Critical success factors of German medical technology supply chains

Enrique GARCIA-VILLARREAL (egarcia@dr-schoenheit.de)
Loughborough University, Loughborough Leicestershire LE11 3TU, United Kingdom

Ran BHAMRA
Loughborough University, Loughborough Leicestershire LE11 3TU, United Kingdom

Martin SCHOENHEIT
Rheinische Fachhochschule Köln, Cologne 50676, Germany

Abstract

This paper investigates Critical Success Factors (CSFs) that affect the performance of organisations involved in medical technology supply chains (MTSCs) in Germany. German medical technology is an innovative and fast-growing industry, which is currently under pressure to reduce costs. This paper presents an exploratory research involving a multiple case study. Six, prioritised CSFs for OEMs within MTSCs that include sales and operations planning, product development process, as well as quality and compliance were identified through empirical research. These findings challenge existing assumptions about CSFs within MTSCs, providing practitioners with strategies that should help to improve operational performance of OEMs.

Keywords: Supply chain network design and analysis, Collaboration and coordination issues in SCM, Medical technology industry

Introduction

Medical technology is any technology applied to save the lives of people affected by a wide range of conditions and ranges from mass production items such as sticking plasters, syringes or latex gloves, to specific equipment such as wheelchairs and hearing aids, to high-tech devices such as pacemakers, replacement joints for knees and hips, to intelligent contact lenses (Eucomed, 2015). Medical technology is considered to be an innovative, fast-growing and promising industry, particular so in Germany as it is the third largest market in the world behind the United States of America and Japan, (BVMed, 2015) In addition to some large companies, around 1,200 small and medium-sized enterprises (SMEs) constitute the core of the sector (BVMed, 2015). In 2014, the total volume of medical technology manufacturing organisations increased by 2.3% to 25.2 billion euros; domestic sales rose 3% to 8.1 billion euros, while international sales increased by 2.3% to a total of 17.1 billion euros (BVMed, 2015). Despite this impressive growth, the medical technology industry in Germany has suffered several setbacks in recent years. Germany's statutory health insurance fund (gesetzliche

Krankenversicherung) has experienced funding difficulties, forcing administrators to reduce schedule fees and thus expenditures on medical technology (Hartford, 2014). Moreover, the German government is targeting this industry as part of budgetary savings, leading to major cuts in research programmes (EY, 2013). Furthermore, Chinese companies are also gaining technological expertise and are on their way to become global leaders in research and design over the next decade. Studies (J & M, 2010; Mayr, 2013) show that a defined supply chain strategy often falls short in this sector. Therefore, understanding which key features lead to better performance of organisations within Medical Technology Supply Chains (MTSCs) is imperative.

In this paper, we investigate multiple cases of OEMs involved in MTSCs and use the results of the analysis to identify those Critical Success Factors (CSFs) that that practitioners in the field prioritise in pursuing opportunities and areas of improvement which require addressing during the design and implementation of Supply Chain Management (SCM) strategies. These findings are then fully discussed in the light of the extant literature. This paper is organised as follows. First, a review of the literature is reported. Then, the methodology and case study design are presented. This is followed by the analysis and discussion of the findings. Finally, this paper concludes with the implications for theory and management practice along with research limitations and avenues for further research.

Literature review

Supply chain management as an area in operations management literature is extremely well served whereas there is a real dearth regarding its focus on medical technology supply chains and their agility as exemplified by recent literature (Gligor, 2014; Mandal, 2017).

Mentzer et al (2001) define supply chains as a "set of three or more entities directly involved in the upstream and downstream flow of products, services, finances, and information from a source to the customer". There are three major players in the healthcare supply chain: producers (product manufacturers), purchasers (group purchasing organisations, or GPOs, and wholesalers/distributors), and health care providers (hospital systems and integrated delivery networks, or IDNs) (Burns & al, 2002). McCurry et al (2005) provides a detailed view of the healthcare supply chain (see Figure 1).

