Localization of Medical Device Manufacturing in Low- and Middle-Income countries

A study to develop key drivers and inhibitors to shifting manufacturing and assembly of medical devices in Low and Middle income countries

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DELFT IMAGING

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Localization of Medical Device Manufacturing and Assembly in Low- and Middle-income countries

Master thesis submitted to Delft University of Technology

in partial fulfilment of the requirements for the degree of

MASTER OF SCIENCE

in **Management of Technology**

Faculty of Technology, Policy and Management

by

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Preface

This report is written to document the thesis work I conducted as part of the MSc. program in Management of Technology at TU Delft. The research was conducted in collaboration with Delft Imaging. When I decided to move to the Netherlands for my master's study, I would never have imagined this is how my life would be right now. From being a mechanical engineer from my bachelor's to where I am right now, one last step to being a Master of Science graduate in Management of Technology, a lot has happened. I am grateful to all the good and bad times that has helped me reach where I am right now. This research was made possible only with the support of a few people. I would like to take this space and time for expressing my deepest gratitude to all these people.

To begin with, I would like to thank my graduation committee for their valuable guidance and constant support throughout the process. I express my deepest gratitude to my first supervisor, **Dr. Saba Hinrichs-Krapel**, for helping me to gather my thoughts and push me in the right direction. This research would not have shaped the way it is, all the way from its conception, to the end without her constant support and valuable insights. I sincerely thank her for the time and assistance during the research and I could not have made it without her continuous support. I would also like to thank my second supervisor, **Prof. dr. ir. Alexander Verbraeck** for his valuable insights and critical comments which helped me look into the topics from a completely different perspective. Though my interaction with him was limited, his suggestions were highly inspiring and have influenced some of the significant decisions that I had to take during the course of the research. I would further like to thank my chair, **Prof. dr. Cees van Beers**, for helping me gain new perspectives on my research and always asking the right questions to make me better my thesis. I am very grateful to Delft Imaging for having given me the opportunity to conduct my research with them. My journey with Delft Imaging has been going on for almost a year now with projects, internships and the thesis. I will always be indebted to the company and my company supervisor, **Mr. Florent Geerts**, for having been extremely patient with me throughout this journey. He has always stood by me like a pillar of support during the uncertainties. His sincere efforts to help me with this research, which goes beyond that of a company supervisor to being a good friend, will always be cherished by me. I would also like to thank **Dr. JC Diehl** for his valuable comments and support to help me find interview candidates and some very valuable validation and direction on the results.

Finally, I owe everything that I have achieved in my life to my parents and my sister. They have made huge sacrifices in their lives to ensure that I am able to pursue my dreams. I will always be grateful to them for blindly trusting all my decisions and providing me with constant support and encouragement. Thanks a lot for believing in me and I hope to make you proud.

Staying away from my family has not been easy for me and it would not have been possible without my friends especially Sreeja Raghunathan, who has stayed by my side, supported me when I doubt myself and helped me fix errors which I overlooked. My friends have been a family to me away from my family. I sincerely thank all my friends in and away from Delft for their constant support and for having given me some beautiful memories to cherish for a lifetime.

I wish you a pleasant read ahead!
Jitin Gopakumar
Delft, August 2021

Executive Summary

International production, trade and investments are increasingly organized within so-called Global Value Chains (GVC) where the different stages of the production process are located across different countries. Globalization has enabled companies to restructure their operations internationally. What makes GVC different from the usual cross-border manufacturing is that these processes are also taken up by third parties who have no stakes in the company offering the operations. For countries, especially Low and Middle Income Country (LMIC) the opportunity to insert themselves into a GVC is important for their development. It could bring in gains in terms of economic development, technical capability building and better employment.

Multiple industries in today's market are part of the GVC, like the textile industry in Pakistan, fashion and eyewear industry in Italy, the automotive industry in Rwanda, medical device industry in Costa Rica and Switzerland. The medical device industry is very specific and challenging. To shift the manufacturing and assembly process of this challenging sector to a developing country or LMIC could bring in further complexities and/or opportunities.

The research was conducted with Delft Imaging, who provide AI incorporated diagnostic solutions to improve people's quality of life around the world, especially the vulnerable communities around the world. The company currently manufactures and assembles its products within the Netherlands in collaboration with its partners. This research was developed keeping in mind the future expansion plan of Delft Imaging to move their assembly operations to Ghana. Currently, their products are assembled in the Netherlands at Thirona (a sister company) after procuring the required materials from suppliers around Europe and the USA. Through this research Delft Imaging (and other medical companies that want to shift their operations to an LMIC) can learn what the key drives and inhibitors to shifting their operations and plan accordingly.

To achieve this goal, the main research question for the research is formulated as follows:

"What are key drivers and inhibitors to be considered while setting up manufacturing and assembly of medical devices in low and middle-income countries?"

Research Methodology

This research follows a Qualitative approach, where a Triangulation approach was used by using multiple data sources and research methods to achieve a better understanding. In this research, data is collected via Desktop research and Interviews, which could help us converge to useful and valid information. The information found through the desktop research was validated by the interviews. The interview process also brought out new information that was very relevant and interesting, especially from the perspective of a company.

Conclusion

The research found the key drivers and inhibitors to shifting medical device manufacturing and assembly to LMIC. The results can be seen in the figure below.

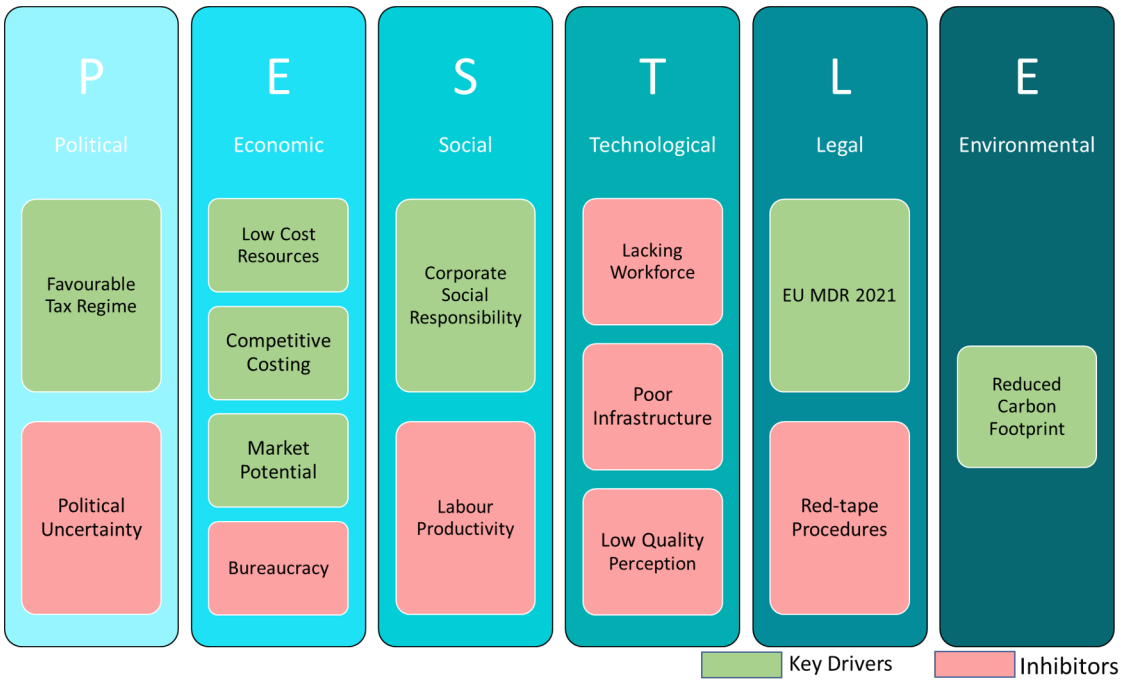

Figure 1: Key Drivers and Inhibitors

These drivers and inhibitors can act as a first step for Delft Imaging (and other medical device companies in High Income Country (HIC)s) to move forward with their shift to Ghana (or other LMICs). These factors should be kept in mind and used to prepare the plan to shift (or not shift). The key drivers act as opportunities that companies can capitalize on. The inhibitors could come up as challenges to the operations of the company unless already considered in the plan. The research also concludes on how the inhibitors should be included in the project plan, with contingencies in mind and move forward.

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Acronyms

CSR Corporate Social Responsibility
EU MDR European Union Medical Device Regulations
FDI Foreign Direct Investment

GDP Gross domestic product
GVC Global Value Chains
HIC High Income Country
LMIC Low and Middle Income Country
RQ Research Question
SQ1 sub-question 1
SQ2 sub-question 2
SQ3 sub-question 3
WHO World Health Organization

1 Introduction

International production, trade and investments are increasingly organized within so-called GVC where the different stages of the production process are located across different countries. Globalization has enabled companies to restructure their operations internationally. What makes GVC different from the usual cross-border manufacturing is that these processes are also taken up by third parties who have no stakes in the company offering the operations. As a result of this collaboration, technology transfer occurs from the foreign firm to the local firm, brings up a multitude of opportunities like the expansion of capabilities including technical, organizational, and managerial skills. They can stimulate other markets related to the ones being set up and eventually lead to an economic upgrade. The added advantage of bringing in the local perspective into consideration could result in better products.

United Nations have no convention of categorizing countries into developed and developing countries. The World Bank classifies countries according to income and this doesnot necessarily reflct developemnt status (Kaplan et al., 2011). All LMICs are considered to be "developing" under the UN (Kaplan et al., 2011). Many low-income countries developed manufacturing activities in GVCs initially through Foreign Direct Investment (FDI), where foreign firms relocated or opened factories in their countries for basic assembly or component production(Nassimbeni, 2003; Whitfield et al., 2020). For many countries, especially low-income economies, the ability to effectively insert into GVC is a vital condition for development by accessing GVC, to compete successfully, and to 'capture the gains' in terms of national economic development, capability building and generating more and better jobs to reduce unemployment and poverty (Fernandez-stark & Gereffi, 2019). Trans-national companies tend to shift their operations and be part of the GVC to utilize the abundant resources available at these destinations such as the workforce, the attractive policy interventions by the countries, and close to raw materials produced for example.

The evolution of GVCs in diverse sectors, such as resource-based commodities, apparel, electronics, tourism, and business service outsourcing, has significant implications in terms of global trade, production, and employment, and how developing-country firms, producers, and workers integrate into the global economy (Fernandez-stark & Gereffi, 2019). Multiple industries in today's market are part of the GVC like the textile industry in Pakistan and New York, the fashion industry in Italy, the automotive industry in Rwanda. There have been introductions of GVC in the medical device industry, especially in Costa Rica and Switzerland. The rising potential of GVC, and the drive for developing countries to step into it provides a welcoming platform to companies.

The development of a new product is essential for the progress and success of any company. The medical device market is very specific, which is challenging. Its design and manufacturing process is complex which requires detailed research, can introduce many risks, and are often uncertain and expensive. (Marešová et al., 2020; Dankelman, 2010) discusses how complexity has increased over time for medical devices and results in three conclusions about the consequences of these increased complexities. One among them is that the devices are often not well designed for the medical environment in which they are used. This issue can lead to higher learning curves, inaccurate test results and/or

could be a danger to the user or patient. To shift the manufacturing and assembly process of this challenging sector to a developing country or LMIC could bring in further complexities and/or opportunities.

1.1 Problem Context

The research is conducted in collaboration with Delft Imaging. They provide affordable and innovative diagnostic solutions to improve people's quality of life around the world, especially the vulnerable communities around the world. Their products include CAD4TB and CAD4COVID AI solutions (different solutions) used to detect Tuberculosis and COVID-19 respectively from X-rays with the precision of an experienced Radiographer, Delft Light, the portable X-ray machine to name a few. The company currently manufactures and assembles their products within the Netherlands in collaboration with their partners, especially on X-ray, Oldelft Benelux (a Canon company) and distributes it around the world as per the requirement. The required components are procured from different countries like the USA, Korea, Italy and finally put together in the Netherlands. The final products are then shipped to their customers. Delft Imaging's major market is in and around Africa. Their branch in Ghana takes care of the post-sales services of the products sold. Delft Imaging works with a wide variety of public and private organizations to develop and implement life-saving technologies like Philips, Canon, Thirona, Friends for International Tuberculosis Relief to name a few.

This research was developed keeping in mind the future expansion plan of Delft Imaging to move their assembly (and pre-staging of CAD4TB) operations to Ghana. Currently, the CAD4TB is assembled in the Netherlands at Thirona (a sister company) after procuring the required materials from suppliers around Europe and the USA. Delft Imaging's prominent market is in LMICs like Africa, Pakistan, Bangladesh, India. The post-market sales and service is handled by Delft Imaging Ghana (previously Universal Delft, a sister company). Delft Imaging, by shifting its assembly operations to Ghana, is hoping to utilize the resources available there and move closer to its market. Through this research Delft Imaging (and other medical companies that want to shift their operations to an LMIC) can learn what factors need to be considered when shifting their operations and plan accordingly.

1.2 Research Objective

The research aims to solve the research opportunity mentioned in the previous section which in turn points towards the manufacturing and assembly of medical products in low and middle-income countries. Studies in GVCs concerning technology transfer and how FDI brings capital and opportunities into a developing country are available, but related to medical devices or health technology is limited. Few other studies looked into the possibilities of local production but concerning the access of medical devices or from the perspective of energy prices. This resulted in the formulation of the main research question,

"What are key drivers and inhibitors for companies to be considered by companies

while setting up the manufacturing and assembly of medical devices in low- and middle-income countries?"

and sub-questions that will help answer the main Research Question (RQ):

Phase I: Exploratory Study

- **SQ1:** *"What are the pros and cons of the global value chain for a company when shifting operations to a low and middle-income country?"*
- **SQ2:** *"How is the manufacturing and assembly of medical devices different in a low/middle-income country as compared to a high-income country?"*
- **SQ3:** *"What are the challenges that arise for a company during the manufacturing and assembly of medical devices in a low and middle-income country?"*

Phase II: Synthesis of Final Solution

- **Research Aim:** *"Derive the key drivers and inhibitors for companies shifting their manufacturing and assembly operations of medical devices to low- and middle-income countries"*

1.3 Thesis outline

This section discusses the format in which the thesis is structured. The Introduction is followed by the Research Methodology in chapter 2.1. Chapter 3 is where a literature survey and desktop research is conducted. Chapter 4 starts with the results of the desktop research and then discusses the interview findings. Section 5.1 tries to bring out the differences in practices between HICs and LMICs. Section 5.2 picks out the challenges of manufacturing and assembly in the LMICs. Chapter 6 combines the results from previous sections to derive the key drivers and inhibitors. Chapter 7 discusses the research and ends with recommendations. Chapter 8 concludes the research compiling the results of the sub-questions and main research questions.

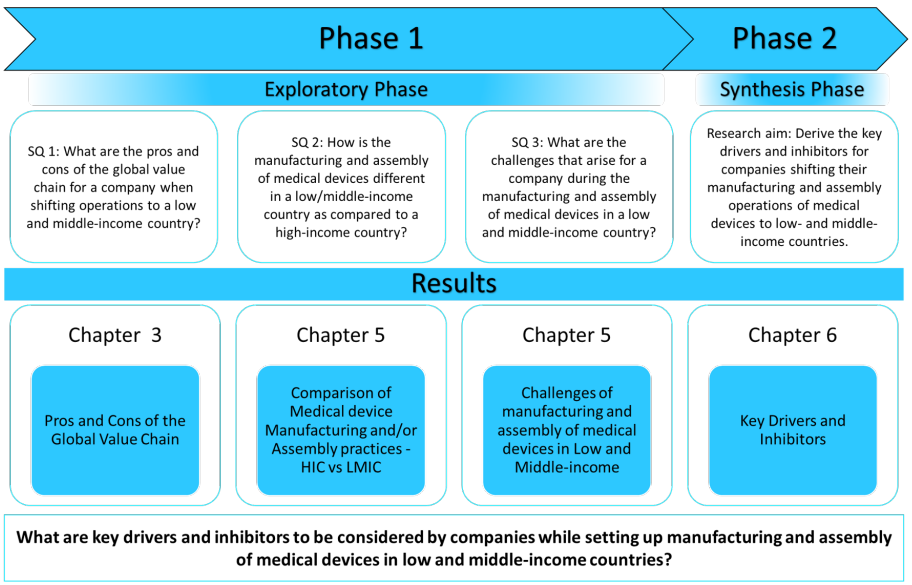


Figure 2: Thesis Outline

2 Research Method

The process of deriving the factors are divided into four parts which can be developed by answering the formulated sub-questions as shown in figure 3. The research question could be considering different factors like local market capability, health technology capabilities, supply chain-related, local assemblage capacity and others when being answered. To answer the RQ, three sub-questions need to be answered which will investigate these aspects individually and once mapped out can be integrated for the RQ. The methods used to answer the different sub-questions will be discussed along with how the data will be collected. The following paragraphs describe how the sub-questions lay foundation to answer the main research question.

The research has been divided into two phases. The first phase is an exploratory study consisting of a study of literature, grey literature and semi-structured interviews with few open-ended questions. The first phase consists of three sub-questions from 1 to 3.

The first sub-question is to understand the merits and demerits of a GVC. This question focuses on the shift of operations in a developing country or low and middle-income country. These merits and demerits will help us understand the extent to which GVCs can be used while organizing the manufacturing and assembly of any kind of product in a developing country. This will also help us give an overview of the challenges and opportunities which will further be dissected. This will be answered purely by literature study of research articles, journal papers, scientific studies and reports found from other than academic publications (after careful review) which will help us understand the GVC clearly by describing the merits and demerits of shifting operations to a low and/or middle-income country. The answer to this question will be one of the three that will be required in the synthesis phase.

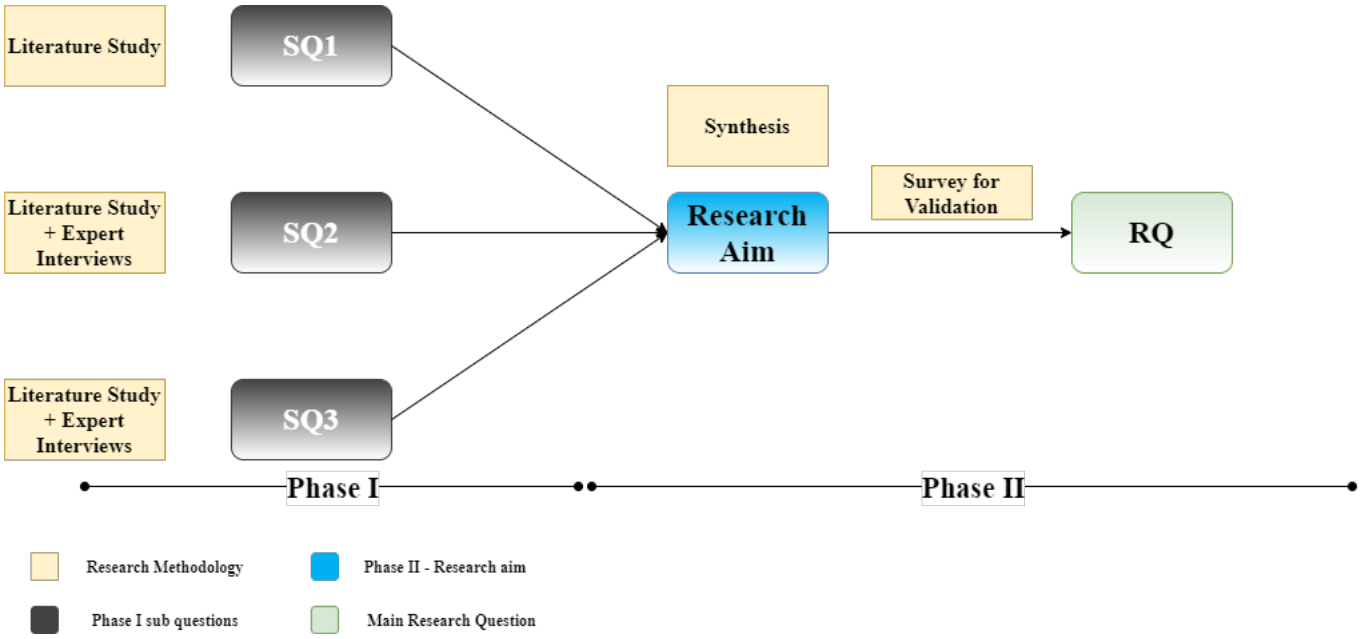


Figure 3: Research Strategy

The second sub-question brings up the major differences in manufacturing and assem-

bly of medical devices in LMICs in comparison to HICs. These differences will help us understand what the practices are specific to the income bracket of the target country. This question will help us understand what are those factors that make it work in HICs and if possible be replicated in LMICs. This will be answered by a mixture of expert interviews and literature studies. The interviews will be towards experts in the field of medical equipment manufacturing and few who have experience in LMIC manufacturing and assembly. The interviewees will be contacts from Delft Imaging who can give more insight into the manufacturing and assembly process in the Netherlands (a high-income country) and university professionals who specialized in projects in developing countries and other connections found via mutual contacts. These differences can be validated by the literature from research papers or journal articles available on the same. These practices will form the second part of the triad required for the synthesis phase.

The third sub-question will bring to light what the challenges of manufacturing and assembly of medical devices are in LMICs, once the practices are followed from SQ2. These challenges can be viewed as opportunities that can be taken up by applying the appropriate actions. This question will be answered by a combination of desktop research and interviews, similar to the previous question. The result from SQ3 will be the third part of the triad required for the synthesis phase.

The second phase is the conceptualization of the solution. This phase is focused on achieving the research aim and is a significant step towards conceptualizing the key drivers and inhibitors for the main research question. It compiles the answers to the first three sub-questions. The factors compiled will comprise the GVC, practices of medical device manufacturing and assembly in low, middle and high-income countries and the challenges in the manufacturing and assembly of medical devices in developing countries.

The results of SQ4 will list out the key drivers and inhibitors to shifting medical device manufacturing and assembly operations to LMICs. The resulted list will be sent out to the interview candidates (in the medical device field) in the form of a survey for validations to finally be able to answer the main RQ. The resulting key drivers and inhibitors will have recommendations on how to exploit these key drivers and on how to overcome the hurdles of the inhibitors. Finally, an action plan is created from the results of the thesis that can be used by Delft Imaging for their future expansion plan.

Health system architecture especially in low and middle-income countries vary across, and governance of these health systems depends on country-specific government roles, mandates, and actions (OECD, 2020). These differences can be advantageous to respond to the local needs but not adequate. The health system requires further support especially in terms of technology. Delft Imaging's future expansion plan of starting assembly in Ghana for its products could help bring this technology into the country and help them provide better healthcare. Through this research, the different aspects of setting up manufacturing, assembly and distribution processes of medical devices in developing countries can be learned. The results can be used by Delft Imaging as a skeleton on how to move forward. Scientific literature can be found individually about Global Value Chains, medical device complexities (design and manufacture), the health technology available in low and middle-income countries but very few integrating or connecting all or a few of them. Different studies bring forward the challenges and barriers faced in the medical

device industry, or how LMICs are lacking in aspects to fully be able to manufacture or assemble products. Very sparse information is available on how to overcome these barriers or what are to be considered when moving these operations. Grey literature in this area can be found in abundance for the formerly mentioned topics. The validity of these should also be considered before using them in this research.

2.1 Research Methodology

When the analysis is done based on the information conveyed through language and natural setting behaviours, the approach can be defined as a qualitative approach. The research conducted also follows a similar approach to achieve its results. Qualitative data are data in the form of words like interview notes, transcripts of focus groups answers to open-ended questions, transcriptions of video recordings, accounts of experiences with a product on the Internet, news articles, and the like (Sekaran & Bougie, 2016). In the qualitative study, a Triangulation approach was used where multiple methods or data sources are used to develop a better understanding of phenomena (Carter et al., 2014). From the four types of triangulation, Method triangulation is used which involves the use of different methods to collect data. In this research, data is collected via Desktop research and Interviews are used which could help us converge to useful and valid information.

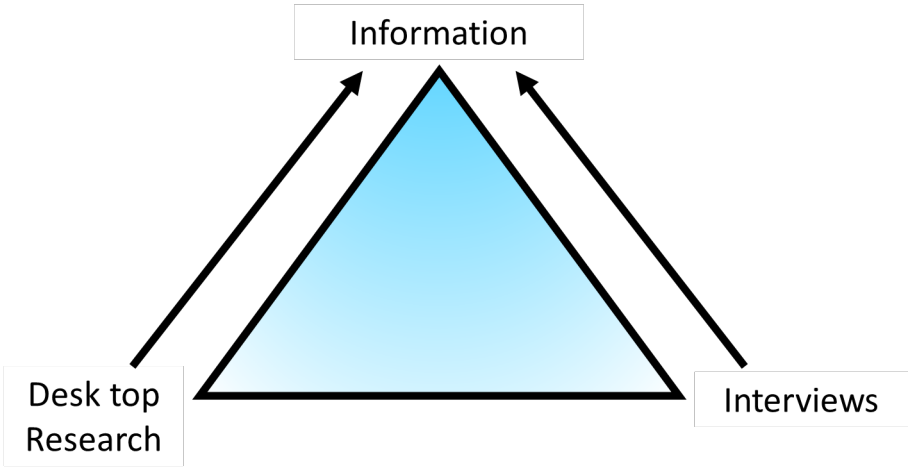


Figure 4: Research Methodology

Data analysis for the two methods used are different. The desktop research uses a literature review which will be discussed in section 2.2. For the interview process, an approach of Miles et al. (1994) will be followed which divides the data analysis phases into three steps: data reduction, data display and drawing conclusions. It should be kept in mind that the three phases are continuous and iterative and not linear. This has been discussed in section 2.3.

2.2 Literature Search

	Concepts: combine with AND			
Synonyms and/or related terms: combine with OR	concept 1:	concept 2:	concept 3:	concept 4:
	Global Value Chain	Manufacturing	Medical Devices	Low and middle income country
	Localization	Production	MedTech Industry	Developing Country
		Assembly	Health Management	LMIC

Table 1: Literature Search - Keywords

The literature search mainly involved using the concepts shown in Table 1 depending on the research methodology. The main platform used to search for literature was Scopus. During initial exploratory search it was seen that combining all 4 concepts together, the results were very poor. The concepts were thus searched as two parts. For part 1, concept 1, 2 and 4 were combined. After multiple iterations the final search string that was used resulted in 375 results. This search mainly answered the first sub question. It was also used to prepare few of the interview questions.

For the second part, concept 2, 3 and 4 were combined to discuss the second and third sub question and prepare for the interviews of candidates closely related to the concepts. The result of that search resulted in only 6 hits. Hence, to not miss out on relevant articles concept 4 was not used for the second part of the search. The second search string thus resulted in 177 hits. The final search strings can be found in Table 2. A detailed list of the search strings can be found in appendix B (Table 19). Although the search mainly used Scopus, other platforms like Pubmed and Google scholar was also used to find articles, conference papers and books. Google search was conducted to find grey literature which could be useful for the research.

When searching for literature related to High Income countries or developed countries and the medial device field, it resulted in 37 hits. Out of the 37 hits only 4 were relevant for this research. This is mainly due to the fact that in a HIC there are definitive regulatory guidelines, legal frameworks and the workforce (knowledge wise) which keeps them structured. Each search was repeated trying to include the necessary concepts and bring the hits down to a reasonable number. Once that was completed the first line of selection was done reading the abstract of all the results. This process eliminated results which were not relevant. The next step was to scan through the shortlisted articles for relevance to the study. This process did not eliminate a lot articles from the shortlist but did bring the number of articles down slightly. Detailed reading of the articles not only eliminated irrelevant articles but also revealed more literature. A snowball approach was followed to gather more relevant articles. This approach is used when we use the reference list or citations from other papers to find relevant articles for the research. After the final short listing, 50 articles (research papers, journals, books and grey literature) were used for the literature review.

Keywords	No. of hits
TITLE-ABS-KEY ((("global value chain*" OR local assembly OR local manufactur*) AND ("lmic*" OR "low and middle income countries" OR "developing countries" OR "emerging economies")))	375
TITLE-ABS-KEY (("medical device" OR "medtech" OR "health technology") AND (manufacturing OR production) AND (assembly))	177

Table 2: Final search strings

2.3 Expert Interviews

An interview is a guided, purposeful conversation between two or more people (Sekaran & Bougie, 2016). It is one of the most effective methods of collecting data in qualitative research as it allows us to understand better and explore the interviewees' opinions, mindset and experiences. From the different available types, a semi-structured interview was used for this research. This type is a combination of unstructured and structured interviews, where more open-ended spontaneous questions are included apart from the formalised list. This allows for further discussions to collect data. The questions were developed using data that was found during the desktop research. The list of questions and prompts that were used for the interview process can be found in Appendix C (11). Before the interviews, a consent form and data management plan was developed. For interviews that are recorded, the consent form was required which mentioned how the data will be anonymized, and what information will be used in the research. The data management plan developed was created to ensure the safety of the data (interview recordings, consent forms and other files). These documents were submitted to the Human Resource Ethics Committee (HREC) for approval. Once approved the interviews were conducted after receiving the signed consent form. Each interview consisted of two meetings, an initial exploratory meeting for the introduction of each other and on the research. Two days before the main interview the questions were sent to the candidates (along with the consent form).

