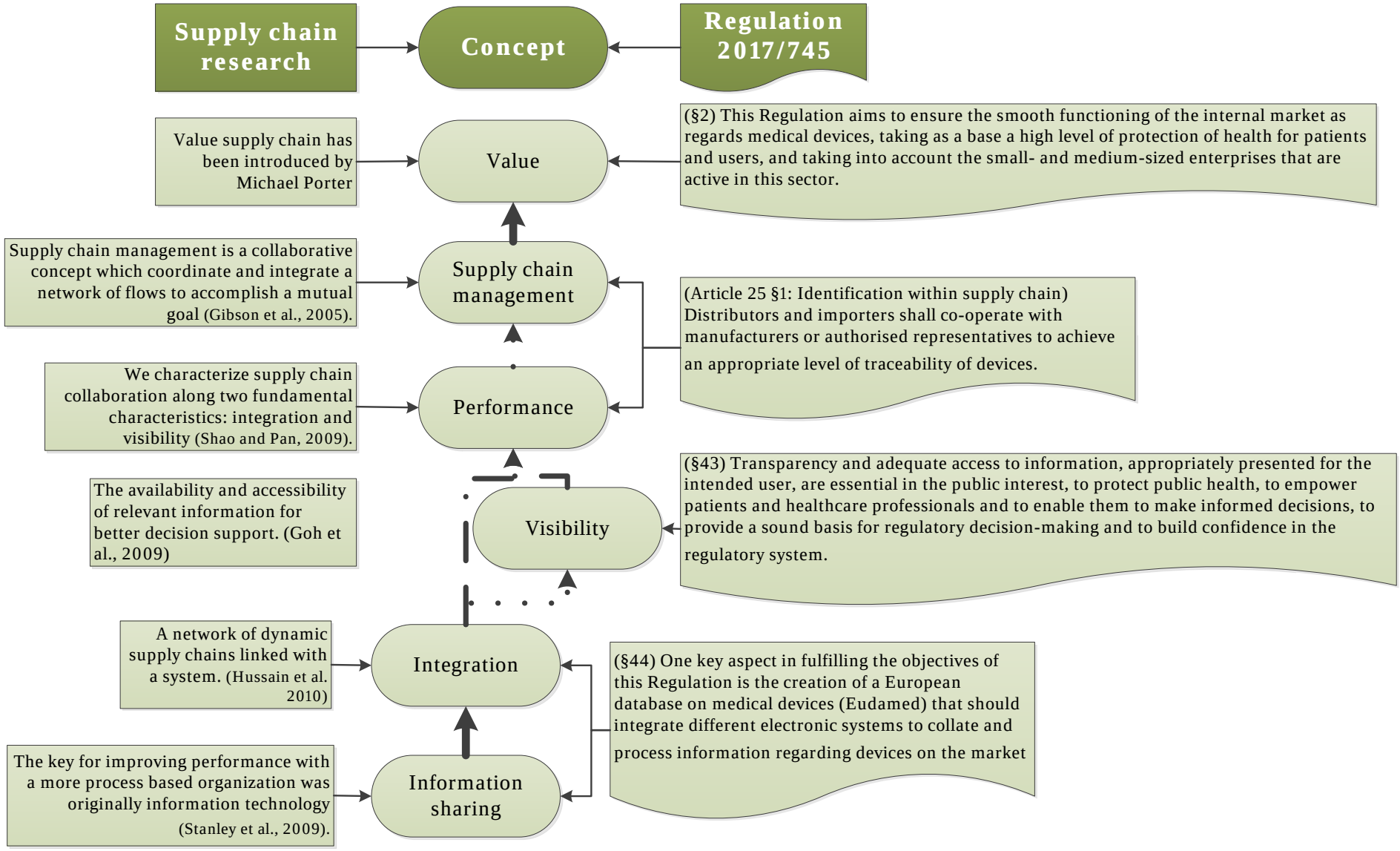

Figure 6:1: A module describing the connection between supply chain academic research and regulation 2017/745 (developed by the author)

to improve the performance and deliver value to end user.

Meagre flows of proper information in the global network of Bactiguard has affected the decision process and can be an obstacle to fulfil the requirements of the new system of medical device (EUDAMED).

Frohlich et al. (2001) argues for internal integration as an essential platform for external information. This fact can explain how internal boundaries in Bactiguard and the use of different platforms of information sharing has limited external integration.

The use of different and un-integrated platforms of information sharing have limited information sharing and decision making process. Mahadenvan (2010) addresses the mechanism of information sharing as a key element for integration performance. The law level of information sharing at Bactiguard, internally and externally, in a wide scope is a result of multiple unintegrated platforms.

6.2 *Barcoding system*

The seconed question of this research is: Can barcoding systems be developed to be used as integration systems or not only as traceability systems. Figure 6:2 presents a module for the connection between integration and barcoding from regulation 2017/745 perspective.