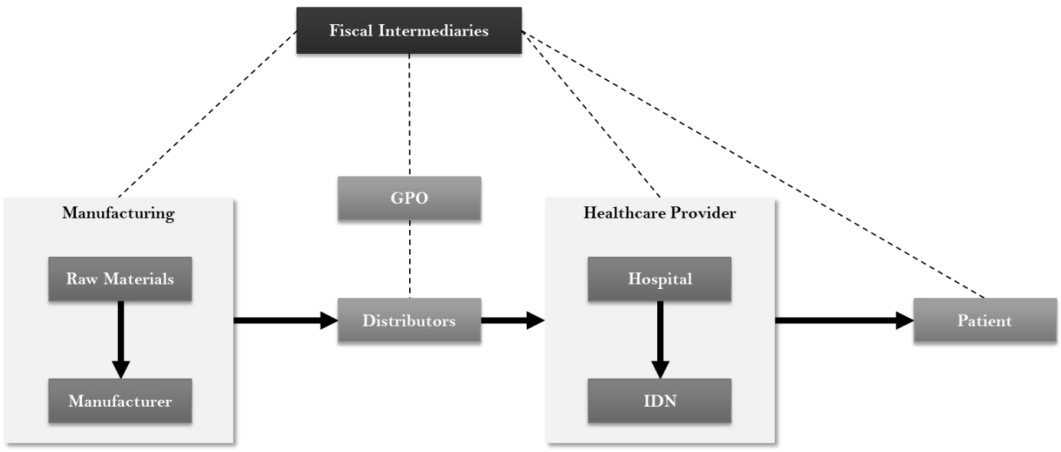

Figure 1: Detailed view of product, information and cash flows in the healthcare supply chain (McCurry et al,2005)

This view is extended to include financial flows as well, underlining the heavy influence of intermediaries or third-party players. Studies by Burns (2000), J and M Research (2010), and Mayr (2013) indicate that a significant portion of the costs associated with supply chains in the health care sector can be reduced by adopting strategies already deployed by the industry sector. In order to provide guidelines for practitioners to adopt the necessary organisational changes, the identification of critical success factors becomes very important.

Critical success factors in Supply Chain Management

There are certain key elements in business that, if working properly, can ensure successful competitive performance for an organisation (Rockart, 1979). Rockart (1979) called these key areas critical success factors (CSFs) and defined them as "areas or activities that should receive constant and careful attention from management". CSFs are used, for example, to identify critical issues in planning implementation, to achieve better organisational performance, to assist managers to execute a better resource allocation, and to serve as guidelines to monitor an organisation's activities (Talib & Hamid, 2014; Boynton & Zmud, 1984).

Early applications of CSFs in logistics and SCM were first found in studies such as Cooper and Ellram (1993), Chiu (1995), and Tate (1995). In the field of SCM, Gunasekaran and Ngai (2003) designed a framework for developing an efficient 3PL system, with factors such as 'strategic planning', 'inventory management', 'transportation planning', 'capacity planning', and 'information management' as the major dimensions. Tummala et al (2006) discovered that resource allocation could be enhanced in areas such as information systems, goal-setting, training, personnel, and aligning SCM initiatives with current priorities and committed resources. Hu and Hsu (2010) employed a survey on the electronics industry in Taiwan to identify 20 critical factors for implementing green SCM, which were then clustered into four dimensions: 'supplier management', 'product recycling', organisation involvement', and 'life cycle management'. Finally, Talib and Hamid (2014) conducted a literature survey of 42 studies and proposed four major CSFs in SCM: 'collaborative partnership', 'information technology', 'top management support', and 'human resources'.