2.3.1 Interview Participants

The candidates for the interview can be broadly classified into three groups:

- **LMIC Manufacturing and Assembly (L):** These are candidates with experience in manufacturing and assembly of products in LMICs. The companies in this group are based out of these countries. Another expertise available in this group are consultants who advise on business development in these countries.
- **HIC Manufacturing and Assembly (H):** These are candidates with experience in manufacturing and assembly of products (medical devices included) in HICs. They have their operations out of these countries and the market in and around them.
- **HIC based LMIC operations (HL):** These are companies who are based in HICs but have their manufacturing/assembly process in LMICs. Their expertise

involves handling suppliers from around the world, contract manufacturers with their main market towards LMICs

Code	Interviewee Expertise
L1	Managing Director of a textile industry in LMIC
L2	General Manager of a Consultancy that helps companies enter LMICs, previous experience in Food Industry
L3	Business consultant for companies entering LMICs
H1	Vice President of Sales and Marketing in medical device industry located in HIC
H2	Managing Director of a medical device industry in HIC
H3	Quality and Regulatory Affairs & Purchasing Manager in a medical device industry in HIC
H4	Product Manager in a medical device industry in HIC
HL1	Chief Operating Officer of a Solar appliance manufacturer based in HIC with operations in LMICs
HL2	Managing Director of a medical device service provider in LMIC
HL3	Chief Operating Officer of a Hand pump assembly based in HIC with operations in LMICs

Table 3: Interviewee code and expertise

The data sources of these candidates were not focused on one country. Figure 5 represents the diversity in the data samples collected. The dropped pins represent where the operations are based for the interview candidates.

2.3.2 Interview Data analysis

The three steps of data analysis for the interview phase can be seen below:

- **Data Reduction:** Once the interviews were transcribed, the software atlas.ti was used. It is a qualitative data analysis software designed to manage and visualize textual, audio or video data. For this research, although the interviews were recorded, as per the consent form, the information was transcribed into a document. The transcribed documents were input into atlas.ti. The next step was the reduction of data through coding. Coding is the analytic process through which the qualitative data that you have gathered are reduced, rearranged, and integrated to form

Figure 5: Data source for interviews

theory (Sekaran & Bougie, 2016). It helps understand and draw a meaningful conclusion. Using Atlas.ti codes were given to these data segments, which portrayed the same information. The process of coding helped bring down the diversity in the data (interviewees from different parts of the world). Once coded, the data can be organized into categories, resulting in patterns and relationships with other parameters. Quantification of qualitative data may provide a rough idea about the (relative) importance of the categories and subcategories (Sekaran & Bougie, 2016). The final list of codes is available in appendix B.

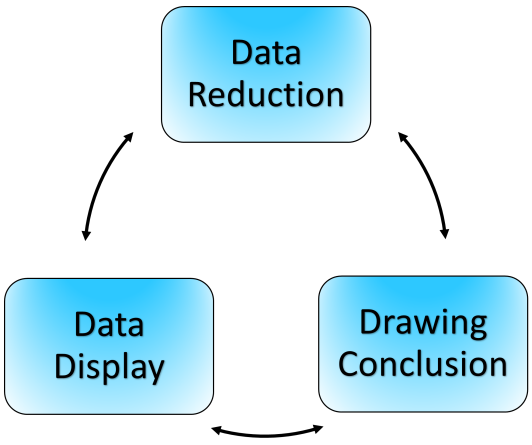


Figure 6: Data Analysis

- **Data Display:** Data display involves taking the reduced data and displaying them in an organized, condensed manner (Sekaran & Bougie, 2016). In the research, using atlas.ti, the data was displayed in a code-document table which summarizes if a code was mentioned by the interviewee as seen below. The findings of the interviews were analysed in atlas.ti. The factors which were mentioned more than or equal to 2 times will be discussed here. In the tables mentioned below, Gr represents the groundedness of the data. It depicts how relevant the particular factor is, i.e., how many times have they been repeated. Each interview candidate is talking about advantages and disadvantages with regards to where their operations are.

	HIC based LMIC operations	**HIC Manufacturing /Assembly**	**LMIC Manufacturer /Assembly**	**Totals**
Blue Gr=11	**x**	0	**x**	2
Yellow Gr=7	**x**	**x**	**x**	3
Orange Gr=7	**x**	**x**	**x**	3

Table 4: Sample code-document table

Relevant quotes of the interviewees are also displayed to convey not just the information but also their emotions during those particular discussions.

- **Drawing Conclusion:** Once displayed, it is at this point where the answers for the research questions are determined by what identified themes stand for, by thinking about explanations for observed patterns and relationships, or by making contrasts and comparisons (Sekaran & Bougie, 2016). This step doesn't stop here but returns to the first step for few iterations to finally arrive at the conclusions.

3 Literature Study

This section starts with the discussion on the literature based on the topics that emerged through desktop research. The first topic is the literature on Global Value Chain (GVC). After discussing the literature, the pros and cons of GVC is brought out from the desktop research to answer sub-question 1 (SQ1). The discussion continues to discuss the medical device industry and the last topic is on the challenges and barriers of local production. The section concludes with a reflection on the topics discussed and the steps forward.

3.1 Global Value Chain

Improvements in communication and information technologies have enabled large firms based in advanced nations, whether retailers or manufacturers, to divide the production chain into specific tasks that can then be dispersed around the globe to take advantage of lower costs, called Global Value Chains (GVC) (Rodrik, 2018). GVCs have evolved into diverse sectors like tourism, electronics, apparel which have affected the global trade, employment and the economy of a developing country. This expansion has been mainly driven by transnational companies who reorganize/relocate their operations mainly due to market competitions and opportunities. GVCs help emerging nations to access the global market by completing specific tasks. De Backer & Flaig (2017) discusses how the rapid growth of global value chains (GVCs) has been an important driver of globalisation during the past decades. Emerging economies have become important partners in GVCs especially in producing manufactured goods. Participation in GVCs is often viewed by governments as a fast track to industrialisation and strategies to increase the participation within GVCs are essentially part of economic development policies.

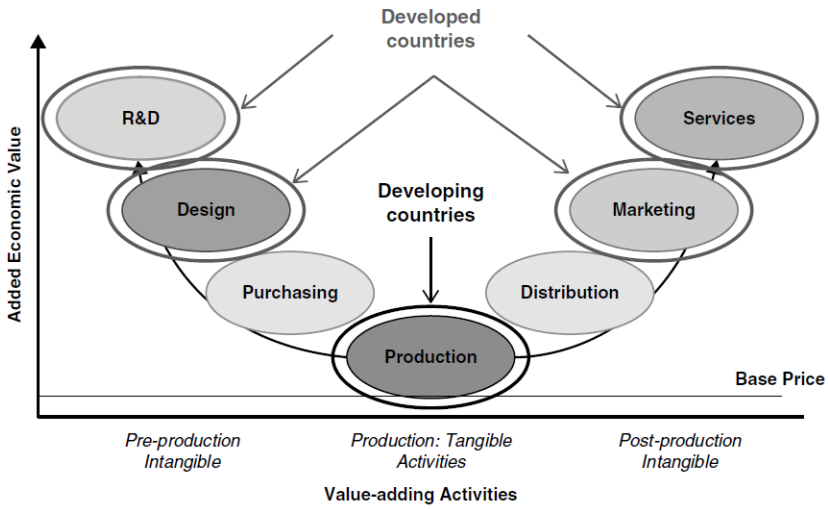


Figure 7: Smile curve of high-value activities in global value chains (Fernandez-stark & Gereffi, 2019)

As shown in Figure 7, HICs are part of the high-value added activities and LMICs in the lower-value added activities. This is mainly due to the lack of skilled work force among other factors like business environment, trade and investment policy, infrastructure as discussed by Fernandez-stark & Gereffi (2019). De Backer & Flaig (2017) studies and

reports how the LMICs are developing and could upgrade by looking into the future of GVCs, although it has to be kept in mind that the model developed in this study is not an exact replica of reality.

Gereffi (2015) also discusses how the emerging economies are playing a vital role in the value chain of a product by being the destination of outsourced standardized activities by companies. GVCs enable LMICs to attract Foreign Direct Investments, skill development by overlapping in business networks of companies by specializing in part of the process. It consists of detailed study of what are the factors that play a role in GVCs and how LMICs can improve their position in the value chain. The study depicts how LMICs can upgrade themselves from the low value added activities (the one which they are part of as per (Fernandez-stark & Gereffi, 2019)) to the high value activities.

World Bank (2014) emphasizes the importance of functional upgrading and development: that is, moving into higher value added activities within the value chain in two ways: seeking upgrading opportunities (within or across activities) or by consolidating and bundling tasks within the value chain. Another report by the World Bank by Taglioni & Winkler (2016) discusses how GVCs can be used for development. Song et al. (2021) proposes policy suggestions that China's high-tech industry can follow to seize opportunities in GVCs.

Abegaz & Lahiri (2021) focuses on the Ethiopian manufacturing sector and examines how FDI and technology transfer/efficiency spillover effects in the sector. Gereffi et al. (2019) discusses the medical device GVC in Costa Rica. Other studies of HIC and LMICs include GVCs in Turkey, Taiwan, Pakistan, India, New York, Italy, Ethiopia, Switzerland and Czech Republic in different industries like apparel, eye wear, med tech (Vlckova & Thakur-Weigold, 2019; Burlina & Di Maria, 2020; Chang, 2012; Bajpai & Sachs, 2000; Javed & Atif, 2019; Whitfield et al., 2020; Hamrick & Bamber, 2019; Doyran, 2013; Gereffi et al., 2019; Bagaria, 2021) which can help us differentiate how the GVCs are set up, what are their major differences, and why they were set up there. These differences can also shed more light towards the answer of the first sub question by bringing out the merits and demerits of a GVC. These pros and cons can be identified by zooming in on why GVCs could be set up in these countries.

Theyel & Hofmann (2020) discusses how manufacturing locations in a GVC affects the organizational agility. Only considering organization agility, the paper suggests retaining manufacturing facilities in the home country for agility of the company (w.r.t innovation and new product development). From the four types of re-organizational activity of companies, the Global network manager uses the advantages of both offshoring as well as retention of facility. This technique can be studied to better understand to develop the factors. The sample size used for this study is focusing on high value manufacturing industries including medical technology, but only companies based in the UK. These aspects more towards the supply chain that the GVC as it is related to not just the value addition for the final product.

Through GVCs multinational enterprises while shifting their operation into LMICs they are investing in the economy of an LMICs. Bajpai & Sachs (2000); Pham et al. (2021) and Abegaz & Lahiri (2021) discuss how Foreign Direct Investments help the betterment of the economy of the country, better productivity and technology transfer due to the

knowledge spillover. Martínez-Galán & Fontoura (2019) observed that higher the GVC participation of HIC, the higher their FDI in LMICs. This aspect also focuses more towards the supply chain aspects.

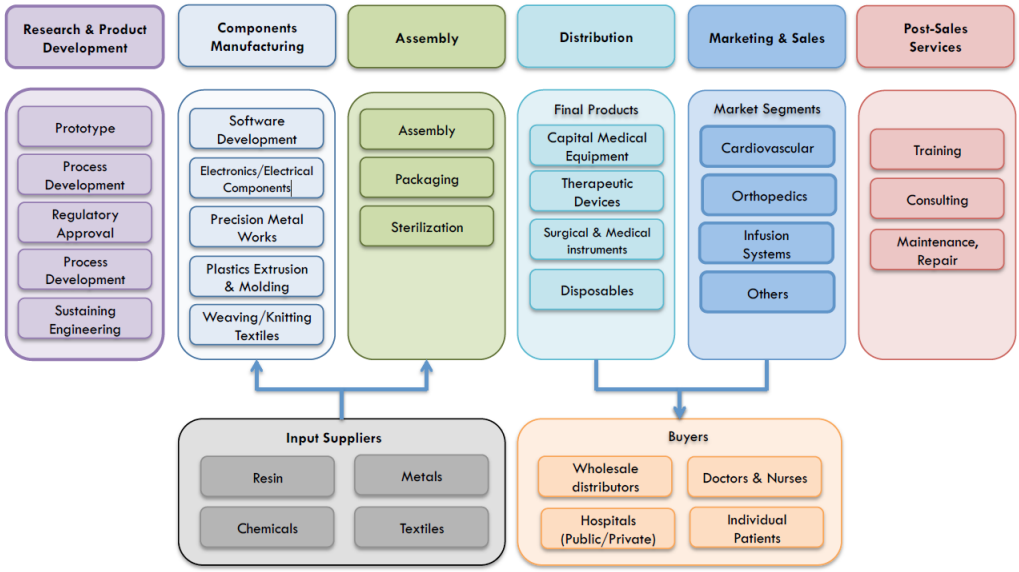


Figure 8: Medical device global value chain (Bamber & Gereffi, 2013)

The desk research done on GVCs has been very helpful. It has enabled answering the first sub-question (SQ1), the pros and cons of GVC in an LMIC. These pros and cons can be listed and will be a step towards the key drivers and inhibitors that will be developed.

Grey literature available like reports by World Health Organization (WHO) (WHO, 2012) addresses the different challenges and barriers faced for local production and technology transfer with respect to access to medical devices. There are World Bank reports as well like the one that was found discussing on how the LMICs can move up the GVC for economic development The information available in this report can be used in the research as well as in the framing of interview questions and validated.

Bamber & Gereffi (2013) as shown in Figure 8 mapped out the GVC of medical devices (for Costa Rica). They provide the different paths that could be taken to upgrade in the value chain. The study was conducted on behalf of the Costa Rica Foreign Trade Ministry, focusing on how Costa Rica can move ahead across the value to chain to hold a better position in the market. The ever growing market does provide opportunities for the same.

3.2 Desktop Research results

From subsection 3.1 we learn the aspects of a GVC and how the it is set up in an LMIC. The pros and cons of the GVC for companies that are considering to shift their operations of manufacturing and assembly was distilled out of the literature, reviewed and discussed in this section to answer SQ1. Learning these merits and de-merits helps us understand the opportunities and challenges that come in when shifting operations to a LMIC. These

pros and cons were selected from there literature where they were mentioned as being an advantage or enabler to the value chain. Similarly for the cons the disadvantages or disabler of the value chain was found.

3.2.1 Pros of the Global Value Chain

As supply chains became global in scope, more intermediate goods were traded across borders, and more imported parts and components were integrated into exports (Gereffi, 2015). This allowed LMICs to gain access to the global market by focusing on specific tasks.

Low cost resources: The first advantage of a GVC especially in an LMIC is the availability of low cost resources, be it suppliers, work force, or raw materials from the perspective of the companies. Low cost is the main factor driving Pakistan's competitiveness as discussed by Hamrick & Bamber (2019). These low resources provide a major opportunity for companies in terms of their total costs. For example, the Czech Republic has established itself a low-cost manufacturing location particularly for automotive industry (Vlckova & Thakur-Weigold, 2019) and now it is one of the most prominent industries at the location. GE Healthcare is another example who located 60% of their manufacturing capacity in LMICs (Ghemawat, 2007)

Skill Development: The second advantage that was found was the development of an institutionalized capacity building where people who take part in the operations develop skills, be experts in a particular section of the process/operations thereby developing a more sophisticated workforce. This can be perceived as an advantage from both the company and county perspective. Companies, localities, and entire countries have come to occupy specialised niches within GVCs period to the point their most significant gains in high and medium-technology industries, which previously were the stronghold of OECD (Organisation for Economic Co-operation and Development) countries were conquered by them. (Gereffi, 2015). (Hamilton & Gereffi, 2009) describes how the suppliers in South Korea and Taiwan were able to expand and diversify in different goods when they worked with the U.S. and Japanese. They enhance their capabilities and infrastructure as they grow bigger.

Developemt of country: The third advantage is the economic development of the country. As GVCs have expanded in scope and complexity, emerging economies have clearly benefited, surging ahead of the advanced industrial countries in terms of export performance (Gereffi, 2015). FDI coming into the country leads to the development of the workforce via knowledge spillovers, better growth opportunities for the individual and country. This is an advantage from the perspective of a country. If the company's Corporate Social Responsibility (CSR) strategies are developed to be coherent to the goals of the company this advantage can also be considered for the company. The majority of FDI activity was directed toward export-oriented production taking advantage of the relatively skilled and cheap labor force, investment incentives and later integration into the EU for some central European countries (Vlčková, 2017).

Uptapped market: The fourth advantage is the availability of a huge market, where the local products are valued far more, untapped market opportunities and an ever growing needs to satisfy. The developing world represents a market size approximately five-times

larger than the developed world (R. A. Malkin, 2007). There is an upcoming trend where people prefer local products than foreign products, mainly to help their economy and cheaper products of similar quality. A study compiled for the Open University in 2012, entitled "It tastes better because . . . consumer understandings of UK farmers' market food" found that consumers were drawn to these markets because of the "producer's passion and commitment to producing high quality food [and] an emphasis on small scale production, where... techniques and recipes are often traditional and local, relying on time-honoured knowledge and skills" (Kasriel-Alexander, 2014).

3.2.2 Cons of the Global Value chain

Here the cons of GVC are discussed which were found from the literature.

Lack of innovation: The first disadvantage that was found was how the operations in LMICs are not closely integrated with the global firm. From the perspective of organizational agility also it was discussed how off-shored operations are affected. (Theyel & Hofmann, 2020) discusses how concentrating on manufacturing in their home countries enables firms to increase organizational agility and stimulate innovation.

Technological Advancement: The second disadvantage is that GVCs make it harder for LMICs to use their labor cost advantage to offset their technological disadvantage, by reducing their ability to substitute unskilled labor for other production inputs (Rodrik, 2018). This disadvantage can be prevented if the incoming firm uses their resources to "set-up" the firm. This "hand-holding" step is very valuable during the initial production/assembly days.

Poor Infrastructure: Productivity issues due to the barriers like unreliable power supply, quality issues or lack of proper technical skills is the third disadvantage found that could occur when operations are shifted. This disadvantage is very specific to the country being shifted.

Political uncertainty: Political uncertainty in the country is another disadvantage to be discussed. This disadvantage could also include the bureaucracy that was found to be a barrier (during exploratory interviews). The best example is how China initially invited companies to set up operations there and once the country was stable drove the companies out keeping their technology and assets in some case due to their policy changes. China's assertive behavior was interpreted by many as an indication that China wanted to maximize its own comprehensive power (Blaauw & Stelt, 2013).

This section answers the first SQ1 thus bringing out the challenges and opportunities companies have when shifting operations.

3.3 Medical Device Industry in LMICs

In this study, medical device covers a wide spectrum of products used in the treatment of patients staring from surgical equipment, cardiovascular devices, diagnostic devices, medical equipment and supplies,ophthalmic, orthopedic and respiratory device.

Medical device industry is fast paced when it comes to its use of new technologies, design or materials to devise better solutions to once those considered impossible. Shih (2008) had demonstrated how the investment in health care is increasing at a surprisingly high rate. Growth in the MedTech industry is driven by rising incomes, and ageing populations, both of which increase demand and rates of innovation (Vlckova & Thakur-Weigold, 2019). In Europe, an average of approximately 10% of Gross domestic product (GDP) is spent on healthcare. It is the second largest market after the US holding 27% of world market (€115 billion market) (MedTech Europe, 2019). Although developed countries still account for the majority of global demand at 70 percent, expanding middle classes in emerging countries represent an important growth opportunity for the industry (Vlckova & Thakur-Weigold, 2019).

3.3.1 Medical device availability

The medical technology segment has tremendous potential. This potential should be recognized by the developing countries including countries and there have been many initiatives to promote the sector (Uwitonze, n.d.). WHO released a report in 2017 bringing a perspective on the global status of medical device policies and its availability across various countries. In order to help build an effective and robust health system, WHO strongly encourages the development of national health policy frameworks that – when implemented – lead to reduced morbidity and mortality, reduced risks and threats to health, and reduced inequity in health (including improved health for women and children) (World Health Organization, 2017).

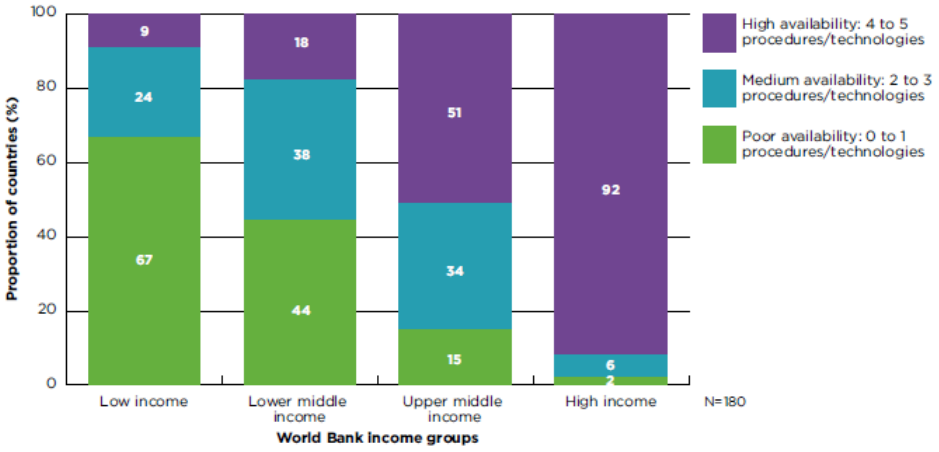


Figure 9: Segregation of (high technology) medical device availability income group wise (World Health Organization, 2017)

Regulation of medical devices is a means of reducing potential health risks as much as possible and enabling patient access to high quality, safe and effective medical devices while restricting access to those products that are unsafe or ineffective (World Health Organization, 2017) which when implemented results in better public health. Figure 9 shows the difference between a HIC and an LMIC in terms of their availability of medical devices (high technology). This is not the case in a HIC due to their advantage of technical expertise, and availability. The absence of this in an LMIC is much higher and could be a reason to the unavailability or their proper usage and acceptance. The report

gives us clear picture in the difference of medical device availability between a LMIC and HIC.

3.3.2 Potential of the industry

The potential of the medical device industry in China, India, Indonesia, and Vietnam is enormous because of each government's promotion of medical care, insurance, and other related policies (Chang, 2012). Over 95% of medical equipment in public hospitals (in LMICs) is imported, there essentially is no local production of medical equipment and, when there is, it is controlled by multinational corporations, often for export (R. A. Malkin, 2007). Dang & Sharma (2019) in their study discuss how in the Indian market the lack of incentives, deficient rules and regulations, import-friendly tax system, and poor research and development setups are some of the factors that not only make India a favourable destination but also increase the imports (of medical devices) in the country.

The opportunities of collaboration with firms in developing countries have increased dramatically in recent years because of two factors: the improving capabilities of firms in developing countries to implement modern technology and willingness of firms to to divide or share products based on manufacturing technologies (Free et al., 1993). Government officials frequently prefer locally manufactured products for a variety of reasons including national pride, use of local versus hard currency, and ease of procurement (Free et al., 1993).

The potential of the industry in an LMIC was discussed in this section. This was mainly done to convey the opportunities that are available in the countries. The lack of locally produced medical devices, the lack of skills for proper use, the acceptance of foreign devices are some challenges that the medical device field is facing in LMICs. Once overcome there is a strong possibility for medical devices to be available, especially in LMICs because of the potential the industry is offering. This discussion makes it clear why the companies are planning to or have already moved operations to these LMICs. This is also a positive outcome to the country where the operations are set up, a win-win for both the actors.

3.3.3 Challenges and Barriers

This section discusses the challenges and barriers that were recognized for local production and assembly in LMICs from the literature survey.

When companies or corporations bring their operations into LMICs, there is a possibility that sub-par products could emerge from these facilities, a major barrier for medical device industry in LMICs. It could be due to the lack of trained technical staff, or reliable infrastructure or power supply (R. A. Malkin, 2007) or quality control issues (R. Malkin & Von Oldenburg Beer, 2013). Bas & Castillo (2016) discusses the differences in regulatory guidelines for biosimilars in Japan and South Korea (HIC) and Malaysia (LMIC). Theses differences in regulatory guidelines can help us understand key points that need

to taken into account when generalizing the regulatory guidelines while setting up production and/or assembly in LMICs. Other studies like Dalglish et al. (2013); Dang & Sharma (2019); Ciurana (2014) and R. Malkin & Von Oldenburg Beer (2013) discuss how the quality barrier can be overcome by rigorous testing and quality control checks, regulatory guidelines, unplanned checks to the factory and a standardised process to eliminate errors and result in better products.

Kaplan et al. (2011) completed a systematic review of literature on local manufacturing of medical technologies and its effect on access in LMICs. They compile and compare the literature to come up with some advantages of local production like competitive costing, reliability of supply etc. While they discuss that in principle local production to be competitive to international producers they found that the locally produced generic versions to be more expensive (6 out of 10). This study compared locally produced and imported medicines. They do mention the extent of cost saving to be product dependent. Similar is the case for the reliability of the supply chain where they mention the condition of local supply chain to improve due to local production but that it cannot be proved empirically. Being unable to conclude these benefits, the next step would be to validate these via interviews which can be used to answer the first sub-question (SQ1) and the third sub-question (SQ3). The study also mentioned about the development of human capital due to local production. A study by Abegaz & Lahiri (2021) also mention how the technology spillover heightens the economy and the people exposed to it (financially and knowledge-wise). Detailed research on the human capital development is out of scope for this research.

Further R. Malkin & Von Oldenburg Beer (2013) discusses the different manufacturing options like contract manufacturing or local manufacturing that can be used healthcare technologies along with the next steps involved with distributors for efficient diffusion of the technology. The study discusses the barriers (disadvantages) and advantages of the options and what could be the best combination. They describe the most successful method used by nearly all working medical devices manufacturers in LMICs is contract manufacturing and using a local distributor who is well aware of the logistics since it is his local market. This can be confirmed using interviews (of candidates related to manufacturing) and be used in the research to plan out how Delft Imaging (or any organization) needs to be set up/ plan out their operations and result in a concrete best practice.

Dalglish et al. (2013) discusses the localized solutions to rising petroleum prices in the health sector in LMICs when moving production. This study can help define the key drivers and inhibitors keeping these long term goals in mind and incorporating the solutions while developing best practices. The challenges and barriers discussed were mainly focused in the areas of quality of final product, local manufacturing practices and benefits that were found during the literature search. We see how in Figure 10 these challenges and barriers are all part of the same supply chain but at different instances in the "chain". The three conditions that exert pressure on supply chain operations of the medical device industry: regulatory requirements, customer demands, new product introductions and the higher inventories required to assure near perfect availability tend to drive up costs (Vlckova & Thakur-Weigold, 2019).

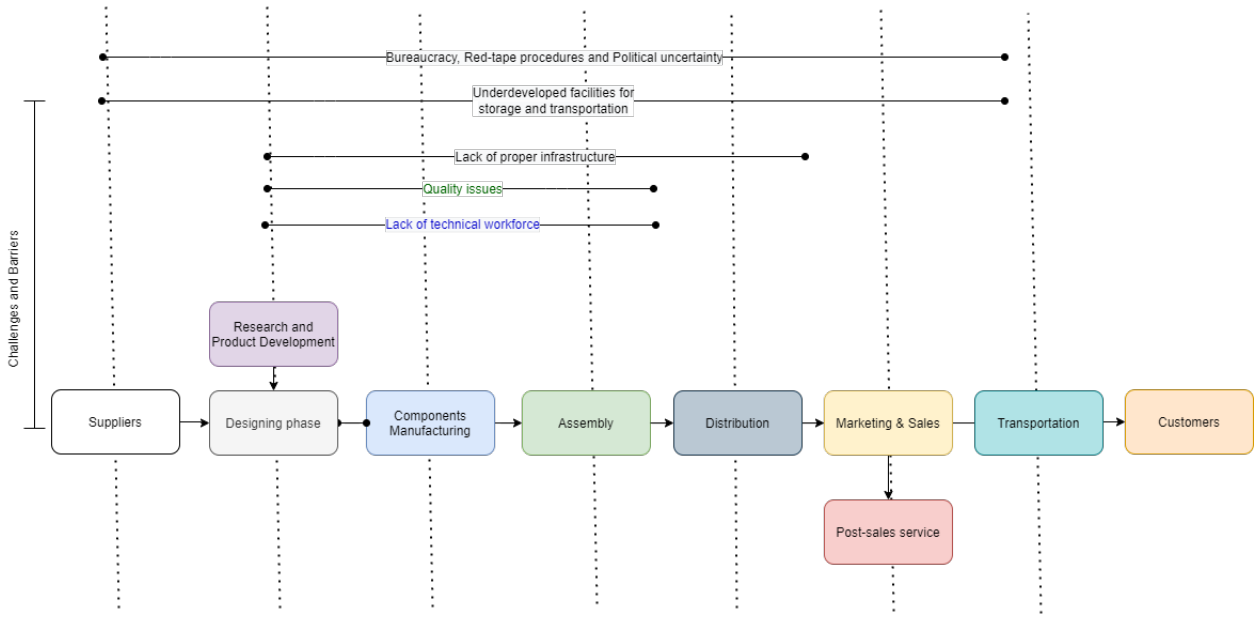


Figure 10: Supply Chain of medical devices

3.4 Reflection

This section summarizes what has been learned through the literature study and reflects on the findings. It also discusses what more needs to be learned through the next steps of research.