Regulation 2017/745, has enforced the use of Automatic Identification and Data Capture (AIDC) in medical device. As well has pointed out barcodes as one of the available options to be used as UDI-carriers through labeling process. Schwägele (2005), described tracebility as the process of indentifing the origion of item. The author is understanting this discribtion as a one direction of information flow, which is the upstream in this case where supplier and manifacturer send information to enduser. Barcodes has been used in many branch as a tracebility system and presented a valuable results in this field.

In the contrary, Hussien et al. (2010) described integration as a dynamic network. In this case barcodes should be able to carry information in both directions up-, and downstream to be identified as an integration tool. The mechanism of information sharing should be directed to all supply chain players to create the system of integration in the supply chain.

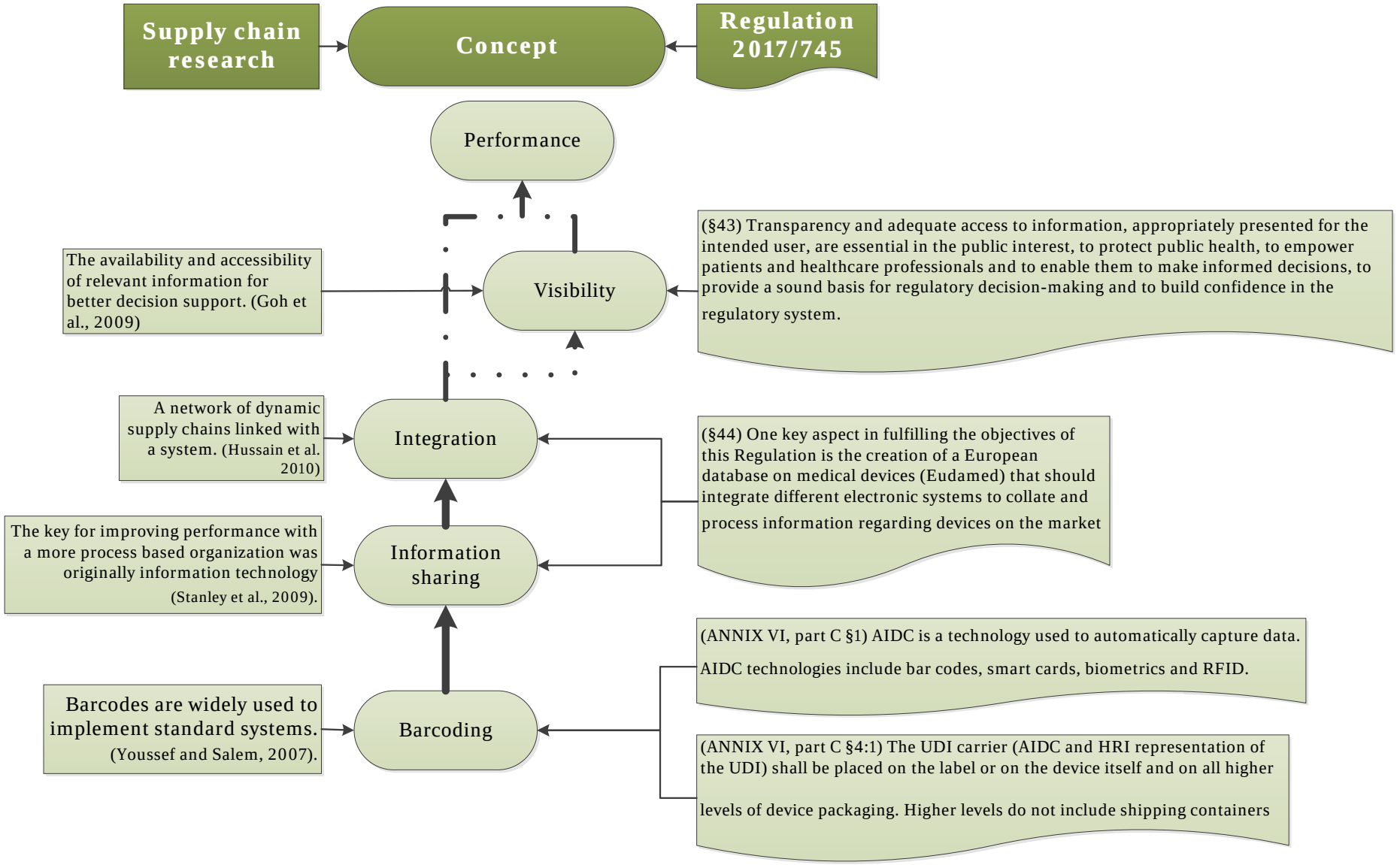

Figure 6:2: A module describing the connection between integration and barcoding from regulation 2017/745 perspective (developed by the author)

Practical findings from case study as well reviewed academic research has not conducted any availability of barcodes to carry information through downstream. In this case from end-user to supplier through manufacturer, and specially in medical device supply chains. Never the less there is no academic research has discussed the possibility of developing the barcode to carry information through downstream.

Based on collected empirical data from case study and academic research, the barcoding systems cannot be developed to be an integration system.