Critical success factors in the medical technology industry

Research on critical success factors in the medical technology industry has been focused towards medical device development, as companies in this market face intense competition, higher degrees of customer sophistication, and where the cost of medical devices greatly influences healthcare systems (Medina et al, 2013). Medina et al (2012) distinguishes between internal and external factors influencing medical device development. Internal factors focus on the organisational context within which design is carried out. Lucke et al (2009) cite the level of experience of designers as a major internal factor. In contrast, external factors relate mostly to cost and profit, research and development (R&D), clinical research, and insurance companies' reimbursement (Medina et al, 2013). Intellectual property protections and overseas market opportunities are identified, among others, as external factors (Medina et al, 2013). Finally, the Food and Drug Administration (FDA), the regulatory agency of medical devices marketed in the Unites States, is suggested as the primary external factor influencing companies' development priorities (Medina et al, 2013). To date, there has been no specific study on CSFs related to MTSCs available in the SCM literature. This paper directly addresses this urgent need from both the academic and practitioner perspectives.

Research methodology

An exploratory research design was deployed, with a multiple case study approach selected, as the literature review revealed limited insights concerning CSFs in MTSCs. In such an embryonic research field, a qualitative research based on case studies can provide better means to identify patterns and develop theory, especially if the relationships between the constructs are undefined (Edmondson & McManus, 2007). As researchers are able to interact with respondents, perspectives are better understood and relevant processes can be closely investigated (Boyer & Swink, 2008). For these reasons, we followed established methodological guidelines for case study research (Eisenhardt, 1989; Yin, 2009). This study was driven by the following research question:

- What are the Critical Success Factors (CSFs) for Original Equipment Manufacturers (OEMs) in German Medical Technology Supply Chains (MTSCs)?

Fifteen in-depth case studies of manufacturing organisations were conducted to obtain a greater understanding of the main issues of German MTSCs. Table 1 provides a summary of the participating organisations.

Table 1: Summary of the respondent demographics

Nr.	Company	Classification according to the GMDN Agency (2012) [1]	Position of respondent	Company size according to IfM (2017) [2]	Number of employees
1	A	Laboratory equipment	Vice President of Supply Chain	Small and Medium Enterprise (SME)	300
2	B	Electromechanical medical technology	Vice President Global Logistics	Large Enterprise (LE)	53 000
3	C	Electromechanical medical technology	Manager of Logistics Planning	Large Enterprise (LE)	12 500
4	D	Non-active implantable technology	Director of Supply Chain Management	Large Enterprise (LE)	3 400
5	E	Electromechanical medical technology	Head of Supply Chain	Large Enterprise (LE)	6 000
6	F	Reusable instruments	Manager of Logistics Planning	Large Enterprise (LE)	4 400
7	G	Hospital hardware	Vice President of Global Logistics	Large Enterprise (LE)	6 300
8	H	Biological-derived devices	Manager of Global Logistics	Large Enterprise (LE)	600
9	I	Non-active implantable technology	Vice President of Supply Chain	Small and Medium Enterprise (SME)	180
10	J	Electromechanical medical technology	Head of Supply Chain Operations	Small and Medium Enterprise (SME)	400
11	K	Diagnostic and therapeutic radiation technology	Director of Supply Chain Management	Large Enterprise (LE)	49 000
12	L	Single use technology	Director of Supply Chain	Small and Medium Enterprise (SME)	500
13	M	Healthcare facility products and systems adaptations	Head of Supply Chain	Small and Medium Enterprise (SME)	200
14	N	Anaesthetic and respiratory technology	Director of Purchasing, Global Supply Chain	Small and Medium Enterprise (SME)	200
15	O	Hospital hardware	Head of Outbound Logistics	Large Enterprise (LE)	15 200

1 = (GMDN-Agency, 2012)
2= (Institut für Mittelstandsforschung (IfM), Bonn, 2017)

A pilot study was conducted (Garcia-Villarreal et al, 2014). This study assisted the authors to generate a justification for the case research design, to implement appropriate adaptations of the data collection plans, and to prepare the next stages of the research on the basis of the pilot study's empirical observations (Yin, 2009).

The primary data collection utilised semi-structured interviews. Following Yin (2009), tests for construct validity, internal validity, external validity and reliability were performed. The data analysis was conducted in two steps: within case and cross-case. All interviews were analysed following the three-step approach of Miles and

Huberman (1994). After individual firm profiles were obtained from within-case coding, a cross-case analysis was conducted (Yin, 2009). Coding was only regarded as complete once agreement between researchers was reached.