During the desktop research the challenges and barriers for local manufacturing and assembly (in LMICs) were recognized and the practices to overcome some of them. The challenge that was noted first was the quality issues of products manufactured and/or assembled in an LMIC. As per the literature study (by Dalglish et al. (2013); Dang & Sharma (2019); Ciurana (2014); R. Malkin & Von Oldenburg Beer (2013); R. A. Malkin (2007))to overcome this barrier by standardized processes to eliminate errors, rigorous testing and strict quality checks, regulatory guidelines to be followed and unplanned checks in the factory that can make sure the resulting products can satisfy the customers. This notion of having only low-quality products can be avoided by incorporating these practices.

R. Malkin & Von Oldenburg Beer (2013) discusses how contract manufacturing provides advantages with respect to scaling of manufacturing, avoid having to learn the local labour laws, customs etc which can increase their speed to the market. The barrier of communication can be avoided by proper training, knowledge sharing sessions. Involving a local distributor who understands local regulations and his/her local market can help overcome the challenge of unfamiliarity in the new market.

As per Bamber & Gereffi (2013) the medical device industry global value chain is set up as shown in Figure 8. The R&D is the highest value segment in the value chain where new products are developed. That is followed by the production segments, the components manufacturing and assembly, usually, the lowest value-added segments in the value chain, usually where LMICs are focused according to Fernandez-stark & Gereffi (2019). The next in the value chain is the marketing and sales phase for the final product. The

post-sale services are also part of the value chain. LMICs play an important role in GVC. Domestic industries have become deeply intertwined through complex, overlapping business networks created through recurrent waves of foreign direct investment and global sourcing upgraded their capabilities in response to larger orders for more complex goods (Gereffi, 2015). As the globalization process progressed companies shifted to emerging economies that provided cheap and abundant raw materials, low-wage workers and a huge untapped market. As retailers and branded manufacturers in wealthy countries became more experienced with global sourcing, developing countries enhanced their infrastructure and suppliers in those countries (Gereffi, 2015). This shift was not very abundant in the medical device industry. Those shifted concentrated their low-value activities in LMICs to exploit the low cost resources.

More clarity on medical device manufacturing practices in HIC needs to be studied. As mentioned in subsection 2.2 the manufacturing and/or assembly in developed countries for medical devices are done with strict regulations, stringent quality control with the presence of a legal framework. These practices need to be studied to better understand what makes it work there are how (if possible) similar standards can be adapted and applied to LMICs.

As mentioned in subsubsection 3.3.3, Kaplan et al. (2011)'s study was inconclusive to find a relation between local production and medical device access. The study although brings out the proposed 'advantages' of local production there is some confusion/ contradiction of the same. As a next step, they will be validated in the interview process to be studied further.

The issue of bureaucracy was not explicitly mentioned in the literature. It was mentioned during one of the exploratory interviews. Further research needs to be conducted on bureaucracy in HICs and LMICs to understand the influence it has on manufacturing and assembly processes.

4 Interview Results

This section discusses the results of the interviews conducted. The interview candidates ranged from experts in the field of manufacturing and assembly of products (both medical devices and others) from both HICs and LMICs, experts from Delft Imaging in the Netherlands and Ghana, contact from TU Delft who have experience in development of products specially for LMICs. Out of the interview candidates, there were companies who have their main operations in HIC and manufacturing and/or assembly process in LMICs. The list of the anonymized interview candidates can be found in Table 3.

4.1 Infrastructure

The term infrastructure can be interpreted in different ways depending on the context it is used. In this research infrastructure is defined as the necessary organizational and physical facilities that is required for the functioning of the companies like electricity,water, buildings, roads etc.

	L1	L2	L3	H1	H2	H3	H4	HL1	HL2	HL3	Totals
Poor infrastructure Gr=11	**x**	**x**	**x**	0	0	0	0	**x**	**x**	**x**	6

Table 5: Groundedness of code - Poor Infrastructure

From Table 5 we can see from the 10 interview candidates, 6 of them have mentioned the poor infrastructure in LMICs as one of the challenge for their operations. The candidates from group H did mention poor infrastructure as a challenge which is in line with the notion that HIC have better infrastructure. L1 mentioned how his company had to stop operations due to unavailability of water for 5 days. L3 mentions,

"Companies like Heineken and Coca cola, in HIC they would typically outsource the logistics, because they can rely in the way they can be done. If you speak to them in LMICs, they will keep ownership of trucks and drivers, because of less confidence in the local resources"

Companies usually tend to keep non-core activities to themselves to maintain the process and quality, which is consistent with Figure 7 where low value activities being common to LMICs. HL3 mentions the lack of digitization being a hindrance to the daily operations of the company.

"the challenge is that they are not yet digital enough, the digitization of their portals. They don't have digital portals to start procedures or to submit proposals. You always have to print things. Give hard copies and soft copies of that, which is also a challenge. They need more hard copies when they can't find the hard copy already given. The second time they can't find the digital copy anymore"

4.2 Technical Workforce

The technical workforce implies the human capital that is required for the companies to function. It includes a mixture of people from low to high skilled at different levels in the organization.

	L1	L2	L3	H1	H2	H3	H4	HL1	HL2	HL3	Totals
Advantage - Cheap labour Gr=10	**x**	**x**	**x**	0	0	0	0	**x**	**x**	**x**	6
Advantage - Competent workforce Gr=7	0	0	0	0	**x**	**x**	**x**	0	**x**	**x**	5
Challenge - Expensive labour Gr=3	0	0	0	**x**	**x**	0	**x**	0	0	0	3
Challenge - Lack of technical workforce Gr=4	**x**	**x**	0	0	0	0	0	**x**	0	0	3

Table 6: Groundedness of code - Cheap Labour, Competent workforce, Expensive Labour and Lack of technical workforce

From Table 6 we see all the candidates from group L and HL have mentioned the workforce to be cheap in LMICs but challenge being the unavailability of the technical workforce. During the interview, L2 discussed how

"Higher echelon staffs, not easy to get good staff members, lower functions it is easier but depends on the product"

Similar comments were mentioned by other candidates who had operations in LMICs except for two candidates HL2 and HL3. HL2 mentions

"I see and have experienced is that the people we have and recruit are highly educated. There's a large number of highly educated people, They are eager, they are very eager to learn. They are dedicated to their job"

But he mentions how this "highly educated" workforce lacks practical experience, to the point where *"some of them have difficulties in holding the screwdriver"*. He adds how they learn quickly because of their higher education level. HL3 on the other hand mentions

"I think talent-wise, it's not a problem"

HL3 is operating in a different country, unlike HL2 where the conditions are relatively better country-wise. The two other factors in Table 6 are similarly correlated. The H group mentions the workforce available to be competent for the job required but expensive compared to the workforce in LMICs. H4 discusses how flexible and competent the

workforce in his company is by mentioning

"Our CEO will tell you like you think about something you think it's an entrepreneurial idea is going to affect so go do it. You don't look at the time you don't look at the money you don't look at anything. So, here you have like this open resources for everything you have and people who can help you" and later mentions *"we are more expensive"*

A point to be noted is that even though the labour cost is lower the productivity of the workforce in LMICs is low. L3 points this out by mentioning

"The cost of labor tends to be lower but at the same time, and that's where my warning goes out, the productivity levels in some countries are dramatically higher that even if cost of labor is twice as high the value proposition is much higher"

4.3 Quality

From subsection 3.4 we learn how the quality of products manufactured/assembled in LMICs can be guaranteed.

	L1	L2	L3	H1	H2	H3	H4	HL1	HL2	HL3	Totals
Quality checks Gr=11	**x**	**x**	**x**	**x**	**x**	0	**x**	**0**	**x**	**x**	8
Quality standards Gr=15	**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**	10
Strict Quality Regulations Gr=6	0	0	0	**0**	**x**	**x**	**x**	0	0	0	3

Table 7: Groundedness of code - Quality checks, Quality standards and Strict Quality regulations

From the interview process we can see how all the companies have quality standards and quality checks as part of the process to make sure the final products satisfy the customers. We see how the strict quality regulations are specific to the H group. H3 during the interview mentioned

"Lesser amount of issues occur in an HIC because of documents present, strict quality standards and regulations"

During the discussion, H2 stressed the point of how strict these regulations are. During the interview process, when asked how strict their quality tolerance is, as it was noticed how companies in LMICs had a longer range of acceptance than HICs. For example, L1 mentions

"So out of 10 we stick to a minimum of 8.5 for our products", similar is the case for HL2 who says *"we said in our quality policy that we want to be not less than three, on the scale of five. Gradually, I foresee that we gradually increase that"*

	L1	L2	L3	H1	H2	H3	H4	HL1	HL2	HL3	Totals
Focus shift from Cost Gr=6	0	0	0	0	0	**x**	**x**	**x**	**x**	**x**	5

Table 8: Groundedness of code - Focus shift from Cost

Another interesting factor that came up during the interview was how the cost was not the most important factor for these companies (seen in Table 8) but their focus shifting to customers and customer satisfaction as a key quality indicator. HL2 discussed how they are integrating the customer feedback by

"We do customer surveys. We survey our customers after training, after an installation, after servicing. We surveyed them systematically so every customer is receiving a survey"

4.4 Market Proximity

	L1	L2	L3	H1	H2	H3	H4	HL1	HL2	HL3	Totals
Close to market Gr=11	**x**	**x**	**x**	0	0	0	**x**	**x**	0	**x**	6

Table 9: Groundedness of code - Close to market

From the interviews it was seen how the marked candidates/companies preferred to be closer to their market. The point to be noted is that these factors can be generalized but need to be customized and adapted according to the country and product in the discussion. Some of the perks of being closer to the market as described by HL1 are as noted in the following quotation.

"The advantages are from distribution because you're closer to the markets, right, so distribution, marketing and sales, post-sales service, customers, all of that is a lot better if you are close to where you're selling". L1 from his perspective also adds *"With respect to innovation you being closer to the market, you are aware of what is the competition, ahead of the competition and scouting the market and make the move much early"*.

4.5 Bureaucracy and Political Uncertainty

	L1	L2	L3	H1	H2	H3	H4	HL1	HL2	HL3	Totals
Challenge - Bureaucracy and Political Uncertainty Gr=20	**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**	10
Challenge - Redtape procedures Gr=6	0	0	0	0	**x**	**x**	**x**	0	**x**	**x**	5

Table 10: Groundedness of code - Bureaucracy and Political Uncertainty

From the interviews it can be seen in Table 10 that bureaucracy and political uncertainty is common in all countries irrespective of the income level of the country. Most of the interview candidates, during this phase of the interview, were very frustrated and were venting out the troubles they faced due to bureaucracy. L1 mentioned,

"A scenario we had with tax authorities, how they ask for a certain number of permits if bribed the process moves much quicker than the official process. It is sometimes not easy". A similar issue faced by L2 was *"The reliability of Government and authorities, like corruption. Even after following all the procedures, there could still be a problem because someone needs an "envelope", not always the case but still a challenge"*.

Similarly, H1 discussed how *"They got you by the short hairs. It was roughly 8000$ to get 200 boots by air freight vs 4000$ to get 3000 boots via containers. So they got us in a position where they can raise prices because your alternative option is too costly"*. HL2 also mentions the difficult process that was gone through, *"So for a country manager, there in South African to get a work visa for him in Malawi, the process is an absolute nightmare"*.

It should be kept in mind that. as L2 mentioned, *" These are not common cases. 90% of the cases are successful but we are all interested in that 10% and find flaws in the system that way"*. A common solution that can reduce the uncertainties is by proper documentation and applying for the necessary permits. A local liaison can also help bypass many of these hurdles since they are aware of these procedures.

4.6 Local Liaison

A local liaison is someone who is from the particular country the company has operations and has knowledge of the regulations, process and market specific to the country.

	L1	L2	L3	H1	H2	H3	H4	HL1	HL2	HL3	Totals
Local liaison requirement Gr=10	**0**	**0**	**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**	8

Table 11: Groundedness of code - Local liaison requirement

From Table 11 it is seen all candidates except L1 and L2 mention a local liaison required when operating in a country (that is not the base country) who can help with the government procedures, local laws and tax calculations to avoid "nasty surprises". L3 mentions

"One of the key advisors is a tax advisor who gives you advices on what taxes will hit you, import duties, and other. He is a pretty key element in the decision of setting up operations in a country".

H1 mentions that *"Best way of action is always be ready with proper documentation and a good liaison to particularly in LMICs, they are critical".*

HL1 already has a local liaison who helps them with these procedures, *"When it when it comes to like, import duties, and that sort of stuff, we have a clearing agent that knows all of those things. And then when it comes to real sort of, you know, legal stuff. Yeah, we obviously work with local lawyers that, that know that way around the local laws"*

H3 also mentions *"A local liaison would help in navigating through the red tape procedures and bureaucracy".*

L1 and L2 are exceptions here because they are already working in a LMIC. They are aware of the procedures and how to move forward.

4.7 EU MDR 2021

The new EU MDR, with the date of application set for 26 of May 2021, imposes stringent requirements that need to be met before such tools can be applied in clinical practice (Beckers et al., 2021). Viewed from the perspective of companies in this segment, the conditions for the production of medical devices are demanding, both with respect to implementation and costs (Maresova et al., 2020).

	L1	L2	L3	H1	H2	H3	H4	HL1	HL2	HL3	Totals
EU MDR 2021 - Unrealistic Gr=4	0	0	0	0	**x**	**x**	**x**	0	0	0	3

Table 12: Groundedness of code - Unrealistic EU MDR

H2 said *"The new medical device regulation has some plus points as well as problems to it from the perspective of a manufacturer. It is really unrealistic, the people who wrote is don't really know manufacturing process".* Similarly H3 during the interview mentioned *"In the recent EU MDR, too much regulations are absolutely counterproductive, especially for companies with R&D and specialized products".*

Companies decided to spend their "time and money" in countries other than the US due to its regulatory restrictions, which resulted in companies shifting to Europe. A similar trend is seen with the introduction of the new EU MDR. This could open up possibilities for Asian and African countries. During the interview process candidates from Europe specifically mentioned how unrealistic these new regulations are that could even lead to

SMEs stopping medical device production or move away to a more suitable country with regulations more suited to them.

4.8 Competitive Costing

Products that are manufactured or assembled in LMICs are able to competitively cost themselves against the competition.

	L1	L2	L3	H1	H2	H3	H4	HL1	HL2	HL3	Totals
Competitive costing Gr=7	**x**	**x**	**x**	**x**	0	0	0	0	0	**x**	5

Table 13: Groundedness of code - Competitive costing

L1 mentions *"Our products are much lower than the cost of products from developed countries but slightly expensive that the products coming from the "far east" like China or India"*. Similar comment was mentioned by HL4 as well, *"You are able to competitively cost your products against your competitors to give you a better margin"*.

An important point that needs to be noted is the name a company could be tagged with when discussing the costing of the product. L3 mentioned how *"Clothing companies like Primark producing in Bangladesh, India, and China, the people working there are not in decent pay and working conditions, that is becoming a problem for Primark as a company. They are cheap but more and more people are recognizing the tag of being cheap, somebody else if paying price of that product"*. Companies should keep in mind an image of "cheap" could be tagged to them, which in turn hampers their reputation.

4.9 Contract Manufacturing

	L1	L2	L3	H1	H2	H3	H4	HL1	HL2	HL3	Totals
Contract manufacturing Gr=7	0	**x**	**x**	**x**	0	**x**	**x**	0	**x**	0	6

Table 14: Groundedness of code - Contract Manufacturing

As discussed in section 3.3.3, most medical device manufacturers use contract manufacturing. From Table 14, we can see that contract manufacturing practice is followed by majority of candidates. *"contract manufacturing is a common manufacturing practice here"*, as pointed out by L2.

4.10 Miscellaneous

	L1	L2	L3	H1	H2	H3	H4	HL1	HL2	HL3	Totals
Advantage - Ease of communication Gr=2	**0**	**0**	**0**	**x**	**0**	**x**	**0**	0	0	**0**	2
Advantage - Economic development of the country Gr=10	**x**	**x**	**x**	0	0	0	0	**x**	**x**	0	5
Advantage - Favourable tax regime Gr=8	**x**	**x**	**x**	0	0	0	0	**x**	0	0	4
Challenge - Cultural Differences Gr=3	0	0	0	0	0	**x**	**x**	0	0	0	2

Table 15: Groundedness of code - Ease of communication, Economic development of the country, Favourable tax regime and Cultural Difference

All 3 candidates from group L, HL1 and HL2 (as seen in Table 15) believe that their operations in LMICs in turn help in the economic development of the country by creating employment, paying their taxes and in turn fill their Corporate Social Responsibility 'meter'. HL2 mentions

"We employ 200 peoples, in terms of our tax contribution to that local suburb is quite significant. we are one of the biggest companies in that area".

The favourable tax regime available in LMICs, in terms of savings on import duties, the special trade zones available and customs union benefits attract companies to move their operations. L3 mentions

"What attracts companies are tax holidays tend to attract business. A lot of the advantages of a free trade zone can be replicated on paper by granting exemptions in import duties and such".

The cultural difference between companies operating in different countries was mentioned as a barrier to shifting operations/ having operations in LMICs by H3 and H4.

	L1	L2	L3	H1	H2	H3	H4	HL1	HL2	HL3	Totals
Challenge - Logistics Gr=11	**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**	0	**x**	8

Table 16: Groundedness of code - Logistics

All the candidates mentioned Logistical challenge to and from their sites. The group L describes the lack of proper roads and port as the reason (Poor infrastructure). L3 mentions

"I think few logistic hurdles like the roads, the transport systems are difficult and will take a bit longer (travel wise)"

Group H has major issues when it comes to shipping, due to the higher costs as well as congestion in these ports. Group HL is a combination of both the challenges of group L and H. H2 points out the developed roads and other related products.

5 Medical device manufacturing and assembly practices - HIC vs LMIC

5.1 Comparison of practices

The first sub-question was answered in the previous section depicting the pros and cons of the GVC. This section discusses the differences in manufacturing and assembly practices of HICs and LMICs. These differences would be helpful in distinguishing what 'clicks' in a HIC and if these can be implemented into practices in LMICs. The comparison will be done under categories that bring out the differences in the process. The practices of companies in LMICs from the literature and interviews and those of HIC from interviews were found and compared in this section.

Infrastructure

The term infrastructure can be interpreted in different ways depending on the context it is used. In this research, infrastructure is defined as the necessary organizational and physical facilities that are required for the functioning of the companies like electricity, water, buildings, roads etc.

Low investments and maintenance over the past two decades have deteriorated LMICs public infrastructure (Bamber & Gereffi, 2013). Firms in these countries find it challenging with the poor infrastructure that is available for them. They tend to work with alternatives, multiples sources to prevent stop in operations. During the interviews, L1 mentioned how his operations had to be halted due to the unavailability of water. Other interviewees also mentioned how poor infrastructure is a challenge for their operations as seen in section 4.1

In HICs the availability of great infrastructure enables the smooth operations of the companies. As discussed in section 4.1 poor infrastructure was never a barrier to their operations. Having operations in HICs they can use the resources of the country without hurdles.

An interesting point to be noted from Table 16 is that all (almost) the interview candidates did have trouble concerning logistics, poor roads in LMICs and expensive and time-consuming transportation of products (raw materials and final) in HICs.

Technical work force

Gereff et al. (2016) discusses the different types of work in a GVC. It is seen how as the complexity of the activity is increasing a higher education level is required. From Figure 7 we see how different value activities are set up usually.

One thing the LMICs have in common is their vast and rapidly growing labour force, which gives these countries an advantage especially in labour-intensive industries and activities (De Backer & Flaig, 2017). During the interviews, all the interviewees except one based in LMICs mentioned how difficult it is to find a person with the right technical skills (4.2). The exception mentioned how the education level of the candidates in the

country is rising but lacking practical knowledge.

None of the interviewees from HICs mentioned the unavailability of the technical workforce. The supply chain manager of the companies in Switzerland cites the availability of highly skilled workers as one of the reasons for their locating operations there (Vlčková, 2017). Their 3-tiered vocational system is highly regarded because of the industry collaboration with educational institutions. Although expensive the workforce is considered competent to carry out the operations in HIC. There is no scarcity of finding the right person, especially for middle and senior-level staff.

During the interview process, a point raised by candidates from LMICs is that even though the labour is cheap and can be found in abundance (for lower levels), their productivity is also lower. The labour laws present in these countries *"are strong and old fashioned labor law – good for individuals but barrier for company."* - L1

Quality

Companies implement multiple strategies to ensure they result in products that are of the best quality. Quality is one of the primary governing factors that decide its existence in the market.

A common problem is the perception or reality that the quality of the device will be inferior in LMICs. The interviews conducted for both the groups (HIC and LMIC) is that everyone practices strict quality checks and standards followed. These practices ensure that the final product developed satisfies their quality audits. The major differences to be pointed out are with respect to the tolerance of acceptance for the final product as seen in 4.3. From the interviews, it is understood that the range of acceptance is higher. Another difference is how companies are shifting their focus from cost to customers. By including customer feedback and customer satisfaction as a performance indicator can eventually drive the product quality higher.

Cost of inputs

The cost of inputs includes the raw material costs, labour costs, overhead costs and other costs which add up to the total costs of the product. This aspect is very product and country dependant. For example, if you are procuring raw materials from LMICs they tend to be cheaper than similar products from HIC. From a general point of view, it is found that in LMICs the total cost of inputs are much lower than HICs.

Competitive costing

This comparison is very location-based. There is a clear distinction between the price of the products that are developed in HIC and LMICs. The products from HIC are on the expensive side when compared to products that are developed in LMICs. There is a difference in the cost of products even within LMICs. As mentioned in the interview (4.8), the products developed in Africa tend to be costlier than the products developed in China.

Innovation

LMICs tend to be concentrating towards low-value-added activities as discussed by Figure 7. Theyel & Hofmann (2020) mentions the full benefits of having operations in HIC can be realized when interpersonal communication and face-to-face interaction are facilitated, thereby avoiding innovation barriers caused by cultural misunderstandings, intermittent workflows due to time differences and imperfect audio-visual communication. Contrary to this, during the interviews, there were different opinions. It was mentioned by interviewee L1 (4.4) that is closer to the market allows you to keep track of the competition, understand the market and be proactive with product development.

Bureaucracy

In section 4.5 it was mentioned that bureaucracy and political uncertainties are present irrespective of the income of the country. The biggest challenges faced in LMICs are corruption, permitting issues (lapses from both company and organization who issue them). Due to a permitting lapse, one of the interviewees' ships was not allowed to enter the port which ended up costing him/her $60,000 * 42 days. Import exports is a challenge from the perspective of HICs, the costs of shippers and air freight, some political changes like Brexit, for example, can affect the operation.

Communication

Interviewees in HICs mentioned that it is very easy to communicate and transfer information to another point of contact in HICs. The difference in language, culture and time zones in LMICs tend to make communication harder. H3 mentioned *"In LMICs there are 7-8 contact persons. because everyone is doing a specific role and this can lead to potential mistakes."*. He was particularly vocal to mention this barrier as one of his biggest challenges to operations.

5.2 Challenges in Low and Middle-income countries

This section discusses the challenges medical device companies have when manufacturing or assembling their products in LMICs. This section answers the sub-question 3 (SQ3),

"What are the challenges that arise for a company during the manufacturing and assembly of medical devices in a low and middle-income country?"

The answer to this sub-question helps us get a clearer picture of challenges and barriers that companies face. These challenges can act as a baseline, seen as opportunities that can be exploited to better the process and eventually add value. The challenges that were mentioned in the literature study, from the interviews and from the previous two sub-questions helped develop answer SQ3.

Lack of technical workforce:

From section 4.2, it was made clear the abundance of workforce available is not able to

satisfy the requirement of companies who require technical skills. The available skilled workforce is very limited. Many learn during their experience in companies and rise. But that is a very time-consuming process. A similar point of view was expressed by HL2. Most of the essential skills for a successful biomedicine manufacturing sector may already be well developed in certain countries (like India, Thailand, South Africa) with academic institutions (Kaplan et al., 2011). HL3 also mentioned how the educational system is developing and much better compared to how they were in the past.

Lower labour productivity

Although the labour cost is low, another challenge that companies face is the lower productivity of the workforce present there. L2 and L3 discussed during the interviews how a similar task in an HIC will be completed by a lesser number of people and lesser time when compared to LMIC workers. The value proposition from HIC workforce is much higher even though the costs are higher.

Bureaucracy

This is a challenge that is very dynamic and unpredictable to deal with. The lack of digitization and ambiguous procedures doesn't add confidence. Interviewee HL3 mentioned this lack of transparency to hinder operations in LMICs. Corruption, another side of bureaucracy, is a challenge to operations in the country. L2 mentions how even after completing all the processes it doesn't move forward due to corruption.

Local liaison requirement

From the interviews it was seen how the local red-tape procedures and bureaucracy hampered the operations of companies, especially companies that are not local to the country. Navigating through the local tax regulations and laws companies find it difficult without the support of an expert localite.

Poor Infrastructure

From the interview candidates in subsection 4.1, all of them who have operations in LMICs mentioned the infrastructure present to be a challenge. The example of L1 whose operations were at a standstill due to the unavailability of water is one of the many according to L2. The lack of developed roads and ports are also challenges that hinder the efficient operation of the country.

Conclusion

Section 5 thus answers sub-question 2 (SQ2) and SQ3. Both these sub-questions used results that were found through the desktop research and the interview findings. The medical device industry, GVCs and challenges for local production that were identified in the section 3 were correlated with the interview findings to map out the differences in the manufacturing and assembly practices. As discussed the literature and some interviews were able to shed light in the practices for LMICs while for HIC the findings were mainly

from the interviews. Similarly for the challenges to local manufacturing and assembly in LMICs the desktop research results and the 'disadvantages' question from the interview questions were mainly used to answer SQ3.

6 Key Drivers and Inhibitors

This section focuses on the research aim of the synthesis phase,

"Derive the key drivers and inhibitors for companies shifting their manufacturing and assembly operations of medical devices to low- and middle- income countries"

The factors identified from the first three sub-questions will be used to hone in on key drivers and inhibitors that companies consider while shifting manufacturing and/or assembly operations to LMICs. A key driver is something that has a huge impact on how well a particular task is done. In this research, the key drivers are those which motivate/enable companies to shift their operations to LMICs. Inhibitors can be considered to be the opposite of key drivers. They are those that stop or slow down a particular process. Here inhibitors are those that demotivate companies to shift their operations to a LMIC. The derived drivers and inhibitors are then depicted in a PESTLE format. PESTLE can be used to identify how future trends in the political, economic, social, technological, legal and environmental environments might impinge on organisations (Johnson et al., n.d.). It is especially useful when entering a foreign market or for a new business venture.

To conceptualize the key drivers and inhibitors, the research process was divided into the exploratory phase and synthesis phase. The exploratory phase consisted of sub-questions 1, 2 and 3. The first sub-question discusses the pros and cons of the GVC in LMICs as seen in section 3.2. These pros and cons bring to light the opportunities and challenges companies face while moving their operations to an LMIC. The second sub-question compares the manufacturing and assembly practices in HICs and LMICs as seen in section 5.1. Through this comparison, once the distinction between the countries is portrayed, the main aim was to learn what specifically works for companies in HICs and (if possible) how can these features be applied to companies with operations in LMIC. Lastly, the third sub-question brings out the challenges that medical device companies in LMIC face as seen in section 5.2. These challenges can be seen as opportunities on how to improve the efficiency of the companies. Compiling the results of these three sub-questions (as per the research methodology) should result in key drivers and inhibitors affecting the operation of companies when they move to LMICs.