7 CONCLUSION

In this chapter, conclusions will be presented based on the findings and analysis of case study, and recommendations on further research.

This research is aiming to determine the integration level in medical device supply chain and the availability of developing barcodes from only tracking systems to integration system from regulation 2017/745 perspective.

Value creation to end-users is recognized within supply chain a long time ago. Supply chain value of medical device market should be aligned with main value of medical device regulation 2017/745, which is securing a high level of protection of health for patients and users. Value creation can be reached by increasing performance levels and the accuracy of decision-making process. Furthermore, both performance and accuracy are requesting a proper mechanism for information sharing flows through the supply chain.

Supply chain visibly, is the key element for decision-making process. While supply chain integration is the mechanism that coordinate information flows. Supply chain visibility can be defined as the availability and accessibility of relevant information to all involved supply chain entities for better decision support. While supply chain integration is the mechanism of the information flows, in a dynamic status to realize information sharing in the supply chain. In consequence, supply chain integration is the platform for supply chain visibility.

Due to the limited time frame of this study, only one medical device company has been investigated. A similar investigation, including several medical device companies can therefore be interesting to further strengthen the results. On the other hand, the investigation of the availability of barcoding system development needs more and deep analyzing to explore it properly.

During the research, the author noticed that barcoding or any other automatic identification and data capture (AIDC) system was not applied in the case study where it

can affect the analysis negatively. The need to explore this topic from a broader and wider scope can be useful to have.

Nathalie et al. (2006) reports about a lack of studies on supply chain standards as compared to standards in technology development, which might be the reason behind considering barcoding systems are the dominant of information sharing technology in the field of supply chain. One of the delimitations of the research is a focus on the information sharing technology. The applicability of the research in other information sharing technologies that can develop integration in supply chain would be interesting.

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APPENDIX: Interviewees & Interview questions

This chapter is including interview questions used during the case study as well a list of interviewees in Bactiguard AB.

Interviewees:

- Emil Jonsson, QA Director
- Helen Bäckroos, Technical Product Manager
- Johan Rugfelt, COO
- Johan Ställberg, Production Manager
- Patrik Engström, Logistics Coordinator
- Terese Wasell, Regulatory Affairs Manager

Interview questions

General: Regulation 2017/745 §40 - §47, §96 & §97

- Describe your role and responsibilities at the company?
- What are your daily tasks?
- What people do you communicate with (customers, others departments etc.) and regarding what issues?
- How is communication handled with the internally and externally?
- What information is communicated and why?
- Do you receive sometimes incorrect information or is there any lack of information sharing?
- Are you familiar with new regulation 2017/745?

- Are you familiar with (EUDAMED) & (UDI) systems?
- Which data identification standards do you use?
- How many people are involved in standards maintenance?
- What information that is useful to you and can be obtained from the ERP-system?
- Do you know how to get this information?
- Do you feel that further training in the ERP-system could be helpful?
- Do you feel that information is provided in a user-friendly way?
- Do you believe that you have sufficient information to be able to perform your tasks?
- Is there information that could improve your daily work that is missing today?
- Supply chain visibility can be defined as the availability and transparency of relevant information between different supply chain actors (internally and externally) for a better decision. As Bactiguard holds several steps of the supply chain, please describe its level of internal and external visibility today and any possible future needs?
- Supply chain integration can be defined as the systematic mechanism that coordinates information flows between supply chain networks. As Bactiguard holds several steps of the supply chain, please describe its level of internal and external integration today and any possible future needs?

Management, QA and regulatory: Regulation 2017/745 §32, §33, §34, §40, §67, §74, §75, §76, §77, §78 & §98

- What are the effect of medical regulations on your supply chain?
- What events do you track? Is device traceability being important for you?
- How do you perceive whether your need for Supply Chain visibility is high or low?

- How knowledgeable are your key suppliers involved in your production process?
- How do you perceive your level of integration with your partners?
- How is your IT system connected to the other supply chain partners' IT systems?
- Do your suppliers and or your customers require that information be transmitted in a certain format?
- Please describe how your data identification technology works: barcode system handling, degree of RFID adoption, etc.

Product design and post market: Regulation 2017/745 §4, §18, §20, §26 & §29

- How big share of the material's specifications are the same?
- How often can product design be changed or modified?
- Do key suppliers involved in information sharing related to materials and product development, and how?

Production & Logistics: Regulation 2017/745 §37 and Article 2 §8, §13, §14, §15, §23, §24, §30, §33, §34 & 2§35

- How does the supply chain of Bactiguard looks like in general?
- How many customer do you have?
- What customer data do you have access to? Is all this data stored in the ERP-system?
- How is communication handled with customers?
- How many suppliers do you have? how many consider as a key supplier? Are they mainly local or global?
- How do you assess the quality of materials supplied by your key suppliers?
- How often do you reject supplies form your key suppliers?

- Do you use the information material's specifications when creating the orders in the ERP-system? If no, why not? What information may be missing?
- Who is responsible for issuing and placing labels on the final product, and how?