Findings and discussion

Six Critical Success Factors emerged as a result of the cross-case coding process. These are discussed in this section in detail.

Joint decision making to match demand and supply with S&OP

Sales and Operations Planning (S&OP) is a both a cross-departmental and cross-organisational process, as it ranges over all operational areas of an organisation and requires inputs of both key supplier and customers (Sheldon, 2006). S&OP is a key process working twofold: it first creates a good overview of future demand trends on the basis of a demand forecast and using input from sales and key customers; then it develops a plan in order to match the forecast against the organisation's existing production and distribution capacities. Nine out of the 15 case companies provided strong evidence to support this factor as critical for success. Managers of almost all interviewed organisations have launched in recent years or are conducting at the moment improvement projects on this area. Forecasting is a core activity of sales and operation planning. Company D developed a tool to compare the current forecast plan with the available capacity budget of all business units, avoiding production bottlenecks, minimising the cost of unsold goods, and increasing on-time delivery to the end customer. As pointed out by Company O, structure, rigour, and the appropriate information platform are required for a functional S&OP process. Here, they set up meetings with clearly defined responsibilities, increased executive participation and visibility, as well as an information management tool that allowed them to gather and feed the appropriate inputs to the process. Based on this, we propose that:

P1 Issues of balancing customer demand requirements and capacity allocation in the supply chain are raised by conflicting goals between departments within an OEM and between organisations in the supply chain of German MT. MTSCs focusing on installing sustainable and robust Sales and Operation Planning systems have a competitive advantage over those who do not.

Reduction of complexity in the design of products and manufacturing processes

Medical technology is one of the most research-intensive industries in Germany (BVMed, 2015). The basis for the economic success of German medical technology in Germany and abroad is the broad range of innovative products it creates. For this reason, the product development process becomes crucial for the supply of innovative products to an organisation's customers (Medina et al, 2013). Respondents consider this factor as highly critical, as the decisions made at the product development process stage account for 70-80% of the product's final costs (Schönheit, 1997). In this context, designers play a major role in the setup of their supply chains and in their degree of complexity. Given the importance of the role of users in the design of products, Company D cooperates actively with surgeons in the design of medical devices and names their finished products after the physician that inspired them.

Activities in product development process have an influence on the performance of other organisational functions, such as procurement, manufacturing, marketing and sales, and service (Schönheit, 1997). Company A launched a project to standardise

information flows between sales, product development, and procurement in order to reduce the risk of increasing their dependency to niche suppliers by increasing their supplier base. These efforts enhanced their material availability while reducing the risk of material obsolescence. Six out of the 15 organisations interviewed have been actively working on shifting the focus from 'developing the best possible product' (Push) to 'designing the most adequate product for physicians' (Pull), an approach that required shifting paradigms present in German engineering organisations – getting away from a traditional engineer's mentality ('made in Germany') to a more customer-oriented and thus economically meaningful approach to design. For these reasons, we propose that,

P2. In order to reduce complexity of future operations, product design requires not only the involvement of physicians, health institutions, and regulatory agencies to enhance product functionality, but also the involvement of stakeholders of the supply chain, particularly manufacturing, sourcing, logistics, sales, and after sales services.

Efficient tracking and tracing brings competitive advantage

The medical technology sector is in a high pressure to deliver products that are safe and effective for patients. Due to the high demands regarding quality, traceability, and security, organisations are requested to deliver documented evidence that the quality criteria regarding processes and products have been fulfilled (BVMed, 2015) and that all manufactured parts can be re-traced, thus becoming an important issue in SCM. A factor rarely found in the reviewed SCM literature, 'quality and compliance' was regarded as critical for success by seven of the case study companies. Many decisions in SCM are influenced by these regulations, as errors can occur during the development, production, sterilisation, storage, transportation or utilisation of medical devices.