6.1 Key Drivers

The key drivers that motivate companies to shift medical device manufacturing and assembly operations to LMICs are:

- **Favourable Tax Regime:**

  The availability of special economic zones, tax benefits and favourable regulations in LMICs like the free trade zone in Ghana for example are opportunities companies can accept. None of the interview candidates were situated in special economic zones. When enquired on the topic of special economic zones, everyone mentioned their positive interests towards it. HL4 specifically mentioned one of the decisions that motivated them to shift to an LMIC was the presence of these special trade zones and favourable tax regimes present. In the PESTLE analysis this key driver

falls into the political environment since it mainly deals with the governmental influence.

- **Untapped Market potential and Market proximity:**

  The developing world market is much bigger compared to the developed world as mentioned in section 3.2.1. During the interview process, candidates with operations in LMICs mentioned how the people from their countries prefer products produced locally. During the interview, HL1 mentioned *"I can imagine that Mozambicans would be more than happy and proud to buy something that's been produced in Mozambique"*. A similar remark was mentioned by L1. Being close to the customers, companies can stay ahead of the competition, be proactive to the customers and innovate keeping the requirements of the customers. This need for locally produced products, the potential of the medical device industry and lack of medical device availability (section3.3) creates a great opportunity for companies to move in. The companies can exploit the resources and facilities available to their advantage and create products for the people. This key driver is classified into the economic environment in PESTLE because of how it will affect the growth of the economy of the country which indirectly affects the performance of the company.

- **Low cost resources:**

  Products produced in the LMICs can be competitively costed compared to products from HICs. The low cost resources mentioned play a big role in this aspect. Although this driver is very product and country dependant, it can be seen, as a whole, the cost of inputs is much lower when compared to HIC operations. Section 3.2.1 mentions how Pakistan and the Czech Republic have established themselves to industries by providing the respective resources for their functioning. From the interview process, it was found how there is a clear shift of focus from cost to customers for companies. They have started including customer satisfaction as one of the main performance indicators and incorporating customer feedback into consideration. This key driver also falls into the Economic environment. The availability of lower cost resources attract capital which eventually leads to the growth of the economy.

- **EU MDR 2021:**

  In section 5.2, the recent changes to the EU MDR were discussed and how the new complex and stringent processes are demotivating medical device manufacturers. Interviewees mentioned how strict regulations like these are counter-productive and unrealistic. This could lead to a similar scenario like the US, where due to the strict regulations of the FDA medical device manufacturers shifted towards Europe, Ireland and Mexico. In 2011, Medical device industry executives and investors complained vociferously that the industry's competitive edge in the United States and overseas is being jeopardized by a heightened regulatory scrutiny (Pollack, 2011). Similarly, this could lead to a situation where the medical device market could shift towards the Asian or African regions where resources are readily available and a lower cost. This falls into the legal environment in PESTLE since it is a regulation that is mandatory for medical device manufacturers.

- **Competitive Costing:**

  Products produced in the LMICs can be competitively costed compared to products from HICs. The low cost resources mentioned play a big role in this aspect. Although they are related this can be considered an important driver when shifting the operations. This key driver also falls into the economic environment.

- **Corporate Social Responsibility:**

  Companies coming into LMICs brings in foreign capital which eventually leads to the development of the country. It creates employment in the country locally, knowledge spillovers which eventually leads to the development of the workforce. The tax contributions companies provide are quite significant. From the perspective of the company, the increasing awareness towards Corporate Social Responsibility is mentioned as a key driver. This driver can be placed in the social environment of the PESTLE chart due to the image that is created for the company in the eye of public. Public opinions tend to have an impact towards the business of the company.

- **Reduced Carbon Footprint:**

  If moved closer to the market, a greater portion of the logistical challenges can be reduced, thereby limiting the carbon footprint of the company. This can be an additional motivation to companies, keeping in mind, not just the environmental strain relaxed but also bring down the costs. The environmental category is where this key driver falls into. The effects of this key driver will eventually lead to better environmental conditions.

6.2 Inhibitors

Inhibitors are factors that demotivate the companies to shift their manufacturing and assembly operations to a LMIC.

- **Political uncertainty, Bureaucracy and red tape procedures:**

  This was a topic that came up during exploratory interviews and rarely came up during the literature survey. Although it was found to be present in both HICs and LMICs, they are much worse in LMICs. The issues of corruption and lack of clear procedures build untrust in the system responsible. Political uncertainty irrespective of HIC or LMICs is something that can occur any moment. It can be considered as a black swan event, a highly unlikely event but with severe consequences if occurred. This inhibitor in the PESTLE analysis will fall under different environments. There is an overlap of the political, technological and legal environment for this inhibitor due to the its affect in government, economy of the country and the rules and regulations/hoops to jump through.

- **Lacking Workforce:**

  Although the workforce available in LMIC is cheaper, as found from the interviews (from section 4.2) the skills available are also lesser. The word lesser is very relative. When compared to people from HICs they might look less skillful, but the difference is on how frugally adaptable they are. HL3 during the interview mentioned how he was amazed by the different ideas that his team had come up with for an issue

they faced. The same person mentioned some people can't even hold a screwdriver properly. This inhibitor can be placed in the technological environment as it deals with the skills of workforce in the country and how it impacts the market/business.

- **Labour productivity:**

  Labour productivity is another challenge that was realized during the interview process. Although the labour costs are expensive in HICs the value proposition from them is much higher. This could be a cultural difference, or the mentality present in the country. HL3 mentioned even though the workforce available is competent they miss the attention to detail. This inhibitor also falls in the social environment due to its link to the capabilities/attitude of the workforce present.

- **Low quality perception:**

  From the interview, it was confirmed irrespective of the country the final products go through a series of quality checks, and international standards followed specific to the product like ISO 13485 for medical devices. The major difference found was the tolerance of acceptance was different. LMICs had a greater range of acceptance which could allow a lower quality product to pass through. Similar to lacking workforce, this inhibitor also can be classified in the technological environment. The final products being perceived to be a lower quality can eventually affect the working of the company and its customers.

- **Poor Infrastructure:**

  The final inhibitor that can demotivate companies from shifting their operations into LMICs. The unavailability of required resources can hamper the operations of the company. The same example cited previously regarding the operation halt to L1 due to unavailability of water gives us an idea of unexpected scenarios. As seen in section 4.1 the companies in LMICs specifically mention the poor infrastructure available as a challenge. This inhibitor can also be classified as in the technological environment. The poor infrastructure can affect the operations in the industry.

These factors have been differentiated and classified using a PESTLE analysis to give us a better understanding of the business environment and how these can be used as opportunities and exploited. A representation of these key drivers and inhibitors in the PESTLE format can be seen in Figure 11

6.3 Validation of the Key drivers and Inhibitors

After finalizing the key drivers and inhibitors, they were shared with the medical device company officials who took part in the interviews (Table 3). Among the 4 that were approached, 3 responded. As a part of validation, a survey was sent to the candidates that asked them to rate how relevant the key drivers and inhibitors are on a scale of 1 to 5, 1 being not relevant and 5 very relevant. A summary of the scores provided by them can be seem in table below.

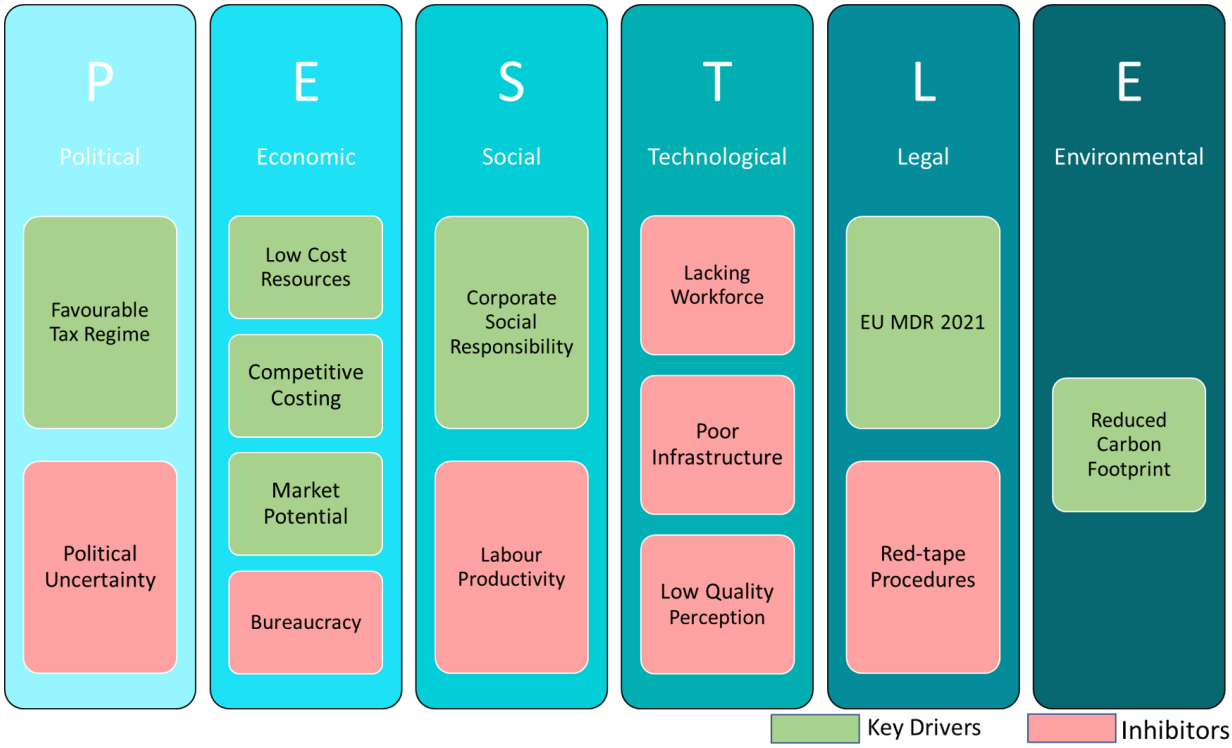


Figure 11: Key Drivers and Inhibitors

Key Drivers					
Favourable Tax Regime	Untapped Market Potential	Low cost resources	EU Medical Device Regulations 2021	Corporate Social Responsibility	Reduced Carbon Footprint
4,7	4,0	3,7	4,3	3,7	3,0
Inhibitors					
Bureaucracy and red-tape procedures	Lacking Workforce	Labour Productivity	Low quality perception	Poor infrastructure	
5,0	3,7	4,3	4,0	4,3	

Table 17: Relevance of the Key Drivers and Inhibitors on a scale of 1 to 5. (average scores)

We see that all the factors have an average score above 3 in terms of relevance. The survey conducted did not ask for their motivation on why they scored the relevance. The most relevant ones in the key drivers and inhibitors are the favourable tax regime, EU MDR 2021, untapped market potential and bureaucracy, labour productivity, low quality perception, poor infrastructure respectively. The relevance is higher for these key drivers most probably because of how they can be relatively huge motivators towards the shifting operations. Similarly the high relevant inhibitors are huge demotivators to the shifting operations for companies.

7 Discussion and Recommendations

7.1 Discussion

This research aimed to derive key drivers and inhibitors to the shifting of medical device manufacturing and assembly for companies in LMICs. It started with the opportunity provided by Delft Imaging, with their future expansion plan of shifting the pre-staging operations of CAD4TB to Ghana. The research, from a specific topic, grew towards a more generalizable topic of local manufacturing and assembly of the medical device in LMICs. The key drivers and inhibitors derived during the research are some of the many factors that medical device companies need to be aware of while looking into the options of moving to a LMIC. During the research and after arriving at the results it was understood how dynamic the factors are concerning the country being discussed. Similar is the case for products. Hence through this discussion, the first point that needs to be put forward is how the key drivers and inhibitors identified can be applied to multiple countries and products keeping in mind that they have to be customized and adapted to the country and product in discussion. The research was not targeted towards one specific country. The conscious decision to select interviewees from multiple geographical locations helped in making the results universally relevant. Countries are very diverse be it in terms of innovation capacity, manufacturing capabilities, income-wise differences etc. The research looks into the capabilities of manufacturing and assembly. Individually these aspects are very different and the requirements for each is quite diverse. Although they are diverse topics the key drivers and inhibitors developed can be applied to them individually after the required customization.

As mentioned in the literature, it was found during the research how the workforce with the required technical skill sets is scarce. Interview candidates with operations in LMICs found it to the main challenge for their efficient operations. An interesting information that came up during the research was regarding the quality of products manufactured in LMICs. Literature study revealed that to avoid sub par products unplanned quality checks to be conducted and following quality standards. The interview process revealed how all the candidates followed the standards required, but the difference was in the tolerance of acceptance of final products. The wider range they use allows lower quality products to slip through. The EU MDR topic discussed during the research was mentioned specifically by the medical device manufacturers. The new regulations are designed to be more customer oriented that the ususal manufacturer oriented processes, thus bringing complexities and procedures in the loop. This is an opportunity for countries in Asia and Africa to utilize and bring in a portion of the medical device market that has been part of the European market. SMEs find these new regulations difficult to the point they have to either move away from the country or move away from manufacturing medical devices altogether. The discussion previously on the latest EU MDR, of how unrealistic it is, and on the complex processes to be followed in subsection 4.7, it has to be kept in mind even though there was a discussion of market shift from the USA, a similar trend could or could not occur in Europe. There is no confirmed direction on how the market is going to react.

The research did not specifically look into any manufacturing capabilities, for example, injection moulding, etc as it was out of the scope of the research. The results derived look more towards the managerial capabilities of shifting operations. In section 4, some of the codes were classified as advantages and challenges. The reasoning behind it being

these codes mentioned as advantages and challenges during the interview. It should be noted that these advantages and challenges can be one side of the coin. For example, knowing someone very close to one of the ministers in an LMIC can speed things up, almost making the bureaucratic procedures an advantage. In these codes, there is the mention of 'cheap labour'. The word cheap is very relative, and in no way meaning disrespect or negativity. The idea behind the code is to convey that, if a task is being done by someone in HIC and the same task by someone in LMIC, the costs involved are found to be lesser.

The conclusion of Kaplan et al. (2011) is there is no clear link between local production and the access of medical devices. To an extent this aspect is challenged by this research. The research moves to the direction which mentions the local production of medical devices increases its availability in LMICs due to some factors like how local customers prefer local products, etc. The study by Kaplan is 10 years old and could be outdated. The technological capabilities, education and infrastructure has changed quite drastically. An updated study looking into these possibilities would add value to the study and will provide a clearer picture.

Concept	**Reference**	**Interview Candidate**
Lack of trained technical staff	R. A. Malkin, 2007	L1, L2 & HL1
Poor infrastructure	R. A. Malkin, 2007	L1, L2, L3, HL1, HL2 & HL3
Quality control issues	R. Malkin& Von Oldenburg Beer, 2013	H1
Quality checks, surprise audits and standardized process	Dalglish et al. (2013); Dang &Sharma (2019); Ciurana (2014) and R. Malkin & Von Oldenburg Beer (2013)	L1, L2, L3, H1, H2, H3, H4, HL1, HL2 & HL3
Local production benefits, inconclusive	Kaplan et al. (2011)	L1, L2, L3, H1 & HL3
Contract manufacturing and local distributor	R. Malkin & Von Oldenburg Beer (2013)	L2, L3, H1, H3, H4 & HL2
Petroleum prices and long term goals	Dalglish et al. (2013)	
Organizational agility or innovation capabilities	Theyel and Hofmann (2020)	L1 (but opposite to the literature)
Bureaucracy, political uncertainty and red-tape procedures		L1, L2, L3, H1, H2, H3, H4, HL1, HL2, & HL3
Local liaison		L3, H1, H2, H3, H4, HL1, HL2 & HL3
EU MDR 2021		H2, H3 &H4
Market proximity		L1, L2, L3, H4 & HL1

Table 18: Literature vs Interview

The literature review brought up concepts as mentioned in Table 18. The interviews conducted allowed the validation of these concepts. Table 18 showcases how the concept

was discussed by an article and the interview candidates who mentioned it.

The topic of infrastructure was pointed out in the literature by few articles, mainly by R. A. Malkin (2007). More clarity on its intensity of being a challenge and how the infrastructure present in HICs facilitate the manufacturing and assembly processes was clear through the interviews. Similar to the infrastructure, R. A. Malkin (2007) mentioned how the technical workforce (especially for middle and senior management) is lacking. During interviews it was made clear that the workforce is lacking actual experience, but are very well educated. The lower labour productivity of the workforce in LMICs came to light through the interviews.

Quality is another aspect that came out during the literature study by R. Malkin & Von Oldenburg Beer (2013) mainly. The solution to the avoid low quality products was also discussed in the literature by Dalglish et al. (2013); Dang & Sharma (2019); Ciurana (2014); R. Malkin & Von Oldenburg Beer (2013). The interviews conduced confirmed these. What new information came out during the interview was how the acceptance range of final products (on a scale a rejected products to best make) was much higher when compared to HIC.

One of the advantages of local production claimed by Kaplan et al. (2011) was that of a competitive cost advantage available for products to those that are produced in HICs. Although it was claimed as a advantage the findings portray it as an advantage. During the interview process candidates mentioned how the cost of inputs in much lower in LMICs (even though they are product and country dependent). Final products manufactured or assembled in African region tend to be cheaper that the products from HIC, but slightly more expensive compared to the products from China or India.

L1's view on innovation capabilities is exactly opposite to the discussion of Theyel & Hofmann (2020). L1 mentioned how he prefers to be closer to market, be innovative by keeping a close track of the competition and the interest by Theyel & Hofmann (2020) mentions the innovation capabilities are much lower if there is an offshore manufacturing facility due to the communication gap. The interviews also brought out some information that were not found in the literature search. The concept of having a local liaison and how that role can help in the smooth operations of the company. The EU MDR 2021, the new latest regulation for medical device manufacturers and its 'unrealistic expectations' a discussion point by candidates during the interview. Another interesting discussion point during the interview was how they candidates prefer to be closer to their market and customers.

The cultural differences and language barrier was brought up as a challenge during interviews. The candidates mentioned how this had impacted the operations of the company. This was never found as a barrier during the literature study. Another topic that was never found during the literature study was the issue of bureaucracy. During the interview process it was found that irrespective of the country the operations are affected by bureaucracy and red-tape procedures. Another rare possibility that can affect the operations of a company is a political unrest.

From the identified key drivers and inhibitors in section 6, apart from the EU MDR 2021,

the rest can be applicable to other industries. It is easily transferable but will require some customization. From the validity survey conducted on the relevance of the key drivers and inhibitors, it will be an interesting discussion to learn the motivation of the candidates for their scores. Not a lot of research is available that looks into the possibilities of shifting core operations like manufacturing or assembly of medical devices in LMICs. This research could act as a baseline for other studies to take place, concentrating more on specific countries, manufacturing capabilities that eventually motivates companies to bring in operations into LMICs. From the side of Delft Imaging this research can be taken forward further by focusing on Ghana. One of the key drivers mentioned, the favourable tax regime, in case of Ghana is the free trade zone available. During this research, multiple attempts of reaching out were in vain as there was no response from their side. Thus, it could be a great starting point. This research can move forward by focusing only on medical devices, especially more candidates from LMICs.

7.2 Limitations

The research did have some limitations. The first one being, not focusing on country the findings can be found to be general. Further customization is required. The research did not look specifically into any manufacturing process, especially those that will be required for medical device manufacturing. One of the key drivers mentioned, the EU MDR 2021 could act as an inhibitor as well. As mentioned predicting how the market will act is something that time will only tell. Another limitation to this research is the unavailability of interview candidates from the medical device sector in LMIC. They could have shed more light into the current process and challenges faced.

7.3 Recommendations

These key drivers and inhibitors identified, if used optimally, act as gateways that motivate companies to shift their medical device manufacturing and assembly to LMICs. This section compiles these key drivers and inhibitors and recommends how to utilize these key drivers efficiently and overcome hurdles due to the inhibitors.

- Bringing in a local liaison can not only help with the key driver of a favourable tax regime but also the inhibitor of bureaucracy and red tape procedures. A local liaison who can navigate the ambiguous procedures of the country, the local laws and regulations and the tax system to avoid all kinds of "nasty surprises". For the distribution phase, a local distributor will also be advantageous who is aware of the market around him and will have connections to move forward. For Delft Imaging the presence of Delft Imaging Ghana (previously Universal Delft) can act as a local liaison to an extent. But when it comes to specifics during the procedures, negotiation of tax benefits etc it will be helpful to have an expert.

- The next recommendation will be on overcoming the inhibitor of technical workforce shortage and labour productivity. The introduction of well-designed training, standardized processes can help minimize errors and result in better products. This will eventually lead to the betterment of the workforce and eventually the country. Delft Imaging when/if shift their assembly operations they need to make sure

their process of pre-staging (for CAD4TB) is standardized to achieve similar quality levels before the shift. LMIC

- To guarantee better products the acceptance range of the final products need to be stricter and shorter. Allowing a lower tolerance can make the process stringent and complex, but eventually, lead to more satisfied customers. Delft Imaging presently has a strict quality assurance process. When moving to an LMIC a similar level of stringency is recommended.

- The poor infrastructure inhibitor can be overcome, to an extent, if backup resources like generators for example be planned. The project plan of the company should always consider slack to mitigate these unavoidable issues and be prepared.

- The special economic zones available provide a great opportunity for companies to shift their operations to LMICs. The regulations and paperwork involved around these need to be carefully considered, especially the tax-related factors. For example, in the case of Delft Imaging, the free trade zone in Ghana can only be accessed if there is a value-adding process occurring at the location. The pre-staging process of CAD4TB can be considered as 'adding value' but the other products of Delft Imaging cannot be considered here unless the process to the final product is re-imagined to 'add value'.

- The latest EU MDR, with their complex and stringent procedures, can increase the costs of the final product eventually making them more expensive. Although the new regulations increase the value of companies, especially in front of competitors without approval, the benefits should be analysed with the costs. With opportunities and facilities available in LMICs, they should be given consideration. A similar level of certification can be provided by auditing bodies in LMICs who are much easier on the regulations.

An action plan specific to Delft Imaging combining all these factors and contingency plans taken into account can be found in Appendix A

8 Conclusion

This section summarizes the results of the sub questions and answer the main research question. The research looked into finding the key drivers and inhibitors to shifting of medical device manufacturing and assembly to LMIC.

SQ1:What are the pros and cons of global value chain for a company when shifting operations to a low and middle income country ?

Summarizing the desktop research, the pros and cons of GVC for companies when moving manufacturing and assembly of medical devices to LMICs are:

- *Pros:* Low cost resources, skill development, development of the country and untapped market potential.
- *Cons:*Lack of innovation, technological advancement, poor infrastructure and political uncertainty

SQ2: How is the manufacturing and assembly of medical devices different in a low/middle income country as compared to a high income country?

The comparison of manufacturing and assembly practices in both HIC and LMIC did bring to light what are the key differences and eventually look into the possibility of applying these into LMIC practices. The major differences that were noticed are in

- *Infrastructure:* Similar to the income differences these countries have similar differences in the infrastructure available.
- *Technical Workforce:* The differences in educational capabilities, especially the lack of practical experiences, the cultural differences have effect on the level of skills.
- *Quality:* Companies irrespective of the country all have quality checks and standards.
- *Cost of Inputs:* LMIC costs are relatively cheaper. This is product and country dependent.
- *Competitive costing:* Very location based but products produced in Africa are cheaper that products coming from Europe, but slight more expensive than products coming from China or India.
- *Innovation:* Literature points out innovation is better in HICs but interviews point in the opposite direction.
- *Communication:* Differences in language, culture and time-zones are barriers to easy communication.
- *Bureaucracy:* Similar to the quality standards, bureaucracy is something all the interview candidates, irrespective of their country had faced.

SQ3: What are the challenges that arise during the manufacturing and assembly of medical devices in a low and middle income country ?

These challenges as discussed can be considered opportunities. Bringing them out from the literature and experiences of interview candidates helps in understanding the difficulties.

- *Lack of technical workforce:* Even with the abundance of workforce available, companies in LMICs find it difficult to find people with the right skill set, especially for mid and senior level positions.
- *Lower labour productivity:* The productivity of workforce in LMICs tend to be lower when compared to the counterpart in HICs
- *Local liaison requirement:* The lack of clarity in procedures, regualtion related or tax system of the country or local laws and practices would be difficult to navigate without a local liaison.
- *Bureaucracy:* An unpredictable and dynamic challenge. Issues like corruption, political disagreements can hinder operations.
- *Poor Infrastructure:* The unavailability of essential resources can be a challenges to the operations.

SQ4: How can key drivers and inhibitors be derived based on the findings from the exploratory phase ?

Compiling the results from SQ1, 2 and 3 the key drives and inhibitors are derived as shown below

- Key Drivers
  - *Favourable tax regime:* Countries have tax relaxations, specialized economic zones that are attractive to companies, especially from HIC
  - *Untapped Market potential and Market proximity:* Being close to the market and using that big market to the advantage of companies
  - *Low cost resources:* Very product specific, but in general lower cost resources available in LMICs
  - *EU MDR 2021:* The "unrealistic" regulations released recently making procedures complex and stringent bring in further hurdles for companies to overcome. This can make shifting operations more attractive and eventually reduce costs
  - *Corporate Social Responsibility:* Shifting operations to LMICs bring in FDI, which develops the country, help improve the conditions like unemployment.
  - *Reduced Carbon Footprint:* Moving closer to the market reduces repetitive movement of products thereby reducing the carbon footprint of the company.
- Inhibitors

- *Bureaucracy and red-tape procedures:* Ambiguous procedures and regulations can demotivate companies to shift to LMICs
- *Lacking Workforce:* Unavailability of required skill-sets can become a huge hurdle to operations of the company
- *Labour Productivity:* The value proposition of workforce in LMICs are much lower compared to HICs
- *Low quality perception:* The wider acceptance range of quality checks for companies in LMICs could make it easy for sub-par products to slip through.
- *Poor Infrastructure:* Unavailability of required resources for the smooth operations also inhibits their operations.

Summarizing and concluding section 7.3, the recommendations in can be applied in practice to move forward to LMICs. The local liaison along with the training and standardized process can help the company with their smooth operations. The stricter quality acceptances will eventually lead to better products leading to higher customer satisfaction. The favourable tax regimes in the country should be explored and capitalized on efficiently. The final recommendation of the latest medical device regulation and how the latest version is bringing in complexities to the process of certifications has been portrayed as a challenge for medical device manufacturers. This also is an opportunity that markets in Asia and African can take advantage of these dissatisfied manufacturers. Companies can utilize the similar level of certifications by auditing bodies in LMIC.

Thus concluding the main research question, the key drivers and inhibitors were established. These drivers and inhibitors can give Delft Imaging (and other medical device companies in HICs) as first step towards moving to Ghana (or other LMICs). These factors should be kept in mind and used to prepare the plan to shift (or not shift). Further studies like a financial analysis can be done to validate the decision to shift. By bringing these factors up, contingency plans can be also be developed to ideally alleviate the potential hurdles as well as exploit the drivers available to maximize its value. These factors derived is not an exhaustive list but does cover a broad spectrum of information. This research has looked into the possibilities of shifting manufacturing and assembly operations to LMIC and the final outcome would be to take the first step towards shifting the operations keeping in mind the key drivers and inhibitors with the contingencies already incorporated in the project plan.

This research is first of the kind which looks into the possibilities of shifting operations, be it manufacturing and/or assembly to LMICs. The studies available either look into one the mentioned factors individually or focused on technological capabilities, innovation etc. With the unavailability of medical devices in LMICs, the rising capabilities of LMICs and potential of the medical industry, moving operations to a LMIC brings opportunities to make more devices available to those required much faster. Following the sustainable development goals (SDG) the research can help achieve the SDG 3 and 8, Good Health and Well-being and Decent work and Economic Growth (United Nations, n.d.) when companies shift. Being optimistic, using these Key drivers and Inhibitors as a starting point, medical device companies can get take the first step towards shifting their manufacturing and/or assembly operations eventually leading to better lives all round the world.

References

Abegaz, M., & Lahiri, S. (2021, 1). Efficiency Spillovers From Foreign Direct Investment and Domestic-exporting Firms: The Case of Ethiopian Manufacturing. *Journal of International Development*, *33*(1), 151–170. doi: 10.1002/jid.3517

Bagaria, N. (2021). Analysing Opportunities for India in Global Value Chains in Post COVID-19 Era. *Foreign Trade Review*. doi: 10.1177/0015732520981470

Bajpai, N., & Sachs, J. D. (2000). *Harvard Institute for International Development Development Discussion Papers Foreign Direct Investment in India: Issues and Problems* (Tech. Rep.).

Bamber, P., & Gereffi, G. (2013). *Costa Rica in the Medical Devices Global Value Chain: Opportunities for Upgrading Industries without Smokestacks View project Services in Global Value Chains View project* (Tech. Rep.). Retrieved from `https://www.researchgate.net/publication/265333160`

Bas, T. G., & Castillo, C. O. (2016). Biosimilars in Developed and Developing East and Southeast Asian Countries: Japan, South Korea, and Malaysia - Overview, Evolution, and Regulations Assessment. *BioMed Research International*, *2016*. doi: 10.1155/2016/5910403

Beckers, R., Kwade, Z., & Zanca, F. (2021, 3). The EU medical device regulation_ Implications for artificial intelligence-based medical device software in medical physics _ Elsevier Enhanced Reader. *European Journal of Medical Physics*, *83*, 1–8. Retrieved from `https://doi.org/10.1016/j.ejmp.2021.02.011`

Blaauw, E., & Stelt, M. v. d. (2013, 10). The driving forces behind China's foreign policy - has China become more assertive? *RaboResearch - Economic Research*.

Burlina, C., & Di Maria, E. (2020, 5). Manufacturing and value-added dynamics in global value chains: the case of Italy. *Competitiveness Review*, *30*(4), 457–470. doi: 10.1108/CR-10-2019-0100

Carter, N., Bryant-Lukosius, D., Dicenso, A., Blythe, J., & Neville, A. J. (2014, 9). *The use of triangulation in qualitative research* (Vol. 41) (No. 5). Oncology Nursing Society. doi: 10.1188/14.ONF.545-547

Chang, T. Y. (2012). Strengths of Taiwan's medical device industry. *International Journal of Automation and Smart Technology*, *2*(1), 3–6. doi: 10.5875/ausmt.v2i1.143

Ciurana, J. (2014). *Designing, prototyping and manufacturingmedical devices_ an overview.pdf* (Vol. 27) (No. 10).

Dalglish, S. L., Poulsen, M. N., & Winch, P. J. (2013, 11). Localization of health systems in low- and middle-income countries in response to long-term increases in energy prices. *Globalization and Health*, *9*(1). doi: 10.1186/1744-8603-9-56

Dang, A., & Sharma, J. K. (2019, 5). Economics of Medical Devices in India. *Value in Health Regional Issues*, *18*, 14–17. doi: 10.1016/j.vhri.2018.06.004

Dankelman, J. (2010). Increasing complexity of medical technology and consequences for training and outcome of care. *Medical devices: Managing the Mismatch - WHO*.

De Backer, K., & Flaig, D. (2017, 4). *THE FUTURE OF GLOBAL VALUE CHAINS* (Tech. Rep.). Committee on Industry, Innovation and Entrepreneurship.

Doyran, M. A. (2013). New York Garment Industry in the Global Market_ Trends, Challenges and Opportunities _ Enhanced Reader. *Journal of Textile and Apparel, Technology and Management*, *8*(3).

Fernandez-stark, K., & Gereffi, G. (2019). 2 . Global value chain analysis : a primer (second edition) *. (November).

Free, M. J., Morrow, M. M., & Green, J. A. (1993). Health technologies for the developing world promoting self-reliance through improving local procurement and manufacturing capabilities. *International Journal of Technology Assessment in Health Care*, *9*(3), 380–396. doi: 10.1017/S0266462300004645

Gereff, G., Bamber, P., & Fernandez-Stark, K. (2016). *Promoting Decent Work in Global Supply Chains in Latin America and the Caribbean KEY ISSUES, GOOD PRACTICES, LESSONS LEARNED AND POLICY INSIGHTS*. Retrieved from `www.ilo.org/publns`

Gereffi, G. (2015). *Global value chains, development and emerging economies Working Paper Series* (Tech. Rep.). Retrieved from `http://mgsog.merit.unu.edu`

Gereffi, G., Frederick, S., & Bamber, P. (2019). *Diverse paths of upgrading in high-tech manufacturing: Costa Rica in the electronics and medical devices global value chains* (Tech. Rep.).

Ghemawat, P. (2007, 3). Managing differences: The central challenge of global strategy. *Harvard Business Review*, *85*(3), 58–68. doi: 10.1108/sd.2007.05623had.001

Hamilton, G. G., & Gereffi, G. (2009). *(PDF) Global Commodity Chains, Market Makers, and the Rise of Demand-Responsive Economies.* Retrieved from `https://www.researchgate.net/publication/289254807_Global_Commodity_Chains_Market_Makers_and_the_Rise_of_Demand-Responsive_Economies`

Hamrick, D., & Bamber, P. (2019). *Pakistan in the Medical Device Global Value Chain* (Tech. Rep.). Retrieved from `www.gvcc.duke.edu.`

Javed, A., & Atif, R. M. (2019). Global Value Chain: An Analysis of Pakistan's Textile Sector. *Global Business Review*. doi: 10.1177/0972150918822109

Johnson, G., Scholes, K., & Whittington, R. (n.d.). Exploring Corporate Strategy. Retrieved from `www.booksites.net/ecs`

Kaplan, W., Ritz, L., & Vitello, M. (2011). Local production of medical devices and its effect on access in lmic_a systematic review of literature. *Southern Med Review*, *4*, 51–61.

Kasriel-Alexander, D. (2014, 4). *Why do Consumers Prefer Local Products?* Retrieved from `https://blog.euromonitor.com/why-the-consumer-preference-for-things-local/`

Malkin, R., & Von Oldenburg Beer, K. (2013, 9). Diffusion of novel healthcare technologies to resource poor settings. *Annals of Biomedical Engineering*, *41*(9), 1841–1850. doi: 10.1007/s10439-013-0750-5

Malkin, R. A. (2007, 12). *Barriers for medical devices for the developing world* (Vol. 4) (No. 6). doi: 10.1586/17434440.4.6.759

Maresova, P., Hajek, L., Krejcar, O., Storek, M., & Kuca, K. (2020, 3). New Regulations on Medical Devices in Europe: Are They an Opportunity for Growth? *Administrative Sciences*, *10*(1), 16. doi: 10.3390/admsci10010016

Marešová, P., Peter, L., Honegr, J., Režnỳ, L., Penhaker, M., Augustỳnek, M., ... Kuča, K. (2020, 3). Complexity stage model of the medical device development based on economic evaluation-MedDee. *Sustainability (Switzerland)*, *12*(5). doi: 10.3390/su12051755

Martínez-Galán, E., & Fontoura, M. P. (2019, 1). *Global value chains and inward foreign direct investment in the 2000s* (Vol. 42) (No. 1). Blackwell Publishing Ltd. doi: 10 .1111/twec.12660

MedTech Europe. (2019). *The European Medical Technology industry in figures 2019* (Tech. Rep.). Retrieved from `https://www.medtecheurope.org/resource-library/the-european-medical-technology-industry-in-figures-2019/`

Miles, M. B., Huberman, M., & Saldaña, J. (1994). *Miles Huberman Data analysis Qualitative Data Analysis A Methods Sourcebook Edition* (Tech. Rep.).

Nassimbeni, G. (2003). *Local manufacturing systems and global economy: are they compatible?* (Vol. 21) (No. 2). doi: 10.1016/s0272-6963(02)00090-6

OECD. (2020, 5). Realising the Potential of Primary Health Care. *OECD Health Policy Studies*. Retrieved from `https://www.oecd-ilibrary.org/social-issues-migration-health/realising-the-potential-of-primary-health-care_a92adee4-en` doi: 10.1787/a92adee4-en

Pham, A. T., Nguyen, M. K., Dang, H. L., & Nguyen, T. X. T. (2021). Can foreign direct investment foster the manufacturing industries' spatial total factor productivity convergence in a transition economy? An empirical approach from Vietnam. *Bulletin of Economic Research*. doi: 10.1111/boer.12265

Pollack, A. (2011, 2). *American Medical Device Makers Look Overseas for Quicker Approval - The New York Times.* Retrieved from `https://www.nytimes.com/2011/02/10/business/10device.html`

Rodrik, D. (2018). NEW TECHNOLOGIES, GLOBAL VALUE CHAINS, AND DEVELOPING ECONOMIES. *National Bureau of Economic Research*.

Sekaran, U., & Bougie, R. (2016). *Research Methods for Business _ A skill-building approach* (Tech. Rep.). John Wiley & Sons Ltd. Retrieved from `www.wileypluslearningspace.com`

Shih, A. J. (2008, 4). Biomedical manufacturing: A new frontier of manufacturing research. *Journal of Manufacturing Science and Engineering, Transactions of the ASME*, *130*(2), 0210091–0210098. Retrieved from `http://www.cms.hhs.gov/NationalHealthExpendData` doi: 10.1115/1.2896116

Song, Y., Yu, C., Hao, L., & Chen, X. (2021, 5). Path for China's high-tech industry to participate in the reconstruction of global value chains. *Technology in Society*, *65*. doi: 10.1016/j.techsoc.2020.101486

Taglioni, D., & Winkler, D. (2016). *Making Global Value Chains Work for Development* (Tech. Rep.). The World Bank.

Theyel, G., & Hofmann, K. H. (2020). Manufacturing location decisions and organizational agility. *Multinational Business Review*. doi: 10.1108/MBR-02-2020-0035

United Nations. (n.d.). *THE 17 GOALS | Sustainable Development.* Retrieved from `https://sdgs.un.org/goals`

Uwitonze, C. (n.d.). *A view on Medical Devices industry in Africa - A case study East Africa* (Tech. Rep.). University without borders for the open society.

Vlčková, J. (2017). *Global production networks in Central European Countries: the case of the Visegrad Group*. University of Economics, Prague Oeconomica Publishing House. doi: 10.18267/pu.2017.vlc.2197.8

Vlckova, J., & Thakur-Weigold, B. S. (2019, 2). Global value chains in the MedTech industry: A comparison of Switzerland and the Czech Republic. *International Journal of Emerging Markets*, *15*(1), 70–92. doi: 10.1108/IJOEM-05-2017-0179

Whitfield, L., Staritz, C., & Morris, M. (2020, 7). Global Value Chains, Industrial Policy and Economic Upgrading in Ethiopia's Apparel Sector. *Development and Change*, *51*(4), 1018–1043. doi: 10.1111/dech.12590

WHO. (2012). *Local Production and Technology Transfer to Increase Access to Medical Devices Addressing the barriers and challenges in low-and middle-income countries* (Tech. Rep.). WHO.

World Bank. (2014, 5). *Trading up to High Income* (Tech. Rep.). Poverty Reduction and Economic Management Unit Europe and Central Asia Region.

World Health Organization. (2017). *Global atlas of medical devices.*

9 Appendix A

Action Plan

The goal of this action plan is to shift the pre-staging of CAD4TB from Netherlands to Delft Imaging. The action plan presented is a five-step plan to move forward as a next step of this research. The plan presented is a basic action plan that tries to incorporate the key drivers and inhibitors research and can be used as the first step towards moving to Ghana.

The first action is to study the free trade zone in Ghana in detail to learn the capabilities and benefits they offer. At the moment the biggest bottleneck to the shift would be the lack of information known regarding the free trade zone. Multiple attempts were conducted to learn more about the free trade zone but wasn't fruitful. This action plan includes the key driver of favourable tax regime.

The next step is mapping out the procedures and technicalities to the shift. A shift of this scale needs to studied properly especially the taxes and legal obstacles that needs to be overcome. Delft Imaging Ghana can act as the local liaison here as these procedures are their forte, since they are working the country for a while.

The third step is the financial study of shifting the operations. This steps incorporates the key drivers like low cost resources and competitive costing. The economic analysis will also check out the feasibility of suppliers shipping to Ghana as well. The fourth step is the development of the training programs and standardized process. This step incorporates the lacking workforce, labour productivity and low quality perception inhibitors. The developed training should be able to minimize the errors and including strict quality standards during the training and pre-staging process should result in higher quality products.

The final step will act as the final step to planning the entire shifting operations. This step will bring in outcomes from the other steps and develop a plan with the required slack and contingencies in mind

Goal: Shifting pre-staging operations of CAD4TB to Ghana

Action Step	Responsible	Resources	Desired Outcome
Free trade zone study in Ghana	Delft Imaging Ghana	Research Associate	Complete information on the free trade zone and how Delft Imaging can use those
Map out the procedures and technicalities for shifting the operations to Ghana, especially the tax and legal specifics	Delft Imaging Ghana	Product and Project Managers	Delft Imaging Ghana acting as a liaison and navigating the procedures (including bureaucracy) for smooth operations
Economic analysis of the shift, especially the finances, the cost advantages/disadvantages	Delft Imaging	Chief financial officer lead team	Financial feasibility of the shifting operations
Develop training and standardized process with strict quality checks (with lower tolerance to mediocre products)	Delft Imaging Ghana and Delft Imaging	Application specialist and Research Associate	Properly trained workforce ready for pre-staging of CAD4TB
Project plan keeping in mind the key drivers and inhibitors	Delft Imaging	Product and Project Managers	Overall plan with milestones and time frame for the shift

10 Appendix B

sl no.	Keywords	No. of hits	Remarks
1	TITLE-ABS-KEY ("global value chain*")	2902	
2	TITLE-ABS-KEY (({global value chain} OR "GVC") AND (manufacturing OR production))	900	
3	TITLE-ABS-KEY ("global value chain*" AND manufacturing OR production AND advantages OR merits OR pros)	127	the results are not specific to lmics
4	TITLE-ABS-KEY (({global value chain} OR "GVC") AND (advantages OR {pros and cons} OR barriers OR challenges OR {key drivers}))	407	tried to narrow the result by being specific to SQ1
5	TITLE-ABS-KEY ("global value chain*" AND manufacturing OR production AND advantages OR merits OR pros) AND ("medical device")	2	narrowed the search to find a paper which was read
6	(TITLE-ABS-KEY ("global value chain*" AND manufacturing OR production AND advantages OR merits OR pros)) AND ("lmic*" OR "developing countries" OR "emerging economies")	62	More specific to SQ1
7	TITLE-ABS-KEY (("medical device" OR "medtech" OR "health technology") AND (manufacturing OR production) AND (assembly))	184	
8	("medical device" OR "medtech" OR "health technology") AND (manufacturing OR production) AND (assembly) AND ("lmic*" OR "low and middle income countr*" OR "low- and middle-income countr*" OR "developing countr*")	0	added lmics
9	(("medical device" OR "medtech" OR "health technology") AND (manufacturing OR production) AND ("lmic*" OR "low and middle income countr*" OR "low- and middle-income countr*" OR "developing countr*"))	49	removed assembly, 10 shortlisted, will access how much of it can be used
10	TITLE-ABS-KEY ((medical AND device* OR medtech OR "health technolog*") AND (manufacturing OR production) AND ("hic*" OR "high income countr*" OR "high-income countr*" OR "developed country"))	37	changed lmic to hic. Shortlisted 4 articles. Not a lot of research for hic
11	TITLE-ABS-KEY (("global value chain*") AND ("manufactur*" OR "product*") AND ("lmic*" OR "developing countries"))	172	The extra results from search 6, no relevant articles other than the previous short listed. Brought in articles that have products in the search
12	TITLE-ABS-KEY (("global value chain*") AND ("manufactur*" OR "product*") AND ("lmic*" OR "developing countries") AND ("medical device" OR medical OR healthcare))	4	no relevant articles other than the previous short listed
13	TITLE-ABS-KEY ((("global value chain*" OR {local assembly} OR {local manufactur*}) AND ("lmic*" OR "low and middle income countries" OR "developing countries" OR "emerging economies")))	375	
14	TITLE-ABS-KEY ((("medical device*" OR "medtech" OR "health technology") AND (manufacturing OR production) OR (assembly)) AND ("LMIC*" OR "low and middle income countr*" OR "low- and middle-income countr*) OR " developing AND countries ""))	6	no relevant articles other than the previous short listed
15	(TITLE-ABS-KEY ("medical device*")) AND ((TITLE-ABS -KEY (({global value chain} OR "gvc") AND (manufacturing OR production))))	1	
16	TITLE-ABS-KEY (({global value chain} OR "GVC") AND (manufacturing OR production) AND ("LMIC*" OR {developing countries} OR "low and middle income countr*" OR {low- and middle-income countries}))	88	Specific to LMICs

Table 19: Search Criteria

11 Appendix C

Code	
Advantage - Cheap labour	Challenge - Redtape procedures
Advantage - Cheap raw materials	Challenge - Regulations
Advantage - Competant workforce	Close to market
Advantage - Ease of communication	Competitive costing
Advantage - Economic development of the country	Contract manufacturing
Advantage - Favorable tax regime	EU MDR 2021 - Unrealistic
Advantage - Logistics	Focus shift from Cost
Challenge - Bureaucracy and Political Uncertainity	Local liason requriement
Challenge - Cultural Differences	Lower labour productivity
Challenge - Expensive labour	Quality checks
Challenge - High input costs	Quality standards
Challenge - Lack of technical workforce	Strict Quality Regulations
Challenge - Logistics	
Challenge - Poor infrastructure	

Table 20: Interview Codes

The consent form, questions asked with prompts and the anonymized transcripts can be found below.

Informed consent form for Localization of Medical Device manufacturing and assembly in Low and Middle Income countries study Interviews

Date: 05th May 2021

Introduction

You are being invited to be part of a research study. This research will look into the possibilities of manufacturing and assembly of medical devices in low and middle income countries (LMICs). The research aims to derive key drivers and inhibitors for companies while shifting their operations to a low- and middle-income country.

What is the Purpose of the Study

The purpose of the study is to answer the following research question:

- "*What are the best practices to be considered while setting up manufacturing and assembly in low and middle income countries?"*

Who can take part in the Survey

The study is planning to interview candidates who either have direct experience in manufacturing products in developed or developing countries and/or those who facilitate this process by providing assistance. The interviews will be recorded, but the video footage will not be used in the research. The interview questions will be shared before the scheduled meeting. The private details of the interviewees like name, position in their company, and company working, will be stored and only shared with the study group. The consent form asks for permission for the details to be stored. The actual details will be anonymized and in the research, only their position and expertise will be mentioned, for example: Managing Director in a Textile manufacturing industry.

Consent Form for Localization of Medical Device manufacturing and assembly in Low and Middle Income countries

Please tick the appropriate boxes **Yes** **No**

Taking part in the study

- I have read and understood the study information dated [07/04/2021], or it has been read to me. I have been able to ask questions about the study and my questions have been answered to my satisfaction. ☐ ☐
- I consent voluntarily to be a participant in this study and understand that I can refuse to answer questions and I can withdraw from the study at any time, without having to give a reason. ☐ ☐
- I understand that taking part in the study involves a video recorded one-on-one interview. The interview will be transcribed later and recordings stored still the end of the research and then will be destroyed. ☐ ☐

Use of the information in the study

- I understand that information I provide will be used for the research of Jitin Gopakumar, and the information will be stored in the repository of TU Delft. ☐ ☐
- I understand that personal information collected about me that can identify me, such as [e.g. my name and my position in the company working for], will not be shared beyond the study team. ☐ ☐
- I agree that my information can be quoted in research outputs ☐ ☐
- I understand that my real name will **NOT** be used in the research output ☐ ☐

Future use and reuse of the information by others

- I give permission for the transcribed interview notes that I provide to be archived in the TU Delft repository so it can be used for future research and learning. ☐ ☐

Signatures

_____	_____	_____
Name of participant and legal representative If applicable)	Signature	Date

I have accurately read out the information sheet to the potential participant and, to the best of my ability, ensured that the participant understands to what they are freely consenting.

Jitin Gopakumar	_____	_____
Researcher name [printed]	Signature	Date

Study contact details for further information: Jitin Gopakumar, JitinGopakumar@student.tudelft.nl, +31645328643

Interview

1. **Introduction on the research**

   Welcome and thank you for finding time to be part of the research. To share a quick introduction about the research I am looking into the topic of localization of medical device manufacturing and/or assembly in low and middle-income countries. The result of the research is to derive key drivers and identifiers for companies while setting up manufacturing and/or assembly of medical devices at the location

2. **Details of the interviewee**

   Name:
   Position and company/organization name:
   Expertise:

3. **Permission to record**

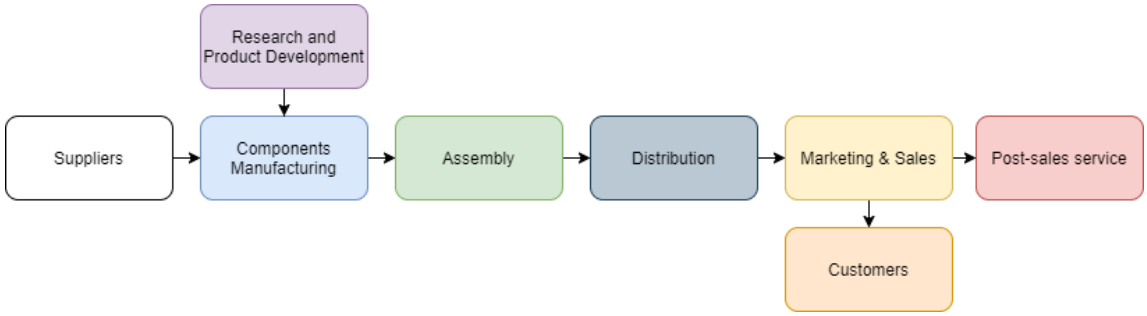
   I would like to record this interview for the purpose of review and transcribing. Once the information has been documented the videos will be deleted from storage. Is that okay with you?

Open Questions:

1. What do you perceive to be the challenges to manufacturing in LMICs compared to HICs?
   - Note the challenges mentioned to see if anything new comes up which wasn't seen till now

2. What do you perceive to be advantages of manufacturing in LMICs?
   - Prompt: with respect to raw materials cost?
   - Prompt: with respect to local workforce?
   - Prompt: with respect to reliability in supply chain
   - Prompt: with respect to competitive costing ?

Discuss the specific aspects after open questions



3. Where in the supply chain (as shown in the simplified process) do you see these challenges and advantages play out?
    - Note the position mentioned.
    - Prompt: with respect to procurement phase after describing what the phase is
    - Can be used to better picturize the supply chain representation in the end

4. How do you maintain the quality of products when manufacturing in LMICs?
    - Prompt: some sort of certifications or standard is followed?

5. How strict are the regulations and policy guidelines available? (what kind of tolerance is allowed for the quality checks)?

6. What are the actual manufacturing practices in HICs/LMICs?
    - Prompt: with respect to contract manufacturing and distributors (only for LMICs)
    - Try to bring in the difference in practices between LMICs and HICs

7. Are you present in a special economic zone or free trade zone? How does that impact the operations?
    - Understand if these zones were a motivation to move production/assembly
    - Prompt: with respect to manufacturing location

8. Have you encountered issues with respect to bureaucracy that have had an impact on the operations of a company (LMIC and HIC)? (please explain the situation)
    - Try to bring out specific points which can be noted and brought up in the literature

Interview-1

1. **Details of the interviewee**

   Name: L1
   Position and company: Managing Director
   Expertise: Manufacturer of textile industry

2. **Permission to record**

   I would like to record this interview for the purpose of review and transcribing. Once the information has been documented the videos will be deleted from storage. Is that okay with you? - **Yes**

Open Questions:

1. *What do you perceive to be the challenges to manufacturing in LMICs compared to HICs?*

For LMIC, I am talking about Ghana. The challenges that I believe are poor infrastructure like water, poor supply of water, poor communication like internet, energy inputs, poor supply of raw materials, congested ports, or poor infrastructure in one word in my opinion. The second one will be unavailability of the right skill set. And last one being strong and old fashioned labor law – good for individuals but barrier for company.

2. *What do you perceive to be advantages of manufacturing in LMICs?*

The advantages of having out factory produce the products for the market in LMIC, close to the market, able to reach immediately. Secondly very close to the source (like cotton), which helps in a wider understanding of sourcing locally and also help benefit the economy of the country. Consumers in LMICs are very proud to but their own products (local products), could be a marketing tool.

Prompt: with respect to raw materials cost?

Another advantage is that imports of raw materials is much cheaper than import finished products. It variers very much depending on the product, but in general I would say it would be cheaper. The availability of a favorable tax regime is another opinion I would add.

Prompt: with respect to local workforce?

In general the wage rates are lower than for example Europe.

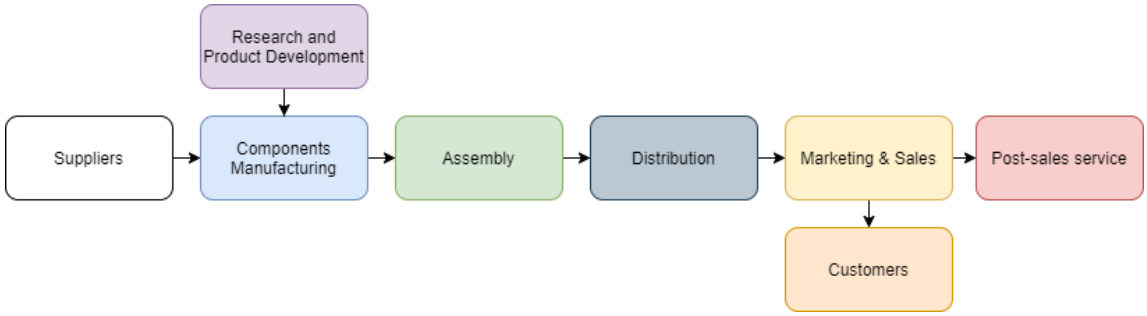
Prompt: with respect to reliability in supply chain

Close to the market – (same point as mentioned before)

Prompt: with respect to competitive costing ?

Depends on the country where the product comes from. Our products are much lower than the cost of products from developed countries but slightly expensive that the products coming from the "far east" like China or India.

Discuss the specific aspects after open questions



The supply chain diagram is straight forward and it can be applied to the textile industry as well.

3. *Where in the supply chain (as shown in the simplified process) do you see these challenges and advantages play out?*

As discussed before I can advantages from supplier to material, marketing to consumers, almost the whole supply chain. Consumers because he/she is proud of the products

Prompt: with respect to procurement phase after describing what the phase is

It is an advantage if the raw materials are available in the country. If the materials have to be done all around the world it could be disadvantages. 2-3 months of shipping time, 2-3 weeks in the port, and problems with transport are also challenges that arise during the procurement phase.

4. *How do you maintain the quality of products when manufacturing in LMICs?*

We have our own set of quality standards and is fixed in certain criteria. The products don't have international standards but they set of rules determined by Ghana central authority which is followed all over Ghana as a convention.

5. *How strict are the regulations and policy guidelines available? (what kind of tolerance is allowed for the quality checks)?*

Because of the specific products we have we discuss the standards to the committee, and then decide the quality level. Random checks are done to keep a check on the quality. So out of 10 we stick to a minimum of 8.5 for our products (almost 15%).

6. *What are the actual manufacturing practices in HICs/LMICs?*

Not valid for this interviewee as the company is completely independent. But is aware that in Ghana there are few companies. 90% of the business is done by third party who are very spread and aware of their local market

7. *Are you present in a special economic zone or free trade zone? How does that impact the operations?*

No present in a free trade zone. It is mainly for foreign companies to attract them. 70% of the products need to be exported. It generates employment in the country and have tax benefits. Since their market is LMIC it does not make sense for them to move into a trade zone.

Prompt: with respect to manufacturing location

Food and beverage companies like to have their manufacturing locations very close to their consumers/market. Similar is the case for textile as well.

With respect to innovation you being closer to the market, you are aware of what is the competition, ahead of the competition and scouting the market and make the move much early

8. *Have you encountered issues with respect to bureaucracy that have had an impact on the operations of a company (LMIC and HIC)? (please explain the situation)*

It is an interesting questions. There is a lot of complicated bureaucracy, certain level of corruption. There are programs which enable easy setup of their company called one stop one shop that enables the company to start functions much quicker. The bureaucracy actually starts when the company is set-up as they know you can't pull out now. A scenario was with tax authorities, how they ask for certain number of permits, if bribed the process moves much quicker than the official process. It is sometimes not easy.