Given the critical nature of medical devices and the potential harm failures during the production and distribution processes can cause, implementing effective tracking and traceability processes is critical. Companies G, H, and N, all have designed, formalised, and validated processes and set up information management systems in line with the current technological trend of 'Industry 4.0'. These systems are capable of collecting information and keeping track of products at all the stages of the supply chain (primary production by suppliers, incoming material, warehousing, production and assembly, sterilisation, warehousing, distribution, and utilisation by the customer) and represent an improvement over previous processes, which were characterised as being bureaucratic, time-consuming, and inefficient. With these insights in mind, we propose that:

P3. As supply chain visibility is a capability that customers are increasingly willing to pay for, selecting the appropriate tools requires process orientation. Providing hospitals and clinics with real-time information on product and spare parts shipping status can provide a competitive advantage for MTSCs.

Increasing leverage of OEMs with appropriate procurement strategies

Both purchasing and materials management constitute basic strategic business processes critical for the success of SCM and not just a narrow support function to the overall business strategy. Although studies such as Bhakoo and Chan (2011) have investigated collaboration and e-commerce within healthcare, the medical technology devices has not been the focus. In the context of supply chain management, the employed procurement strategies play a major role in the creation of value for industries in the medical technology sector, as medical devices have a relatively short life cycle in comparison with products from other industries. Conventional procurement strategies (VMI, EDI, Just in Time, Supplier Kanban) are applied by almost all of the large enterprises in this research. All Case companies note that it is important to evaluate

procurement strategies from a holistic perspective and consider the impact these might have in other organisations in the supply chain. Company H warns on using low cost country sourcing as a procurement strategy, as lost margin can be generated at the very beginning of a project when suppliers cannot deliver the agreed quality. Geographical distance, language and intercultural issues can also become barriers as well.

Power relationships also play a role in the selection of the appropriate suppliers in the medical technology sector. Case companies C, D, and K have implemented Just in Time strategies with several degrees of success as a means to reduce stocks, forcing their suppliers to deliver raw material and components in small quantities and on immediate basis. Furthermore, Case companies D, K, and O have implemented VMI, making suppliers responsible for both stock overflows and stock-outs of at the OEMs' warehouse facilities. In contrast, Companies L and M, both SMEs, are not strong enough to put pressure on suppliers to adopt such practices. Hence, we propose that:

P4. Although procurement strategies such as VMI, Kanban, and JIT appear to be more beneficial for large German firms with power over suppliers, SMEs require their procurement strategies to be based on the product lifecycle in order to reduce the risk of inventory obsolescence. Cooperation and process knowledge exchange is beneficial for both OEMs and upstream organisations when designing and implementing alternative procurement strategies.

CRM positively affects the configuration and complexity of SC operations

Customer relationship management CRM) assists organisations in mining available customer data and information in order to understand customer requirements and to improve their value propositions. This involves collecting and logically using customer and other relevant data to build a consistently superior customer experience and enduring customer relationships and an integration of processes, people, operations, and marketing capacities (Swift, 2000). Several respondents noticed that the relationship with end customers has turned more complex in recent years. For instance, Company C has noted a shift of the way they do business with their customers. In the past, they would show up directly at a hospital with a new product in hopes that it would enthuse physicians and purchasing managers with its features and, based on this, they would negotiate prices and number of units to deliver. Nowadays they must negotiate prices with intermediaries such as Group Purchasing Organisations (GPOs). Healthcare providers turn to GPOs in order to save time and money necessary to negotiate thousands of individual contracts. This however, seems to make it harder for some of the interviewed OEMs to get first-hand information on customer needs. For these reasons, we propose that:

P5. German MTSC firms require a shift from pure cost-orientation to service-orientation in order to remain competitive in the market. This is not limited to the strategic involvement of physicians and managers in issues such as product design, but also by designing and implementing tailor-made concepts for logistical supply and after sales services.