Interview-2

1. **Details of the interviewee**

   Name: L2
   Position and company/organization name: General Manager
   Expertise: Helping companies to set up in LMICs**,** Previous experience in Food manufacturing industry (Supply Chain Manager)

2. **Permission to record**

   I would like to record this interview for the purpose of review and transcribing. Once the information has been documented the videos will be deleted from storage. Is that okay with you? **- YES**

Open Questions:

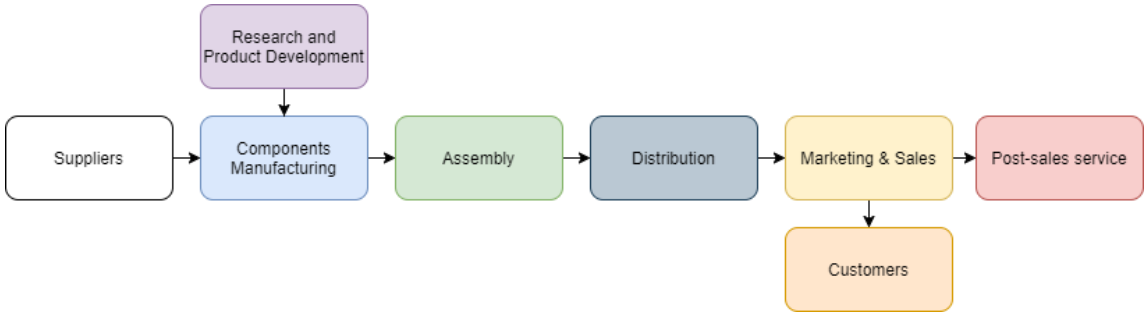
1. *What do you perceive to be the challenges to manufacturing in LMICs compared to HICs?*

Was not clear from the interview questions that it focused on medical devices, keeping that in mind the challenges are distance to the market, like if you are producing in LMIC and market in HIC, there are logistical challenges leading to a higher environment footprint. The cost of electricity and water can be a challenge. A friend had issue with water and had to stop manufacturing. Higher echelon staff, not easy to get good staff members, lower functions it is easier but depends on the product. The reliability of Government and authorities, like corruption. Even after following all the procedures there could still be a problem because some one needs an "envelope", not always the case but still a challenge. Labor productivity is another challenge. The wages are lower in LMICs but that also leads to lower productivity. If one expensive guy in Netherlands can make a hole in the ground, he digs the hole and finishes the work in 2 hr. In Ghana it could be 5 people with 2 managers and take 5 days. Of course an exaggerated story, but the point is very valid. Challenge of indigenous laws which could hinder foreign investments. For example some laws tend to ask to give up 51% of the company to a local citizen. Not a sponsorship but if you take an indigenous partner the money that comes in is lesser (200,000USD) compared to (500,000USD) and for trading it is 1 million. For example Vivo energy (rep of Shell), imports oil to LMIC. No added value to LMIC. By making local partners who set up petrol stations, they are part of the partnerships which makes them invest money into the country. The laws tend to drive out foreign investments. Just majority in staffs is not enough but want to handover the company.

2. *What do you perceive to be advantages of manufacturing in LMICs?*

Lower staff costs, Close to raw materials, Negotiate temporary tax exemptions, Fill in corporate social responsibility when investing in LMICs as they are rising in importance. There is a group called Vulture Capitalist that come in, take out and in 4 years are gone. It is difficult for an entrepreneur to work in that fashion.

Discuss the specific aspects after open questions



I

3. *Where in the supply chain (as shown in the simplified process) do you see these challenges and advantages play out?*

I see suppliers of raw materials as an advantage thinking of the food industry. I am not sure of the medical industry. You can be closer to where the raw materials come from and can add value which is an advantage. Components manufacturing is a disadvantage to my understanding but assembly is an advantage like Volkswagen. R&D is a challenge, but is mainly product dependent. Positive for Agri products but in my opinion medical industry could be a challenge but not fully aware of it. Distribution and distance, depends where the market is. Also dependent on where the customers are, especially if customers are in developed countries.

With respect to procurement phase it mainly depends on the market and product. When needed Shea nuts which grows in west Africa its an advantage as we are closer to them. Within medical services, we have to see if it is a medicine manufacturing company depending on the raw materials from the country it is an advantage and vice versa. Entirely depends on your raw materials and where you are setting up.

4. *How do you maintain the quality of products when manufacturing in LMICs?*

The first thing I had in mind was my experience in the food industry. We had standards called HCAAP – Hazard critical analysis points**, was implemented. The training procedures are done for staff to make sure the required steps are followed like protective clothing. Similar is the medical industry, on what can be used, quality checks and standard regulations. Similar is the case for any industry where quality assurance steps are taken care of to produce higher quality products.

5. *How strict are the regulations and policy guidelines available? (what kind of tolerance is allowed for the quality checks)?*

Depending on the company. A good company will be strict and follow all specific standards like ISO etc. If it is a crooked company, they do try to cut corners which result in sub-par products and a bad name to their company.

6. *What are the actual manufacturing practices in HICs/LMICs?*

I did not understand this question at first. *After a clarification on the question* Yes, contract manufacturing is a common manufacturing practice here in LMIC. In the shea nut industry, you are in contact with the factory, who crushes and makes the butter. We conduct quality checks to make sure good quality products are produced. A commercial relationship is there but you are demanding higher quality standards, keeping an eye on the final quality.

7. *Are you present in a special economic zone or free trade zone? How does that impact the operations?*

I am not present in a free trade zone but in a FTZ there is no company tax for 10 years, pay a flat rate of 15%, which is lower than other normal markets but higher compared to ivory costs (2%). 70-75% needs to be exported (out of Africa?), no customs for that. Whatever is coming in Ghana needs to be imported into the country. The FTZ is mainly for companies involved in exports who's main market is not LMIC. These could prove to be motivation for foreign companies to come in. It does create employment in the country, and help their economy.

With respect to manufacturing location depends on the market the company is selling. A free zone status is also possible for a company. For innovation, what you see a lot is that there is a boss there are always in contact with the mother company. There is always staff also available in the manufacturing location., thus not impacting much.

8. *Have you encountered issues with respect to bureaucracy that have had an impact on the operations of a company (LMIC and HIC)? (please explain the situation)*

I know a number of companies who did face this. Formally you have to abide to all the rules, but sometimes even after completing all the process there is no movement in the process due to corruption. A personal experience of mine, when I needed a tax credit certificate, they can easily check only my records and grand me the certificate but they wanted the transaction details of people in the organization even though it was not related. Found another way to get it done though. Companies have backed out due to these issues, money is demanded. A wooden pallet manufacturing companies in the free zone had face problems with the authorities. The managing director found that it was cheaper to manufacture in the Netherlands. Corrupt officials keep coming back for more. If we are strict and don't take part in the "process" they stop working for us. Big companies, MNCs usually have lesser problems. These are not common cases. 90% of the cases are successful but we are all interested in that 10% and find flaws in the system that way. This is not the case in all LMICs. These are just some bad experiences which I am aware of . *REDtape procedures**

Interview-3

1. **Details of the interviewee**

   Name: L3
   Position and company/organization name: Business Consultant
   Expertise: Advising and supporting companies for market entry in Sub-Saharan Africa

2. **Permission to record**

   I would like to record this interview for the purpose of review and transcribing. Once the information has been documented the videos will be deleted from storage. Is that okay with you? - **Yes**

Open Questions:

1. What do you perceive to be the challenges to manufacturing in LMICs compared to HICs?

As discussed during the exploratory meeting the split between manufacturing and assembly is quite essential. It is often not understood by companies when they are planning to enter into African market is that a substantial portion of supplies in order to start either assembly or manufacturing activity has to come from elsewhere. The other conclusion we drew last time was that assembly is relatively easy, to control in terms of quality and process, whereas manufacturing is a lot more complicated because then you have to take a bigger responsibility in the supply chain. In my opinion assembly, you are getting the parts you need for your product. They have been tested for quality, so you know what you get at the right time and managing the procedure and logistics. When talking about manufacturing a choice has to be made on how deep in the supply chain has to be done to check the quality. That is a completely different game. If you compare HIC and LMICs, the HICs have quality standards organized and regulated which makes manufacturing a bit easier. There is a common understanding of a minimum quality level. The conversation was very interesting last week. In my perspective when clients come to me with a requirement I ask them to make sure they are made sure to get into the supply chain of a assembler and then take a gradual course to buying parts locally. That distinction is really important.

2. What do you perceive to be advantages of manufacturing in LMICs?

Depends a bit on the product, but my first response to that question is easier access to markets assuming you manufacture something that is in demand in that particular country. The cost of labor tends to be lower but at the same time, and that's where my warning goes out, the productivity levels in some countries are dramatically higher that even if cost of labor is twice as high the value proposition is much higher. For example, the cost of hiring someone in Nigeria, because of a massive over supply of labor available that costs is very limited. Now there is a few things that stand in the way. Firstly, the business ethics, do you

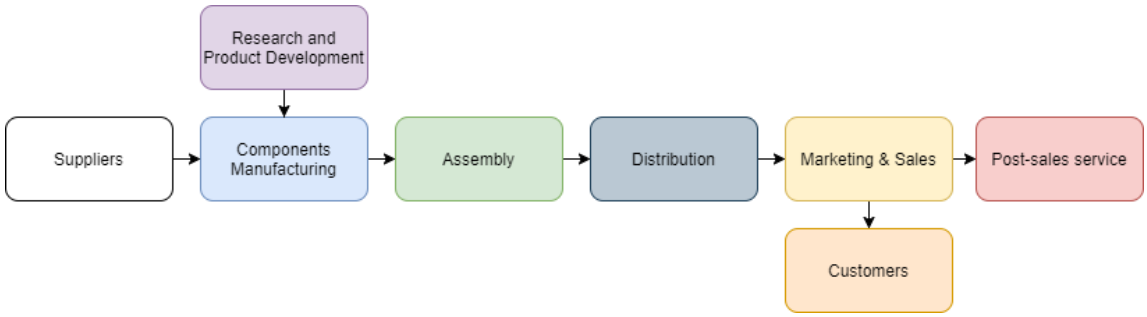
want to pay market rates or give them a pay where they can sustain a life. The advantage of labor being cheap in a country is perceived in a different way than 10 years ago. My response is definitely if you are looking for advantages, definitely the access to the market. Another one is that the material that you use could be very close by. For example if you want to produce chocolate and set up a factory in Ivory coast, the cocoa beans grow in the streets. It is that easy to get access and no complicated logistics. Shipping cocoa beans to be processed in Europe instead of sending ready made chocolate which is more compact, there is not a standard answer to this honestly. Very product and market specific. Most of your interviews might talk about the low wage, be in mind companies with a great image might not want to be associated with taking advantage of the low wages. Clothing companies like Primark producing in Bangladesh, India, and China, the people working there are not in decent pay and working conditions, that is becoming a problem for Primark as a company. They are cheap but more and more people are recognizing the tag of being cheap, somebody else if paying price of that product. You don't want them to show up in the paper as being exploiter of people. There is a risk of going of a tangent but will be good to mention it for a social cause.

With respect to reliability in supply chain, as mentioned last time, in the assembly side you can keep control of the quality, whatever happens around needs careful planning in LMICs. U have to set standards. Heineken is a great example. As soon as they start a factory they educate their suppliers in their supply chain. They force the suppliers to adopt some processes to maintain the quality of the raw materials. After a while they pull out the company representative, and do unplanned quality checks and auditing. It is like a virus, it spreads. If you start assembling or if you start the end part of manufacturing, the more circles around your product gets a quality impulse which is the best bet to start. Heineken example is a good example, because the machinery and process is something that is imported, first they start buying waster locally, then yeast and slowly all the raw materials are sourced locally step by step and develop their supply chain.

With respect to competitive costing ?

Logistics is always the touchy point there. There's two elements, the actual logistics and the regulatory costs – trade barriers, import costs, like the chocolate that could be produced in Ivory Coast might be more expensive in the market than the chocolate produced by the cocoa beans from Ivory Coast and processed in Europe. In a local scale you are not pushing the product beyond the borders of the country, there is definitely a benefit to be achieved. If you are looking to export in around the world you might end up with other costs which could drive up the costs. But that is opening another can of worms. That is typically another topic to be looked into once a location is finalized.

Discuss the specific aspects after open questions



3. Where in the supply chain (as shown in the simplified process) do you see these challenges and advantages play out?

Everything left of the Assembly box is the biggest challenge. The quality challenge, the procurement of raw materials getting to your plant, unless there is an exception and tie-up with a university. I think except for few logistic hurdles, the roads, the transport systems, are difficult and will take a bit longer. Companies like Heineken and Coca cola, in HIC they would typically outsource the logistics, because they can rely in the way they can be done. If you speak to them in LMICs, they will keep ownership of trucks and drivers, because of less confidence in the local resources. It is a different approach. Many companies involved in the manufacturing or assembly they don't have dedicated distribution service. Companies tend to keep non-core activities to themselves to maintain the process and quality.

4. How do you maintain the quality of products when manufacturing in LMICs?
    - Already discussed in previous questions

5. How strict are the regulations and policy guidelines available? (what kind of tolerance is allowed for the quality checks)? – **rephrase the questions*****

I am not sure I can answer that. I would say quality is not always the first driver in these countries. But that doesn't mean there are quality products arounds. There are less regulations but they are not necessarily easy to bide with.

6. What are the actual manufacturing practices in HICs/LMICs?

With respect to contract manufacturing and distributors (only for LMICs),It is a complete mix of different practices. Like Heineken where they bottle beer and others they brew it. Another example is Volkswagen in Rwanda, they produce and disassemble cars in South Africa, then reassemble in Rwanda. The idea is that they are making better margins, lesser taxes that when bringing a completely assembled car. In the context of the legislation it makes sense but in a logical manner it doesn't make sense. In previous times the companies tend to send the machines used to manufacture the products in LMICs. In India there was a car from British times which even though it was stopped manufacturing in Britain they still

manufactured the cookie cutter car until recently. They also similarly brought in the machinery into the country.

7. Are you present in a special economic zone or free trade zone? How does that impact the operations?

It depends on whether they are serving the local market or international market. For an international market it is definitely an advantage. What attracts companies are tax holidays tend to attract business. A lot of the advantages of a free trade zone can be replicated on paper by granting exemptions in import duties and such. In general they tend to accelerate free trade zone. Different rules for different countries. They are not defined by region. It is actually something to bear in mind when looking into country entries. That is my experience. One of the key advisors is a tax advisor who gives you advices on what taxes will hit you, import duties, and other. He is a pretty key element in the decision of setting up operations in a country. I can say this because I learned it the hard way. It is difficult the legislative and political changes after being set up. Depreciation etc. could change within countries and these kind of make or break your decision. There are these "nasty surprises" that you could be hit with if you are not completely aware of. These surprises can be avoided by completing a detailed discussion with a tax advisor of the particular location.

8. Have you encountered issues with respect to bureaucracy that have had an impact on the operations of a company (LMIC and HIC)? (please explain the situation)

Permitting permitting permitting. It is amazing how little attention is given to permits and same with the tax advisory. Of course new rules and regulations might show up everyday (decided and applied immediately). But if you don't prepare and investigate (without making assumptions). People fail to ask the questions. Permitting is important. Analyze the entire process and make sure all the regulatory bodies are involved. There is always going to be a surprise even if you take good guidance. In my previous employment I was doing a project in Tanzania, we failed to organize the permitting of one of the boats. It ended up staying outside the ports for 7 weeks. A vessel like that costs $60,000 a day. That for 42 days. You can imagine the loss. Well who's to blame here. It happens. For a company who wants to start, build the plan and plan slack into the plan that can help you run into delays like this at least once.

Interview-4

1. **Details of the interviewee**

   Name: H1
   Position and company/organization name: VP Sales and Marketing
   Expertise: Medical device manufacturer and distributor in HIC and LMIC

2. **Permission to record**

   I would like to record this interview for the purpose of review and transcribing. Once the information has been documented the videos will be deleted from storage. Is that okay with you? - **Yes**

Open Questions:

1. What do you perceive to be the challenges to manufacturing HICs?

Probably the first and foremost challenge is the cost of labour. The cost of inputs. Those are the two challenges that I have faced. Time zone difference is a small challenges but it is easy to mitigate

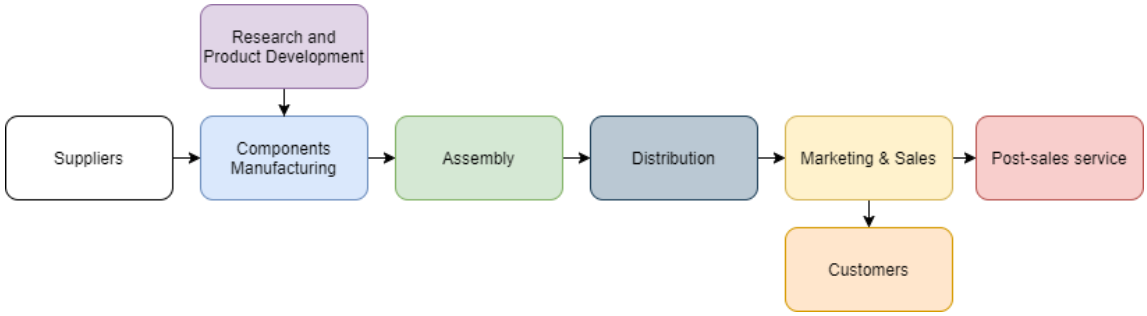
2. What do you perceive to be advantages of manufacturing in HICs compared to an LMICs?

Consistency of communication and language. If I am doing something in Netherlands they speak English. It is not the same in China or Bangladesh. \

Fortunately we have domestic production under our own roof, that may account somewhere around 20% of our products. Our China partner, who is much closer than a contract manufacturer, we share designs and patters of our products, that has been little bit easy. He did raise his prices in 5 years, but also added staffs to his staff, that way we can get more containers on the water. But this is from China, which could be more closer to a developed country.

Competitive costing - I have to think for a second. I am going to be a little inaccurate but in the continuum. Our China cost is lower compared to our US costs. The magnitude is 40% +/- 10%. The good news is that when u have it you got it. So we don't incur shipping costs. But if you beef up your inventory, you can save 20-30% but that will have to be offset on the carrying costs. If we had interest rates of 5% instead of 2 or 3 that gives you time to think if it costs less or does it really because of the transport costs and container costs. The container costs have gone up by 3 times. The rates changed from 1200$ to 3600$. The raise is said to be due to the pandemic, but I think that is not the case. The got you by the short hairs. It was roughly 8000$ to get 200 boots by air freight vs 4000$ to get 3000 boots via containers. So they got us in a position where they can raise prices because your alternative option is too costly.

Discuss the specific aspects after open questions



3. Where in the supply chain (as shown in the simplified process) do you see these challenges and advantages play out?

Right now we are seeing and hearing delays of supplies from our suppliers that goes into the manufacturing. Everything is not as consistent as it was pre pandemic. It has not been a big deal but on the assembly side of our partners in China has added staffs and that helped us ramp up the production and that then comes to the distribution segment, where he can send container of products more frequently so that we can anticipate the bottle neck on the ports. We are opting two ports because one of the ports always has a very long waiting period like 2 weeks, that is a hell of a long time when you are running on a thin inventory. His addition of staffs has been helpful. As far as distribution is concerned FedEx and UPS is slowing down, also their costs are higher. The shipping costs and the cost of wood which translate to boxes, all of that pricing goes up. For us the post sales service, we don't do services unless it is very urgent. We are slowly getting back into hospitals now. Our customers are there, they might have little bit of pressure from their hospital administrators because they been poorly affected financially because they had a loss of revenue. The need for our products are there but there might be more constraints from them.

Shipping and the distribution of the past three months have been a real hotspot for us because we had to airship 3 shipments. Out containers were help up in the port which costed us 50000$ because of delays in containers disbursement from the ports. It is out of our hands, we responded saying we can go through another port and don't deal with the bottleneck, where 30-50% of the good coming into the country go through that. We don't have perishable goods, so we will be last on the list in the queueing systems. That's when in the company we learned about the alternative port where it is not so backed up. So distribution has been a big deal and then followed by shortages of supply.

4. How do you maintain the quality of products when manufacturing in HICs?

For us it really is simple. We do a quality control where we physically touch all boots to check for defects, On the front end we try to design in the sewing process so when you sew

them together with different stitching they end up with the least seam possible. For example if you have a high seam and that boot is used by a diabetic it can break his skin. So if we do it in the front end in a nice way stressing with your LMIC or HIC these seams are really important. You do test runs, review the quality and give them thumbs up or down and set the standard, but we also have a second quality check to confirm the product. There is no international standard as such. This is something we have set for ourself. We don't confer with our competition. If they screw it up and end up with poor designs I am not happy with the bad outcomes for patients but I am happy as to how they produce a shit product and I don't.

5. How strict are the regulations and policy guidelines available? (what kind of tolerance is allowed for the quality checks)?

It is interesting on that question because for our quality control at our facility in the HIC it is much easier to reinforce the message because we actually have some non-English speakers (not first language) who sew and work in the warehouse. So your ability to convey and train them is a lot harder than if I were to work with you are very fluent in that it could be your first language. So when say how strict the guidelines are, for us it is very human oriented. We convey the result by going through rejections and approvals which they notice and work accordingly. This is not the same in LMICs. It is like the game Telephone where the message is distorted at the end of 4-5 iterations. So you have to be concerned of that message when you are communicating tolerance of acceptance.

6. If contract manufacturing, licensing are few types of manufacturing processes, what is the manufacturing practice followed by you?

Well we do both in house and contract manufacturing. We have the sewers in the HIC and the partner in LMIC which is a contract manufacturing but we work much closely. 98% of our market is in the HIC. Getting started in Saudi and UAE. The customers in Canada and Switzerland there is not middleman. With the UAE and Saudi it is going through a local distributor. You much have a local distributor to facilitate supply in these countries.

7. Are you present in a special economic zone or free trade zone? How does that impact the operations?

I am not an expert on that. We used to have something (changed to something else under new leadership), there was a different tariff schedule that was renegotiated between neighboring HICs. It is not a free trade zone but a liberalized trade zone. But no, we are not in any such zones like ones seen in Abu Dhabi.

You have to ask yourself what magnitude of business you are going to do and them what eh available labours is. If you are mechanized and you just need to set up the machinery that you can pump our product. Compared to our products where we need sewers, the intricacy and availability of your manufacturing will encourage or discourage the use of free trade zones.

8. Have you encountered issues with respect to bureaucracy that have had an impact on the operations of a company (LMIC and HIC)? (please explain the situation)

The only most recent bureaucracy was when we were tried to clear our products for air freight there were some hiccups along the way and I had to call the regulatory body at the importing airport as well as border patrol and customs and we put together a very nicely described here's our manufactures and their regulatory body certifications, the importer details, our regulatory information. Once I had that packaged and send around, some agents were absolutely hopeless. But the agents at FedEx and UPS were very helpful and our products were released that day. One of the DHL agents had their thumbs up their ass for 2-3 days that it delayed our products. Best way of action is always be ready with proper documentation and a good liaison to particularly in LMICs, they are critical. Not that I am advocating it, but in a HIC there is a very formal set of procedures and that gets done way. A formal liaison is not that important in an HIC but wouldn't hurt to have one. I had talked to some representatives who were very helpful, proactive and insightful.

9. Did something stop you from moving to an LMIC.

I think what stopped us from doing that we had a personal connection with a company in China. If he has set up in Mexico we would have been there. But in any LMICS you would an onsite manger and a liaison who should work here who is going to do the day to day operations. If you want a HIC company to start operations in LMICs there will be a hand holding phase which is very much required.

Both the facilities produce the same product. For us maintain the same amount of customers, it is a lot more people to manage, higher costs, and headache. It is mainly a backup for us. Any quick changes can be done quickly. It is diversification, buffer and for R&D.

Interview-5

1. **Details of the interviewee**

   Name: H2
   Position and company/organization name: Managing Director
   Expertise: Manufacturing and assembly in an HIC

2. **Permission to record**

   I would like to record this interview for the purpose of review and transcribing. Once the information has been documented the videos will be deleted from storage. Is that okay with you? **- Yes**

Open Questions:

1. What do you perceive to be the challenges to manufacturing in HICs?

This is sort of obvious things around cost. There can be a lot more red tape in general the compliance issues are difficult in HIC. But generally speaking there are not many issues in HIC. You are prone to some political issues, in particular the HIC, we have to put things in place to mitigate that issues, like we need Europe representatives and that whole another level of bureaucracy stacked in top. But generally speaking, it is all into costs – raw materials and work force costs, along with all ancillary costs that goes with it. There is generally lot of red tape procedures which go around all health and safety related but sometimes it can be overburdened. WE seem to have more regulation./ More taxations in the HIC which is extremely high.

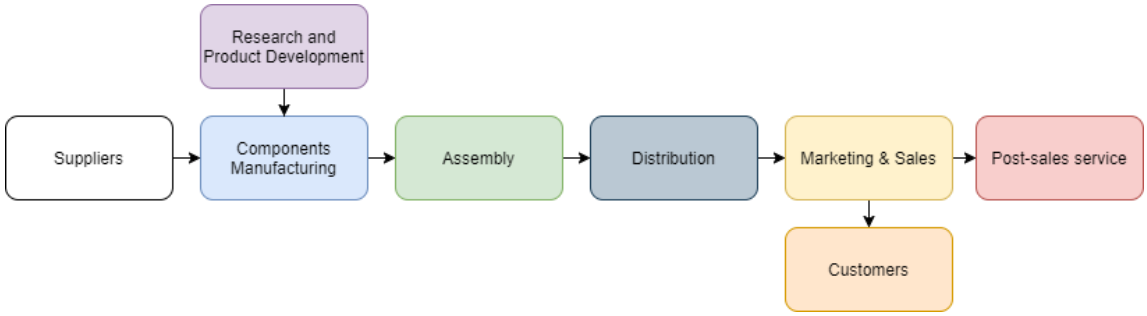
2. What do you perceive to be advantages of manufacturing in HICs?

These are more the drawbacks in LMICS. Finding the right staff, maintaining control – commercial control, financial control when you are far. The biggest one is quality and legislative approvals. These are biggest issues in LMICs which are advantages in HIC. Some big international; companies do seem to ignore safety issues. They just pay compensation and cover it.

Prompt: with respect to reliability in supply chain – Reliability issues are always a problem. I used to lecture on consumer reliability. Insurance don't cover negligence and insure only the residual amount. In number of countries the burden is far less. Our market is the limited resource setting. We made the decision when we set it up. That gave some challenges, especially when we went for a loan. We are one of the few companies who are quite successful. Things manufactured in the HIC have a sort of premium quality. People think it is of much higher quality. If people know it is from China there is an impression of it being a lower quality product. People trust on the quality of products from the UK. There are few logistical challenges. We sell to 80 countries but there are very few we cant get into. Some the

bureaucracy is quite difficult and u need to make sure that your paper work is in place before you are good. The other problem is selling to low resource countries around the world are charities, NGO or through the government. Tracking where the funding comes from, and answering the right questions is difficult, even though they are not very relevant. The other big issue which we have is unfair competition. That is not for a commercial basis. It is from NGO< charities, and universities that sell low cost equipment. They are not low cost but subsidized. There is a big difference, especially if you look at the long term prospects of the product. Students, PhDs and professors work on an equipment, they have funding to develop the product. Eventually these aspects are not considered when you compare the costs of developed product to that of a commercial product. People need to be realistic when they cost their products. I think with some experience and realism and trying to make sure you are covering all; areas of the cost. Overhead costs are what kill a company if not taken care of. You need to have a company that has a good margin, especially in this field because you will have pro bono work to do. There will also be maintenance costs that drives the cost up. I think you have to identify all the positive aspects of your products. A lot of our products look expensive but our products easily work for 10 years when compared to the competition. When including the run time cost I believe our product tends to work out cheaper. People don't take into account the life time costs of products which is a big deal for us.

Discuss the specific aspects after open questions



3. Where in the supply chain (as shown in the simplified process) do you see these challenges and advantages play out?

You have got a lot of work to do for post market vigilance and if you take the current situation lot of people are making products that they are not familiar with and lot of them are by passing the legislation requirements. That has gotten worse in the covid situation. The idea of open sourcing medical equipment is ridiculous. It is almost like posting the plans of an MRI scanner or nuclear reactor that anyone can whip up. In HIC we had this massive scares, where if anyone can make a ventilator we will buy it , said by the Prime minister. It is insane., 80 years of development cannot be crammed into 6 weeks. I don't think a single one of these ventilators has ever been used successfully on a covid patient. It is quite scandalous. Other areas in there, control and distribution is quite difficult. Finding reliable local distributors is a mammoth tasks. We worked our way through loads of under financed , under reliable and unrealistic contacts to where we are. Supply chain is going to a challenge in on where you are in an LMIC. India and Pakistan are not that bad. There are some areas that can manage these technology

manufacturing,. If you are looking in Africa, there are some p[laces in South Africa, Egypt is it. Finding countries who can manufacture products to the required quality is difficult to produce. A big organization wanted me to make the ventilators in Kenya. When I checked the list of companies who were going to make it they weren't viable options even though it is a great idea. It can hamper the company reputation as well. Some of the larger companies who open offices in LMICs, it is almost a loss making opportunity, but fills up their Corporate Social Responsibility meter.

4. How do you maintain the quality of products when manufacturing in HICs?

I employ people that know what they are doing, loads of record keeping and lot of processes in place and you are constantly audited by external bodies. So you can already maintain control of the products, which allows us to produce consistent and quality products. The company is an ISO 13485 company for the manufacture of medical devices., We have some advantage being a small company. We are quite flexible and lean in what we do,. Our turnover is quite big because we are efficient in what we do.

5. How strict are the regulations and policy guidelines available? (what kind of tolerance is allowed for the quality checks)?

They are incredibly strict. The requirement for external testing in extremely high. Personally some of the requirements are for organizations to make money that quality. It is the medical devices., some are single use. But I think it is more about making profit that patient safety. I see a lot of equipment that has a date on it. In reality these products last much longer. Most of our products are not one time use. So we try to minimize the use of consumables which otherwise don't make sense.

6. What are the actual manufacturing practices in HICs?

It is actually quite difficult to do if you have larger volumes to do. We licensed out ventilators to two large companies during the covid times. By the time they are were running the need had passed. In that case there would have been high volume and worth doing else not really.

7. Are you present in a special economic zone or free trade zone? How does that impact the operations?

Sadly we are not, there is some residual funding which we can use. We never had substantial money that way. I think these zones are a great motivation for companies to come and shift their operations there. Chasing big companies can leave the location and leave a big hole in the economy. I don't think it is a long term solution.

8. Have you encountered issues with respect to bureaucracy that have had an impact on the operations of a company (LMIC and HIC)? (please explain the situation)

Yes, it has happened. Bureaucracy for good reason I tolerate. For the sake of bureaucrats I will argue quite strongly with a lot of organizations. There was number of countries in Europe who

asked us products which wasn’t needed. Good stuck between borders for a long time which lead to a loss. The new medical device regulation has some plus points as well as problems to it from the perspective of a manufacturer. It is really unrealistic, the people who wrote is don’t really know manufacturing process. If you are assembling on the same location where manufacturing there is less logistically challenging. You need to able to react quite quickly, A real balance between holding stock and manufacturing should be made to be able to survive with these challenges.

Interview-6

1. **Details of the interviewee**

   Name: H3
   Position and company/organization name: Quality and Regulatory Affairs & Purchasing Manager
   Expertise: Medical Device manufacturer in HIC

2. **Permission to record**

   I would like to record this interview for the purpose of review and transcribing. Once the information has been documented the videos will be deleted from storage. Is that okay with you? – **Yes**

Open Questions:

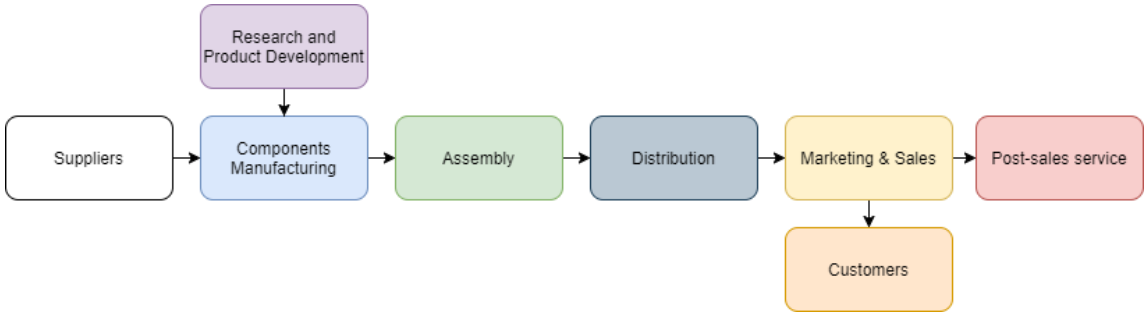
1. What do you perceive to be the challenges to manufacturing in HICs?

For us there are 4 topics Sometimes there are very strict regulations, too strict which makes it difficult to find suppliers who satisfy all these criteria. The other point is in you will have suppliers who have very small production line in HIC and big volume in LMIC therefore has same problems as LMICs. Even though you pay a lot of money the product is coming still coming from LMICs. The strict regulations are also different around different European countries. The MDR and MDD are slightly different which is not here in LMICS. There normally not so strict and not so hard as the laws are not this specific. The cultural differences are also a big challenges. Even though we are saying the same world, the meaning and way it is taken is different. It could be difficult to understand. Very hard to reach a conclusion.

2. What do you perceive to be advantages of manufacturing in LMICs?

Normally the HICs have a stable and regulated market which makes it easy an faster to qualify new suppliers. Regarding quality you find valid quality certificates from suppliers which makes us understand how they are experts. Other countries are reduced to make foreign countries as partners. Also the responsible personnel and more highly educated, lesser number to connect, lesser mistakes. In LMICs there are 7-8 contact persons. because everyone is doing a specific role and this can lead to potential mistakes. The ease of communication is the advantage and easier to prevent mistakes. HIC companies are very customer focused which is a huge advantage. This doesn't seem to be an important key indicator for LIMC companies. The main aim is cost. With HIC there is a lot of work before cooperation and with LMIC there is more work after you start work. Very often problems, miscommunications can occur. So it is more like lesser amount of issues come in an HIC because of documents present, quality standard and regulations.

Discuss the specific aspects after open questions



3. Where in the supply chain (as shown in the simplified process) do you see these challenges and advantages play out?

For us it is mainly he component manufacturing. It is visible and feelable in this part. Easy and simple product in the market make it a challenge for us to make specialized products. Also the corona crisis shows how the market is vulnerable. R&D complements manufacturing loses focus from what is going on in 5 years to profits of the company. We feel it that the prices of goods are very high and logistical challenges

4. How do you maintain the quality of products when manufacturing in LMICs?

In HICs, they are focused on customer satisfaction. A part of that is the certifications ISO13485. We really see authorities focusing on the market and start to also certify production lines in LMICs. A big part of customer satisfaction is the claim handling process. HIC focus on quality assurance. In LMIC is it that you dispose the product and but a new one. HIC companies try to lean why this claim occurs. In HICs the QAA is already prepared and more details are discussed but in LMICs it is done only required. Companies in LMICs are not really prepared for this requirement. In my personal opinion the LMICs when they start focusing on the customer satisfaction they rise above in the competition. The last 10-15 years was all about price. Now it is changing to customer satisfaction. I believe the LMIC manufacturers will overtake and rise above all the global competition once they shift their focus towards customer satisfaction. What you also find in HICs is everything more prepared from the beginning. They know they will need an ISO 13485 certification . The suppliers should also be ISO certified. The HIC market is more reactive to the customer needs and are actively going through standards and regulations before a customer asks for it.

5. How strict are the regulations and policy guidelines available? (what kind of tolerance is allowed for the quality checks)?

It is really a hard question as it is very dependent. As we see in the recent EU MDR, too much regulations are absolutely counterproductive, especially for companies with R&D and specialized products. Quite a long time FDA in the USA has very strict regulation, and the result was the lot of specialized companies shifted to Europe where the regulations weren't that strict. But now the new regulations that have come and even more strict. The MDD till May 2021 was not as hard as the FDA in US. Europe is going right now going the opposite way

with the strict regulations. Lot of SMEs have stopped manufacturing the specialized medical devices which are not highly profitable especially with the stricter regulations. In my opinion Europe will lose the medical device market. As the regulation gets too strict, just like FDA it will be difficult. Saudi Arabia is working with FDA to realize the needs of manufactures and how they can speed up the R&D. Europe is going back with the new regulations. Only the big companies will be profitable with these regulations. This is the problem with too strict regulations. In my opinion the EU over worked on the regulations which could fire back on them. We see that now most of our knowledge and products are going to the Asia and Africa where they are not only interested in the products but also on how to make the R&D move forward faster unlike the EU. Most of the medical device companies is EU is small companies and with the new MDR it will be troublesome for them. This is a chance for Asia and Africa to attract these businesses there.

6. What are the actual manufacturing practices in HICs/LMICs?

We have contract manufacturing. The main companies which we have here are parts for our devices. Semi-finished products are procured from them. They are situated here in Austria. From LMICs we have some products coming as well, but they are very low risk parts. Higher risk class product are made in Austria. There is a major difference between these suppliers. Like I said before there are 8-9 people to connect for a small thing compared to 1-2 in a company in HIC. This communication barrier is a major difference that I see. We are also more flexible, because the producer is just 50km compared to 1500kms. The logistical cost and obstructions are another challenge. It is profitable if we sell high volume products. But that is not the case for most of the medical devices.

7. Are you present in a special economic zone or free trade zone? How does that impact the operations?

We are not a big company, but our suppliers are. There are some regulatory and tax benefits for them which in turn works out for us. I don’t have the exact knowledge on how it impacted us. Normally it is better to have all the operations under one roof, but it is again product dependent. More companies are involved more complex the process gets. There is also a difference in country rules which is dependent. So I can’t really comment perfectly on it.

8. Have you encountered issues with respect to bureaucracy that have had an impact on the operations of a company (LMIC and HIC)? (please explain the situation)

A local liaison would help in navigating through the red tape procedures and bureaucracy. A local partner or distributor who knows the market and is able to make sense. Of course it really is there. It is complicated worldwide. Especially the Asian market, we saw this view, where each country has different procedures which is complicated. Hard to handle thing, which can be tried to fix by a local liaison. We have to go country per country, go in detail what are in requirement and then move forward. Sometimes it is “interesting” these differences and you have to devise how to reach this market. We are facing bureaucracy which just keeps getting more. In our opinion it is preventing SMEs to enter these countries who are very innovative and have great products. The regulatory requirements forbid these devices a chance to prove itself that it is helpful for patients.

9. Do you have plans to moving to an LMICs?

We thought about it but it is part of marketing for our company that we are located in HIC. An opponent of us is in LMIC which is 30 kms away. The income there is 1/3rd that of us. The quality of products is something that needs to kept in mind and is what demotivated us. Maybe if we have high volume sales we will think about it again.

Interview-7

1. **Details of the interviewee**

   Name: H4
   Position and company/organization name: Product Manager
   Expertise: Medical Device manufacture and assembly

2. **Permission to record**

   I would like to record this interview for the purpose of review and transcribing. Once the information has been documented the videos will be deleted from storage. Is that okay with you? – **Yes**

Open Questions:

1. What do you perceive to be the challenges to manufacturing/assembly in HICs

You know, that, like the in the high income country, like some people will say, you will have a higher quality comparing with the low income or middle income country, that's for sure. You can debate on that. But the cost is much higher. There is like no doubt about that. Also, for us, since our customers are based on LMICs, it's not also about manufacturing, it was also about being close to your customers. So here we develop, we improve our products based on our way of seeing the development roadmap. So and we look like by we can say that like Western eyes. But however, we're offering a solution for the LMIC, especially like for us as definitely changing. So we should look by those eyes, like, by our customers eyes to see how can we improve? How can we develop our products and solutions? This is also like, we have a lot of creative minds who have a lot of creative brains, but you still cannot 100% feel the customer, if you're not from their country, if you don't understand their culture, if you don't understand their needs. We know that like we know we do research, but you still you cannot compare us to people who manufacture or make the products. They're in LMIC. Yeah. So the most to sum up the most difficult parts of the challenges that we face is, of course, the cost, of course, the transportation of the products. It also takes time takes effort takes money. And the or not say the luck or creativity. But I would say there is a cultural difference

2. What do you perceive to be advantages of manufacturing in HICs?

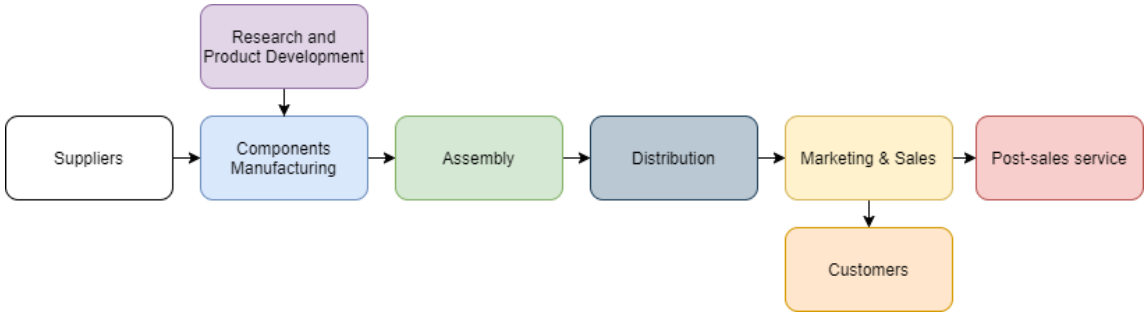
The flexibility that we have here? I mean, like in the high income country, you have open resource for everything, but literally for everything here for us, for example, like our CEO will tell you like you think about something you think it's an entrepreneurial idea is going to affect so go do it. You don't look at the time you don't look at the money you don't look at anything. So, here you have like this open resources for everything you have, like people who can help you. I mean, for example, especially for us, in the in the field of artificial intelligence, I can assume that it's quite difficult to Find there in low income countries, the

same amount of people, of course, you will find there but they don't have this strong background in this different fields that as we have here. So this is the best advantage or the most advantages that we have since we are based in the HIC. Yeah, the stronger background with the strong facilities that we have here, not only like the money, the people, the laws, and the rules here, how support the entrepreneur roles, how they support the employees and employers just to be strong.

- Prompt: with respect to competitive costing ?

It's comparable. Yes, it is. You have to be right. I think you have otherwise like you lose the market. Yeah, true. But I mean, they know like, for example, the customer is no when you offer like when you show them? Like, of course, it's I think we are more expensive. But at the end, like if you look about what we deliver, and what our other competitors deliver, then you will see like, okay, there is extra money, but there's extra things that are be have been done here that other competitors maybe are not delivering

Discuss the specific aspects after open questions



3. Where in the supply chain (as shown in the simplified process) do you see these challenges and advantages play out?

Suppliers and component manufacturing. Yes, I would add also like for I would add, like, so make it like marketing, sales, then customers, then post sales service. And then from that point, our back to the research, product development, like a feedback, because we get the feedback from the customer we to analyze what customers need, how their experience is, with this product, then based on that we give feedback to our product manufacturers to like, we need this. Yeah, I think for us distribution, because before that, it's under control, we control it. Because like, you know, we know our suppliers will contract with them were there with them, we supervise and manage the components manufacturing and assembly. I personally, I go there to supervise that. And also for the alternate distribution, we made sure like the sales lead the whole process, that communicate with the customers, the post-sale service, the warranty, etc., and also ask for feedback. So we Have 100% control on everything besides distribution, we have 100% control on everything after distribution, but the distribution itself, also we try to control it, but it's not our hand we something that we

don't do it, we outsource it, but there are shippers who do that. Okay, this is I think, the bottleneck that we are facing right now.

I think advantage is how we are like, managing each step of his diagram. So we know our suppliers because we are part of the supplier. It's not like it's not Yeah, we are a kind of like, then we are the sister company of a supplier. So, we are a part of this supplier who's been doing this job for 100 years. So, we know that then we are in the ground to control and manage the component manufacturing process and assembly and I think we are good enough also an after the distribution. So in the way that we work, our strategy, our business model works, tell now I can say that it was efficiently.

4. How do you maintain the quality of products when manufacturing in HICs?

The quality of products also is something for example, that we have to do as a European country, as a HIC company. Yeah. So how because first of all, like, you cannot be a manufacturer, especially in the medical devices here in Europe, if you don't, like you can, but then you cannot go also to the market and prove yourself as a manufacturer, if you don't have the ISO certification, and if you don't have the CE certificate, which is kind of European or Asian standard to prove that you have high quality products. For these certificates, they made sure that everything is well calculated in terms of this, like special in the quality of the products you have, like manuals, you have procedures that you have to go through. And not only procedures also people for example, you have to do a assembly, to pre stage you have to test then another one has to do to come and to check if the pre staging was good. Then Delft imaging because we're just distributor we don't make the products, but we also have to go there and like me personally as my target as Product Manager, I have to test the all the products that we are going to sell. Okay, so there is a strict loop that forces us to make sure that the quality of the products are 100%, more than excellent, I would say.

5. How strict are the regulations and policy guidelines available? (what kind of tolerance is allowed for the quality checks)?

Yeah, there is kind of flexibility. It depends also on what do you, what does our customer ask for? Yeah. So if you can improve that this customer, for example, ask for this thing. Exactly. Which has, for example, if a customer asked for a used X ray system, you know, like, it's not nothing new, but it still functions good. And then you will have an agreement with the customer and this is her or his need, then you can prove that it's not like, it's not as the new but since it works tell the minimum limit that should work on that is okay.

I think I would call it contract manufacturing, because, but it's the model itself depends on each project. But yeah, normally, because at the end, we sell the manufactured product, right. So it's their job to deliver us high quality products. And it's our job to also to always look for opportunity for new products for new development and for new projects. Yeah. So it's Win-Win relationship, it's always like this win-win. But it depends on which model your company or your office is following. Some people you know, like would follow

subscription model, then your ask your manufacturer to provide you as much as possible. Yeah, it depends on the model that the company is following.

6. Are you present in a special economic zone or free trade zone? How does that impact the operations?

I don't think so. However, what I want to mention is here you know, like in the HIC, you have to pay the 21% that the WT tax for everything but since we are company who deliver and ship or sell the products to LMIC, so then we don't have to pay this. Because like here when you buy anything for example, like if you go now to pull up contract to buy anything that will you will see when if one person included or it is called btw included, I have seen that Yeah, but since like, for example, if we are going to sell to another one here, we have to pay but since we are doing our business outside HIC you we don't pay that

7. Have you encountered issues with respect to bureaucracy that have had an impact on the operations of a company (LMIC and HIC)? (please explain the situation)

Yes, but I understand this bureaucracy, and also like, we have to be very realistic, because, like, each country has its specific rules, right? So when you try and like, again, it's double when it comes to the medical devices, because each country has a specific vision about how this system should work, what is the safety, what is the resolution? What is the limitation that each country has its own rules and laws wherever. So the accuracy begins when we want to ship something from here to here because you have to understand that everything about the HIC itself since we are based in the HIC, you have to understand, you have to start the procedures. When it goes from the HIC, then you're like you finish with the small load then you have one bigger which is HIC. If you're shipping outside the HIC then you have different rules, different regulations, that You also have to start with understand what should we do? What should we offer? What documents? Yeah. And again, finish from HIC, then the system should go to like LMIC to this country, you also have to understand the same thing again and again. So it's something we can understand why anyone can answer why? Because like you are moving from country to country. because we can avoid a lot of these things. We can start basically from LMIC. It's like, yeah. Imagine like, then, like, the customer will pay directly from there, or our like, still, like, even if we're going to ship outside the LMIC, it's still from LMIC to LMIC, much easier, much faster, less effort, less work, less money, compared with the Netherlands to Nigeria.

8. What do you think of the new MDR 2021 announced in Europe?

So actually, it you can say it's going to help us make our like business much worse, it's going to make business much worse, because it's going to affect us if guy like with more progressive with a lot of procedures that we have to follow more, on the other hand, is going to help us because first of all, I believe as much restrict These rules are still help us. Yeah. And since we are like, where you can say 90 95% matching this rules. So that was this, like more difficult restricted rules that can kind of maybe filtered the companies that don't match. So I think we will be an best and a better position as a company, which fits that rules, if we do that if we match these rules but trying to stick to these rules can drive up our costs and a risk of losing the medical device market from Europe especially the SMEs. Especially comparing with Asia or like, yeah, it's, there's a huge difference. Yeah,

exactly. So and one thing that helps, that makes the products more expensive, and then I'm the customer because at the end, anyone if you offer two solutions, one much cheaper than the second one, even if the second one has more features, but if the price is very high, Like the difference is very big then. Okay, I would go with the cheaper This is like the human how people buy.

Interview-8

1. **Details of the interviewee**

   Name: HL1
   Position and company/organization name: Chief Operation Officer
   Expertise: Manufacturing and assembly in China and distribution in Africa

2. **Permission to record**

   I would like to record this interview for the purpose of review and transcribing. Once the information has been documented the videos will be deleted from storage. Is that okay with you? - **Yes**

Open Questions:

1. What do you perceive to be the challenges to manufacturing in LMICs compared to HICs?

I would say, infrastructure, both in terms of transport, but also in terms of the actual facility where you might operate. So moving goods around the country, into the country, are always challenges. But then also on your actual premises that you might have, you know, the quality of the building, the quality of the internet, of the wiring in the building, all that sort of stuff is generally less well organized in lower middle income countries. So I would say those are and so that's on the sort of infrastructure side. And then the other is, is people and education. Yeah, you know, it's, it's relatively easy to find staff, but well educated, sort of middle to senior management stuff is either very hard to get or sell really quite expensive. I wouldn't say in terms of sort of manufacturing capability and that sort of stuff. I would definitely see class China as high income country. In terms of infrastructure, manufacturing capability, people, it's all super high standards.

2. What do you perceive to be advantages of manufacturing in LMICs?

Well, for us, in our case, at least we sell in low and middle income countries. So manufacturing, there would mean that we manufacture closer to where we actually sell. So that reduces lead times. So you're more reactive to whatever happens in the market. Yeah. So that's a massive benefit. And one of the main reasons we've looked at it in the past. And the other reason was, we've looked at it in the past is that well, two more actually, one is just job duration. You know, in the end, I mean, we're a for profit company, but with a social sort of viewpoint as well. So it just, it feels like the right thing to do to want to create jobs locally. And I'm finally but that's always a little bit more tricky is that in theory, you can get some savings on stuff like import duties. And that sort of stuff when you produce locally, rather than, you know, import everything from elsewhere. But that's only, you know, that's like I said, that's the theory. So for our products, for example. I mean, I haven't looked at this in years, but we make solar home systems, so that's basically your solar, solar panel, batteries and lights. importing the components of those items isn't necessarily

cheaper in terms of import duties than it is to import the entire finished product. Okay. So there, you really need to look at the details of you know, is that actually on the balance of things. Are we gaining anything by looking at locally?

- Prompt: with respect to raw materials cost?

Well, so I think that this is the main issue also. And that's one of one other reason that has always held us back. So what we produce is, well, their electronics products, right, so the rules are rules for everything that we make. comes out of LMIC anyway. So or, or at least somewhere in the far east. Right? So I mean, we looked at actually sourcing solar panels locally in LMIC, there are companies that have solar panel factories in LMIC I remember Jingo solar, which is one of the big ones worldwide. They have factories in LMIC, but also a factory in LMIC. But they're trying to produce solar panels were still cheaper than the ones produced locally in LMIC. So it just yeah, it just doesn't really make much sense. So. So I think that for us that might be different for different industries, but for us, because it's mainly electronics, all of the components come out of LMIC anyway. So yeah, it just also felt like we didn't gain too much there by sort of assembling or producing locally.

- Prompt: with respect to local workforce?

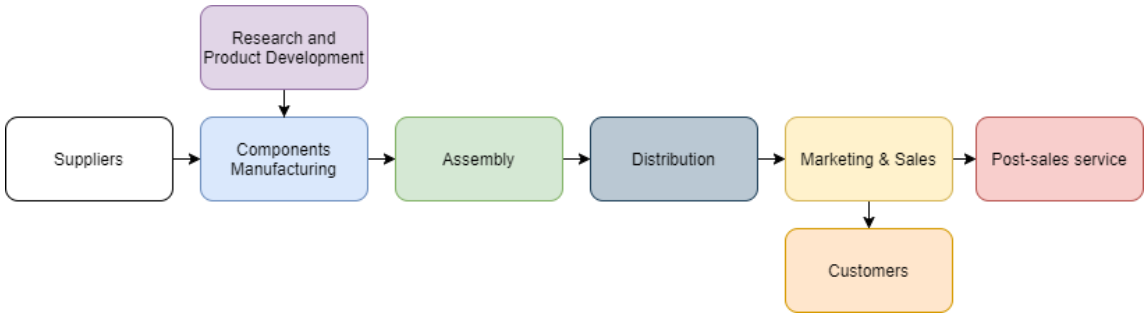
Yeah, yeah. I mean, we see that every day. I mean, we don't manufacture locally now, but even in our salespeople instead of the management team, so, you know, salespeople and technicians sort of, you know, let's call it a low level job or entry level jobs, there's plenty of people and finding good people to be found as well motivated people that really want to, you know, really want to get ahead. But once you start getting through sort of middle and senior management, it becomes really hard to find good people that want to stick around. And, yeah, that that's a constant struggle. And that's just, you know, the way we see it, at least, it's mostly an educational thing, right. So there just aren't as many people around that I've had a very good level of education. So that means it's hard to find good people that can sort of form your middle and senior management team. So the way I mean, the way we're seeing it happen is that actually, we have people that move that start at sort of the entry level jobs and sort of move up slowly. But you know, that takes a lot of time. Right? To that, I would say is, is a main challenge. Yeah, it is cheap to find sort of junior level jobs, definitely cheaper than in, say, LMIC. But once you get to middle and senior management that isn't necessarily much cheaper, because these are people that are, you know, in short supply, so and they tend to be, you know, employed by the big multinationals that are present in every country. So they're, they're generally very well paid. I mean, there's still a bit cheaper, I would say, then, than, say an expat. So it's still better to hire locally than it is to put an expat in there. But still, there, you're not really saving much money anymore. Yeah. But obviously, you know, what, if you would consider actually producing locally, then obviously, the majority of your cost is going to be the actual labor as the actual people working in the factory. So they're definitely you're saving on labor costs.

- Prompt: with respect to competitive costing ?

Well, I think you can be, I think it would probably be hard to be to be cheaper. I think you're always going to end up being a little bit more expensive than something that's

producing the say LMIC said the reason but there might still be other reasons to still choose for that. I mean, cost is only one factor, right, so another. Another reason to do it was like I said, you know, job creation, and the fact that that is something that is just important for a company, it helps a lot in any kind of you know, any organization that wants to sell, or work with local governments, it helps hugely if you can say that you produce locally, even if it's only part of your product. And then yeah, depending on sort of the setup, depending on which country it is, and which Customs Union, there are parts of it, it can help in in at least, you know, reducing tariffs and stuff like that when you when you sell or ship to other countries. But I would say just purely on cost price, it's going to be really hard to do it cheaper just because of the infrastructure and the efficiencies that they that they have in in China.

Discuss the specific aspects after open questions



3. Where in the supply chain (as shown in the simplified process) do you see these challenges and advantages play out?

Well, I would say the challenges play out almost everywhere. Yes, every step. Yeah. The advantages are from sort of distribution on what's so just because you're closer to the markets, right, so distribution marketing is sales, post sales service customers, all of that is a lot better if you're if you're close to where you're selling.

4. How do you maintain the quality of products when manufacturing in LMICs?

Yeah, I guess, I guess it depends which countries you're comparing it with. I know, for example, in Africa, that anything that is made in LMIC doesn't necessarily have a very good image and in terms of quality, so Europe is a different, or Europe or the US, that's a different matter. But stuff that is made in China, people generally don't really have a very positive image of in Africa is four years, they received shits quality from that. So that actually, you know, just comparing to LMIC, I don't think that that is necessarily something that people would perceive as a quality product. So I would say, I mean, the only way to really get rid of that image. Well, let me say, I think it's actually something that that probably, you know, local people that you're producing a form wouldn't necessarily have a

problem with, uh, you know, I can imagine that Mozambicans would be more than happy and proud to buy something that's been produced in Mozambique. And for those arts, and those are going to be your main customers, I would imagine for those outside of those countries, like I don't know, investors, or you know, government officials, or other stakeholders that have a more, let's call it worldly view, the only way to do that is to make sure that you adhere to certain quality standards in every industry has certain, you know, quality standards in place that you can, you know, get your tests, get your products tested on. And so I would say that will be the way to go to ensure or to clarify to the outside world that what you're producing is in quality is just as good as anything coming out of Europe or the US or China. Yeah, well, obviously, we don't produce locally anymore, but any products that we buy from our suppliers, are lighting, global certified, okay. So that's, it's an organization that was originally started and funded by the World Bank and the IFC, and they developed a quality program, basically. So if you're a manufacturer of solar products, you can get your products sent off to a lab, and they run them through a whole series of tests. And if they pass, then then you get like a lot of lighting global certification. And that is, yeah, that's a at least a confirmation that your products have a certain minimum quality. And so that for a lot of like, grant programs, and government run programs, for solar products, that's a requirement that your products, the products that you use in those programs need to be lighting level certified.

5. How strict are the regulations and policy guidelines available? (what kind of tolerance is allowed for the quality checks)?