Speed to market and flexibility are imperative for MTSC firms' production systems

The objective of an integrated production system is to produce more products in the same or shorter time with less cost while ensuring the expected quality. This is possible when work cycles are as short as possible and all non-added value activities are eliminated or at the very least, reduced. This results in shorter lead times, less work-in-process, and higher productivity for an organisation, which translates into a better

responsiveness of its supply chain (Schönheit, 1997). Company D mentions that a key element to achieve agile, flexible supply chains is a production system that supports them, especially when several links of the supply chain belong to the same firm. Concentrating on changing previous management culture, refining target systems and ensuring process orientation within the organisation where the key elements of the implementation of their production system in several sites. Focusing on added-value activities in the supply chain is critical and restructuring these activities can provide opportunities for improvement. Company M was on the verge of losing a customer due to late deliveries. After the implementation of a Lean Production System in all of their manufacturing plants worldwide (an endeavour that took almost two years), the company was able to improve their on-time-delivery rates by 30% while reducing their fixed costs by 20%. Slow and long supply chains hinder a company's ability to respond quickly to customer demand and, as the life cycles of medical devices are very short, manufacturers face the risk of inventory obsolescence (Li et al, 2006). For this reason, both Companies C and H have focused on improving material flow by streamlining their value streams starting from their suppliers to their distribution centres. They also have focused on carefully defining the information requirements between organisations and the instruments used to transfer this information. Based on these findings, it is proposed that:

P6. Agile production systems that focus on speed to market and flexibility are better suited to support German MT supply chains, as product life cycles are shorter than in other industries. However, consequences of these process changes should be agreed with upstream business partners in order to create win-win scenarios and long-lasting relationships.

Conclusions

MTSCs have received limited coverage in the existing SCM literature, subsumed by generic supply chain research interests. However, in light of the increasing recognition of the importance of healthcare systems, their efficiencies and effectiveness, MTCSs have a key contribution to make. This research is an initial attempt to contribute empirically and practically to not only the wider body of SCM literature, but also work on CSFs along with sectoral focus on medical technologies.

This paper's contribution to theory is threefold. Firstly, the findings indicate that there are six CSFs for German MTSC firms, prioritised as follows: (1) sales and operations planning, (2) product development process, (3) quality and compliance, (4) procurement strategies, (5) customer relationship management, and (6) production systems. CSFs have been the subject of previous research in the field of Supply Chain Management but none has investigated the important and growing MTSC sector, which recent literature has labelled as 'supply chain laggards' (Mayr, 2013); this study provides elaboration and practitioner insight from the perspective of both LEs and SMEs of the German MTSC sector. Thirdly, this paper also clarifies a shift in our understanding of the importance of several CSFs to practitioners, such as information management and inventory management, which have been previously been perceived as more important than they actually are. Importantly, this study highlights pre-eminent factors for the success of SCM which have not been adequately recognised by previous research in particular: quality and compliance, product development process, and the production system itself. This paper provides empirical evidence about which strategies are being used by practitioners in the MT sector in order to improve the performance of their supply networks. Each of the identified CSFs is summarised in testable propositions, which sever as a starting point for further scholarly inquiry. Managers can

use this work as a guideline to develop or restructure their own supply chain policies. The insights from the case study organisations documented in this research will be of interest to organisations both in and beyond this sector.

Limitations and future research

One limitation of this study is that the target group of the case study was the head of the SCM operation of each case company. Although researchers were involved in the discussions in order to overcome this limitation, the insights provided by this respondent group may not be representative of the perceptions of other stakeholders in the MTSC. An additional limitation is the fact that it only represents the context of German MTSCs. Future research into the medical technology sector should seek widening studies that include other countries in order to gain a better understanding of the MTSC as a whole and thus enhance the generalisability of the research findings.

There is great scope for further research that would build upon work in this area. The first entails using the results of this research in order to compare and contrast MTSCs in the US and Japan. Such a study could assist in overcoming the lack of generalisability of this research and test the relationships established in this paper. Future research could also provide further investigation into the relationship between the identified CSFs and the results achieved after implementing strategies based on these factors.

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