No, it's there. At least for these standards I just mentioned, there are international standards. So there isn't. And as long as you pass it, it's fine. But there's no room for negotiation. So yeah, the only thing that they do is if you run your products through those tests, and there's certain points where you're not compliant, obviously, they give you the opportunity to improve and resubmit a product or make changes that will then ensure that you do pass. We mostly rely on because, again, we don't produce ourselves so we really rely on our supplier to mainly do that for us. But we do regular tests on you know, sort of just random checks on stock, that new stock that we received and see if there's anything funny with them. And then we reports, because we sell, you know, 1000s of products a month and when we get obviously we get quite a few back also from the field that have some kind of issue and so we have like a monthly reports that we send to our suppliers to say okay, we've received This many products this month that we went through, and we tried to repair and these are the issues that we found. And that's then you know, we work on that with our supplier to make sure that we can fix those products or if there's really a real quality issue with the product, ultimately, the supplier can address that and give us the support that we need for that. It's a supplier customer relation. So it's a LMIC company, but I have a support office in LMIC, and they have a team of engineers in LMIC as well. And from there every what I would say probably once or twice a year to actually send one of their engineers over to our operation in LMIC and LMIC, to work with the local team, and it goes through all the checks and make sure they follow the right processes and that sort of stuff.

6. What are the actual manufacturing practices in HICs/LMICs?

A bit of a mixed bag, I would say I mean, in principle, we just buy whatever, that's how they kind of started, we just buy what they make, just readymade and off the shelf. But we have over the years sort of done some I would say co designing where we take their, their electronics, their batteries, sort of the inside of their product is theirs, but the casing on the outside is the thing that we designed. So it's kind of like co production, you could you could call it, I guess that goes a little bit more towards sort of OEM manufacturing. But in principle, this the starting point is that we just buy whatever they offer. Now we distribute them ourselves. So we have our own distribution companies in LMIC and LMIC, those are the two countries where we sell. And then we work with our own sales agents, our own technicians, that that sell directly to the end consumer and service to consumers. It's was a HIC company originally, but it's, we only have two people in HIC. And we have 200 people in LMIC. And of those 200 people in LMIC, there are 3 expats. And everybody else is local. So it's, it's by all means a local company. And the same goes for LMIC. So they're just Yeah, they form part of a HIC holding company, but it's a locally registered company run by local people.

7. Are you present in a special economic zone or free trade zone? How does that impact the operations?

Well, LMIC and LMIC, and parts of this customs union, basically, for the southern part of LMIC. So all of the countries, I think it's from the DRC, and for the South are parts of that Customs Union, which means that everything made within this region is exempt from duties when it goes to one of the other countries. So that, I mean, that is potentially interesting. But yeah, we don't produce locally. But that's one of the reasons that for example, we're looking at seeing if we can get our TVs there. There are TV factories in LMIC. So if we would buy there, then we save 20% on duties for both LMIC and LMIC, comparing to buying them in LMIC, which is what we're doing right now. Yeah. So that's stuff we're looking at. But yeah, so that's, I think you have customs unions like that all over Africa. It is not really like a free trade zone or a special economic zone, it's just a customs union. So there's no specific benefits to sort of them, you know, the comments damage or factory there. I know there are places like that, I think in Namibia, there's a few places like that, think about Africa, but where we have never really suited them, because there's none of them near where we are. We really rely on our supplier, and really sort of, I mean, we have one main supplier, but we know very well what's going on elsewhere in the market with other suppliers that, that, that make other products. So it's really so we rely on sort of the markets to develop and to find new products and develop new things. And then our job is really just to make sure that we're aware of those developments and sort of, you know, grab our opportunity when. But we don't do any of any sort of R&D ourselves.

8. Have you encountered issues with respect to bureaucracy that have had an impact on the operations of a company (LMIC and HIC)? (please explain the situation)

I would say generally speaking, also, judging by what I hear from, you know, companies in in other countries, other parts of LMIC, we're very lucky in LMIC and LMIC, in the sense that it's the process of, for example, importing goods into the country is really quite transparent and works quite well. So we've never had, you know, I know, in other countries, it's very customary to have your goods stuck in customs for like four to six months, even without having any idea of when they're going to be released. We don't have that issue. We

do have in LMIC, for example, we were having issues in you know, around paperwork for the country manager, for example. So the country manager, there was LMICan search to get a work visa for him and LMIC, the process is an absolute nightmare. So yeah, we've been working on that for like six or eight months now. And it's still not finished. Right. So that is definitely something that that is. That's not helping. But I would say generally speaking, both LMIC and LMIC are fairly, there's no major issues that we've sort of come across in terms of your bureaucracy, or bribery, or whatever. But I think what also helps is that as long as you as a company, at least, that's our experience. You know, as long as you have all of your licenses, and you do you know, you follow all the rules that are there, then there is, you know, there's never any reason for them to really, they'll check on you. And they'll control whether you're following all the rules. But obviously, as long as you are following the rules, there isn't really anything for them to pick on into the financial. So that helps a lot. And I guess also, you know, where sort of our head office in LMIC, for example, is in one of the suburbs of the capital. Like I said, we employ 200 peoples in terms of our tax contribution to that local suburb is quite significant. were one of the biggest companies in that area. So they're also happy to have us so I, you know, I guess that that works both ways. When it when it comes to like, import duties, and that sort of stuff, we have a clearing agent that knows all of those things. And then when it comes to real sort of, you know, legal stuff. Yeah, we obviously work with local lawyers that, that know that way around the local laws.

Interview-9

1. **Details of the interviewee**

   Name: HL2
   Position and company/organization name: Managing Director
   Expertise: Service provider in LMIC for Medical Devices

2. **Permission to record**

   I would like to record this interview for the purpose of review and transcribing. Once the information has been documented the videos will be deleted from storage. Is that okay with you? **- Yes**

Open Questions:

1. What do you perceive to be the challenges to manufacturing in LMICs compared to HICs?

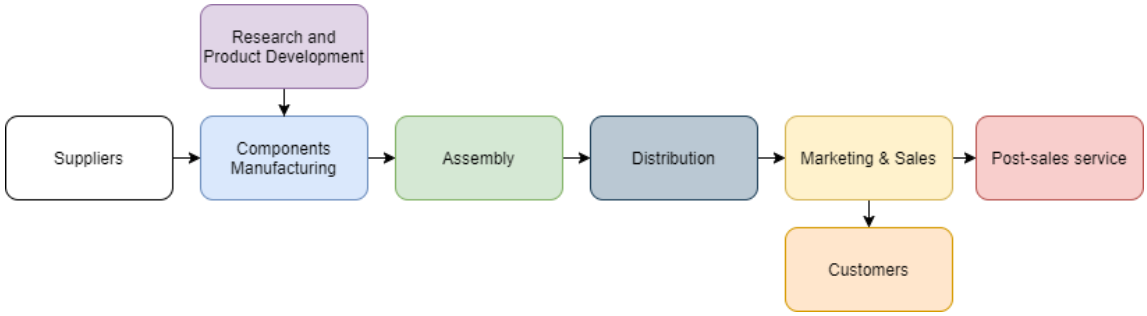
Yeah, I think I identify can identify a few. Major one would be for me, lack of transparency. I mean, lack of transparency on procedures, of governmental organizations and all kinds of authorities. You can't really find actual procedures on the internet. If you find something, it is either very old, or you can find something, anything at all. And if you find something you confront, you ask people to show no, it's not applicable. It's different reality is different from what is on the internet. So even when you ask questions, I don't think people involved to do not know, exactly the whole procedure or the whole? Everybody knows part. So to summarize, the procedures are fair of governmental organizations. And authorities are, usually how I perceive it, not transparent. That makes it difficult. Okay. There's always you always meet something which you didn't anticipate and is also to be to be done or to be applied before you will get a license or before you get approval. Yeah. Another one would be that they are not, and I can only talk about LMIC and LMIC, the other countries maybe surely own a little bit experience. But it's LMIC and LMIC. Lack of I think the challenge is that they are not yet digital enough the digitization of their portals, they don't have digital portals for to start procedures or to submit proposals or to do always you always have to print things. Give hard copies and soft copies of that that is also a challenge. They need hard copies that way you can they can find the hard copy. So they will be the new digital copy. The second time they can find a digital copy anymore. Yeah, I think I can list one and then additional challenge, they usually lack at least the people I met, lack practical skills are educated. Their theory was good enough was good high level, theoretically trained people, but few practical with few practical, practical skills to deal with. They were academically they are academically trained. And I think those universities or high school, whatever you call it, these institutions lack enough possibility for internships. They lack tools, they lack practical workshops in their institutions. So we saw, for instance, from our engineering staff that some of them are even having difficulties in holding the screwdriver. Okay. But the, so that's more or less a challenge, a few practical few practical skills. But

the advantages are very eager to learn. And they want to they want to be they want to discover the world.

2. What do you perceive to be advantages of manufacturing in LMICs?

The advantages I see is that I experienced even is that we have the people we recruit are highly educated. There's, there's a large number of highly educated people, They are eager, they are very eager to learn. They are dedicated to their job. So this staff is if you know how to find them, their staff, competent staff. And highly motivated and eager to learn, which is very, very good for the company. Yeah. Of course, there's aspects of lower cost of labor. It's also an advantage. Yeah. And another advantage is that by doing this, you as a company, but by working in a lower middle income country, as a company also fulfill some social responsibility, I think by developing that lower middle income country, yeah. by your presence, and by your business. I experienced that those people who apply for jobs with us, and we had a vacancy, and they were all very competent, and they are the people we are looking for IT staff, biomedical engineering staff. And they're quite huge number of people who qualify for the job we recruited for. I was impressed by their level of dedication.

Discuss the specific aspects after open questions



3. Where in the supply chain (as shown in the simplified process) do you see these challenges and advantages play out?

Actually, it was applicable to almost all maybe not for the suppliers. But for the rest? I think it was applicable. Even for advantages it is similar. Because even for marketing and sales, we have people they are very, they are always impressed by the eagerness to, oh, if we identify that we're not good in something, they will go to internet to find a training and they will try to develop train themselves. So it pickable for all of those boxes you have in your, your flowchart.

4. How do you maintain the quality of products when manufacturing in LMICs?

I think yeah, we started from scratch. Yeah, and but we have procedures, we have standard operation protocols. Within these procedures and SOPs there are quality checks. Now, how do we do we do customer survey, we survey our customers after training after an installation after servicing, we surveyed them systematically so every customer is receiving a survey. So we analyze these things. And we are also working on ISO certification surveys. That one is also helping us to maintain improve and maintain our standard of output our services. Yeah, our service,

5. How strict are the regulations and policy guidelines available? (what kind of tolerance is allowed for the quality checks)?

We tried, we this is a part we're just starting, we are currently in the registration process for ISO and ISO is that is what we are doing is also requesting something like that. And we have this a scale of one to five, like, from one to five. But we are yet to develop this, the tool to measure to and to be able to measure their quality, more or less we are doing so how strict, we said in our quality policy that we want to be not less than we want to score not less than three, on the scale of five. And gradually, I foresee that we gradually increase that to 3.5. And probably for the real tool, you have to develop the tool.

6. What are the actual manufacturing practices in HICs/LMICs?

Yeah, we are branch we are a unit of the ultimately, we are even changing our name. Also, though we are separate company we are more or less a branch where we tend to we don't have any contracts. I think that contract is between us and our partner.

7. Are you present in a special economic zone or free trade zone? How does that impact the operations?

No we are not. We need to learn if the free zone if you if you add value to the, to the things to the to the product. And I think that one has not yet been really sorted out and was something assumed by people in company that they could use the free space for storage, or for from do a professor distribution as a distribution center, but that's not possible. Okay. Because you have to add value to the product you are bringing in. I don't think we really studied it.

8. Have you encountered issues with respect to bureaucracy that have had an impact on the operations of a company (LMIC and HIC)? (please explain the situation)

Yeah. So for To be more specific is for instance, the importation of products. No processes, very not transparent takes a lot of time. So you do before you start, you don't know the cost. You pay at the end. Yeah. And you don't know the time you spent before. Getting invoices paid is another issue sometimes but you have a contract with the Ministry of Health for our LMIC project, and the contract reads that when we submit an invoice for something we are entitled to submit an invoice for the are to pay us within 30 working days now, but for example, it took 93 days for our 2021 invoice to get paid. Okay. So and it is it is only done after you've paid visit you call them you follow up you. If so, this one is very bureaucratic. It lies on desks and you can trace it up and they will tell you left they'll tell you right you

can trace where it is just takes time. You're just lying somewhere I don't think they're even working on it but they will tell you all kinds of stories. And another example is getting products accepted. In LMIC for instance, we've installed X ray systems in February this year. And they were all working when we left. Yet it took the customer up to now one by one. Start using this equipment. If not yet signed acceptance of the systems because they haven't. They're not using they haven't even checked whether it is working so well. To close the deal, and I have made with the customer you need them to sign off that they received what they bought. Yet they are not yet signing it. And their argumentation is that they haven't seen for themselves that it's working and when I ask them to go and but what were stops them from trying out if it is working. You're saying I They need approval from a local authority to use the system. They don't have staff, they don't have this. Very big, very bureaucratic, difficult . One really normally you don't even get your money if you if it's not accepted what in this case, we've got our money, because the deadline for the Global Fund to pay expired on 28th of February. Okay. So, by the end of March, I think they paid us their money. But that's not the normal procedure. No, you only get if you can show a signed acceptance report is difficult. Well, I think it would help if we had somebody in LMIC, physically. Going there, you always have to go there to trouble them, they have to see you, you have to worry them so that they feel the pressure that you're waiting for them you're waiting, because waiting on a distance waiting it or not doing anything at a distance and only be reachable through WhatsApp or by phone. Zoom is very simple. It's very easy. If somebody that's how it works in LMIC, and I think in LMIC as well, you have to go there and sit there so that they know that has to do something for you. It would speed up the process.

Interview-10

1. **Details of the interviewee**

   Name: HL3
   Position and company/organization name: Co-founder and CEO
   Expertise: Assembly of products in LMIC and sold in another LMIC

2. **Permission to record**

   I would like to record this interview for the purpose of review and transcribing. Once the information has been documented the videos will be deleted from storage. Is that okay with you? - **Yes**

Open Questions:

So we are based in the HIC right now. So we are producing the pumps in LMIC. And then we are selling in different countries. So these countries, we have our own offices to sell in two offices. And then the but the production does not happen in these countries. But it's happens in LMIC since about a year. And before that, we were doing like how to explain, we were getting components from different parts of the world, mainly HIC. And we were we are consolidating in HIC and then sending it out. And now, we do that in LMIC and most of the parts are first in India, and except one particular component, or two critical components, which still go from HIC, to LMIC and then goes to other countries.

1. What do you perceive to be the challenges to manufacturing in LMICs compared to HICs?

It's been more than a year now we are doing in LMIC. And, and the challenges and so perception more experience is on the reliability of suppliers, especially around timeline, yeah. And around quality. So how it works in HIC, if you, so basically, we do not own production machineries. So we always get our path from different suppliers. And we consolidate, we do simple machining, like post processing, but we rely on suppliers to supply the components. And that in HIC, for example, if you order something, you get Okay, a lead time of six weeks. And then at that six weeks, you will actually get your path. So the lead time can be longer, sometimes six, sometimes eight, sometimes you get in the rotation, 12 weeks. And that's different in LMIC. And so normally, the supplier promises something shorter, so you will get something in two weeks, four weeks. But it can happen that in four weeks, when you call them. They're like, Oh, okay, what was your part again, or like they, they actually haven't started the production in that time. So we have had issues where a four weeks lead time took a year to completely get all our parts. So that's that, I would say is the major issue. It also depends, I think, on what kind of companies you work with in LMIC. So there are large corporates, and then there are these small manufacturing companies. So we mostly work with the smaller companies. And that I would say is the biggest challenge. We also source from LMIC, in the past also now. And that's different in LMIC there, you can get a more reliable quotation of timeline. And the communication is easy. For example, you just talk and you can really source

things sitting here. And that's the second one in LMIC. That's, that doesn't really work. So you cannot really find suppliers sitting in the HIC. And there is no, so there is LMIC Mart, but it works very differently. Like with LMIC market, you cannot get that, it doesn't work, certainly if you write messages you can really source from here. So that's another issue is this communication with suppliers, finding the right supplier would still be an issue. So for us, we started out. And the third factor, so if you are international company is the trust factor. So for example, we started out as we wanted to do it in partnership with other companies, so we didn't want to have our own assembly facility was up, and when that didn't work out, so you know, reliability and all that. So then we decided to have our own facility, have our own team, and then things started getting much better. And so I would say, timeline, communication, this trust or reliability factor, especially if you're a foreign company, and then you know, like, people will think of, that's also I think, different compared to LMIC in LMIC, you will get a price and this is reasonable, but you will get to prices, if you are a local company or a foreign company. And then you do not know if you are now you never know if you've got a good price or not. And, and the last and that's probably the most when you think of perception, the first thing that will come is the quality, that also in the quality of parts, there will be issues. So you should expect there will be some rewards to be done. Not everything is so even though it's worked in CNC, there were certain things, so all this compared to here, like if you had to produce in HIC, so more uncertainty, I would say,

2. What do you perceive to be advantages of manufacturing in LMICs?

cost! cost! Yeah, that one is its cost. So just on the previous one, one more thing that I also know from other companies doing, especially in India is suppliers will not say no. Ask, can you do this? They'll say yes. And then the challenge. So sometimes this delay in timelines comes because they only look at in detail later. So that's a challenge. on the good side, the cost. I mean, it's so depends on what you are looking to source and in which country. So if you're looking to do machining activities in India, it's, it can be really cheaper. And that's why you should also expect some of the previous challenges and then the live in peace with that. And also, in our case, it's also about streamlining the supply chain. Right. And in HIC, like, so at least for a company like ours, like a startup, if you were to do this kind of like assembly work or, you know, then basically we were engineers, and we were sitting in the workshop, okay, let's do pizza, and let's pack some things, let's assemble some things. And you would, because we are not making a factory is the workforce that you would basically employ like, students, at the most otherwise very qualified people and take it as a part time thing. That's how we were doing like, okay, on the side, let's also do that. And then that's not really you cannot scale a business in that way. Whereas in India, so, if you have the, so one is the part first and the other, like the availability of the manpower for that kind of jobs, and that you could really, when everything works out, you could really say, Okay, now we really have the capacity to supply as much as anybody want and maybe, yeah, be able to grow much faster.

- Prompt: with respect to raw materials cost?\

it's depends on the material as if we go into specifics. For example, aluminum actually is cheaper in HIC or LMIC than LMIC, for steel and things like this material by material. But in general, the cost of production is lower. When it is about more of the south of that more complex machinery items, cheaper in LMIC, machining, similar or sometimes cheaper in

LMIC, it's also depends on what size of pumping you go and who is sourcing a lot. LMIC depends on who is, you know, asking the price? Yeah, depends on your negotiation skills, and you don't get like a catalog with prices and all that. Yeah, it depends a lot on that. But overall, in our case, at least, we were able to reduce the cost of production and for our kind of product, which in the end goes to farmers. It's really price sensitive. So, yeah, for us, it was a good thing to go to India and that the challenges I mentioned, but despite that, we then take it as our plan to also for future products. So once the R&D phase is over to really if you want to go into commercial manufacturing to do it in LMIC, and that so the last thing might be in the low income countries, for example, we work in LMIC. LMIC is not really a big market for us there was not much happening, but compared to them doing it in LMIC or LMIC. I mean, there is a lot more facilities, you will get almost any type of material, almost any production facility. And all that in LMIC. So that will be different. If you were to try to do it in LMIC and LMIC, you will run into, you know, like, you will not get all the parts, you'll definitely not get all the production facility, those are not really manufacturing economies. Even though from income perspective, you can say it's all low and middle income. And there are countries who specialize in manufacturing and at least in our case, it wouldn't make sense to have it fully decentralized in each country where your market is, but still have it centralized. Yeah. In some country where the manufacturing scene is a bit.

- Prompt: with respect to local workforce?

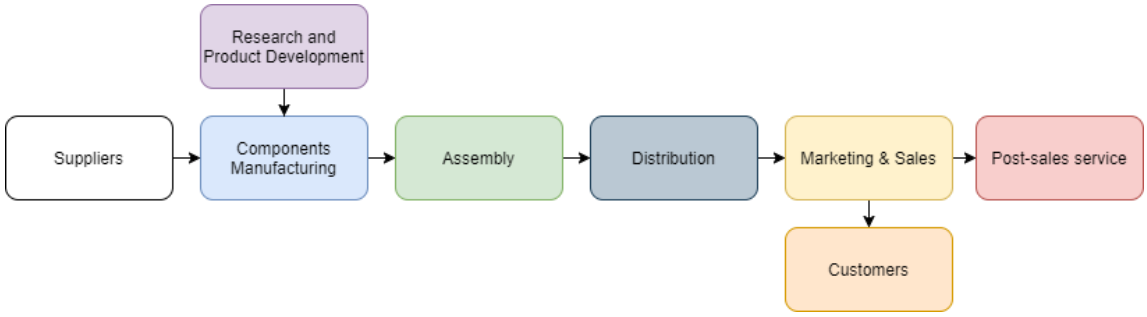
On the Human Resources side, and I come from LMIC, that, also, of course, back that, but I think talent wise, it's not a problem. System wise, so working style, working culture, attention to detail, you know, those kind of things, you have to train specially on this attention to detail? Or if it's really you know, about quality and accuracy. So not I'm not talking of the assembly workers, but also engineers. Sometimes it's, we are more of a yes, culture, and like, you know, a bit more abstract and, you know, like, it's around 80%, than then it's good and attitudes, those kinds of things you have to work on, but compatibility wise of the human part, I think, with proper training, that's not a problem. And it's also about, so if you go into manufacturing, so at least that's what I think, like, if you are in HIC, you really don't find that kind of workforce. So the engineers here don't really talk about manufacturing, or you know, whereas if you think in LMIC, that's where the economy is. So more people are exposed to that kind of economy. It's easier to find like the assembly line workers. Also, like the engineers are more prepared to do, like your production.

- Prompt: with respect to competitive costing ?

You are able to competitively cost your products against your competitors to give you a better margin. And it's on the first one, there are two aspects where the costs could be reduced. One is simply the costs are lower of material of human resource. Yeah. But sometimes, and that is, depending on your product and your flexibility with the design, if your market is low and middle income countries, yeah. And if you are then going to LMIC, or one of those countries, then the expectation of the customer in our like, so for example, you can get very high grade material here in HIC. But customers are not really expecting that. So if you're flexible with changing some aspects, which are designed to say, Okay, this will also work. So just as an example, we were using aluminum frames, because that's what is easily found here. And you know, corrosion is a big thing here. And in LMIC, we do it galvanized iron. So, it's just about because they're most of the things are done with the organization and that. So sometimes you

get to that feedback, and you can actually align better your product with your target customers. so it is Not reduced quality necessarily. It's, you know, just the right amount of quality.

Discuss the specific aspects after open questions



3. Where in the supply chain (as shown in the simplified process) do you see these challenges and advantages play out?

Yeah. Now, some of the challenges I mentioned, most of them are in components manufacturing. Yeah. Assembly, we do it in house. So less. Research and product development, we don't do it there so much. And that's. So if you talk about suppliers in those countries, normally, if you say, Okay, here is a design, can you produce this? The question will be, can you give me a sample? So if you're really doing it for the first time, yeah, it's quite difficult. So the research and product development stage probably makes sense to keep it closer. If you are in the HIC, like here, in HIC, then another challenge that I didn't mention previously around probably, it's part of distribution. I saw a question later also about like bureaucracy or government processors, sometimes what is difficult? So for example, in our case, we still have some components that go from HIC, first to LMIC, and then you export it out. Yeah, and the Import Export can be quite troublesome. Okay. So especially the import part is really troublesome, your parts can be in at customs for days, it can really create a lot of stress. It's very different from, for example, here in the HIC. If some, if you are getting apart from LMIC or LMIC, you're either offers and without any involvement, it arrives at your place. Yeah, you get an invoice from customs for the customs duties later, you pay them. And that is very different than LMIC that like their questions, and they're not clarities. And then you always get surprised costs and stuff. And so when you are importing something in LMIC, you know that there will come this week where we be like, super stressed, because and yeah, you don't know what to expect. That's also Yeah, challenge, especially now with COVID on the distribution pad as to the logistics part, of course, that's especially to the current situation, that's very difficult also, especially from LMIC.

4. How do you maintain the quality of products when manufacturing in LMICs?

We're learning so it's, it's not yet fully there. But most mostly, it's about detailing as much as possible in your production drawings, so sending out all the instructions or having it written. And then we have a local team, so we're checking so in the beginning, so when we didn't have a team, or in the first few suppliers, we didn't check immediately. And normally, for example, in HIC, if someone sent your suppliers and paths you would expect that it's all set, it's all verified normally, of course, here also you have issues. But in LMIC, now, we really, you know, like if someone is producing you really make sure all the dimensions are in tolerance, everything and then send it back for rework If that is not the case. You should expect that there will be something wrong. So you know, like and have it checked. So I would say it's mostly about documenting it well enough. So that's why if you have done one production run one round of production in the developed country, you sort of have the experience, you sort of know what things can go wrong, and if you have it documented, then it's easier versus if you start from scratch. And you yourself do not know what can go wrong, then it can be modeled.

5. How strict are the regulations and policy guidelines available? (what kind of tolerance is allowed for the quality checks)?

In our quality check we define that in production drawings. And that, partly, we also take the feedback and try to improve our design to accept more tolerances accepting the fact that if you're not doing it in HIC, if you're doing it, you should also, you know, wherever possible, wherever design allows, design it for higher tolerances, also what we're doing. And yeah, otherwise, it's defined and then done.

6. What are the actual manufacturing practices in HICs/LMICs?

Yeah, no, that didn't work out in terms of timeline reliability, you couldn't really control. But that's, that could be specs specific to us, although I have other stories as well. It's about so in our case, our product is very specific. And basically that we want to contract assembly are like this consolidation part. That normally is no company's business in also, more companies are doing component manufacturing. So it could be an additional service, sort of or, and that. So this aspect of quality checking or following up with suppliers, all that that didn't really work out in our case. We have a mix of local distributors and out offices. So there are some countries where we have our own offices, and there are some countries where we work with distributors. For us, the technology we are working on is not something that is widely known, and that you can so for us, in some countries, we want to be closer to the market to get the feedback of the product to basically showcase that this is how it can be done. So the other distribution partners, get an example. And also we have our own lessons learned the whole feedback mechanism. chose to have few focus markets when we are working ourselves.

7. Are you present in a special economic zone or free trade zone? How does that impact the operations?

No, we are not specialists, special economic zone, we tried, but we didn't understand and probably we're too small to have something like that. And that was because the rent and like, if you lease part of that, itself was too much and we can't operate in that kind of project.

Okay. And you hear a lot about like, making India, scheme and stuff. And that's why I asked in the beginning perception or experience. So, when we made the decision to go to India, we expected there would be such benefits, but we haven't really gotten any of that and also. So, there could also be like, if you're a startup for example, in LMIC, there are a lot of tax benefits. But if you are a foreign subsidiary, then you are not considered a startup. So if you are with foreign investment, so you can branch of a foreign company, then a lot of those benefits do not apply. Okay? So in our experience, we do not have Yeah, so much of the benefits a bit could also be that we do not understand the policies fully and we have not fully like looked at our options would also be, but in general, the options are limited. As soon as you are a foreign company, either private if you are really a large multinational, again, you have benefits probably at a SME size, we don't experience. With COVID, like, you don't get to easily travel. But, but in our particular case, I would say it's actually helping process because by doing manufacturing there, it's also much easier to focus on development here. And like I said, talent is not a problems, you will find talent also in LMIC. If you can work in a collaborative way, actually, so for our designers, it's a relief in a way because the part of all supplier contact and quality management and that is being done there. So actually, they can focus more on wishes that, you know, and it's also goes faster to say, okay, and this design, and then we have colleagues in India, we can get a quotation, then you can change some things to. So, but so far, we always have the first prototypes, first few units made in here. And then only we transfer the manufacturing, so we haven't done something where you are from the basic research, then immediately producing in India, there, I think there could still be challenges, because of all the things mentioned before, plus, then logistics. So, if you just produce a sample, and you want to check it, and all that, like you have to get it here. So it can be months to do the prototyping that we still do here, the first unit and so we still do it here at the moment, then we talk, Okay, now let's produce more of a commercial batch size.

8. Have you encountered issues with respect to bureaucracy that have had an impact on the operations of a company (LMIC and HIC)? (please explain the situation)

Import export, that's one and not mentioned so far, and that could be LMIC specific, maybe other countries also. So transfer of funds transfer of money. So, if you want to produce for example, in our case in India, then you need to incur a lot of costs. Yeah. And it's not as easy as okay then you know, I transfer money to India and then I because in India for example, you are not allowed to take an important loan, for example, and so there are these kind of things so which makes it Yeah, so, more difficult and aspects, but that is also maybe is specific to us in a way. It depends on it. So if you have a subsidiary in LMIC, then you have benefits but also challenges. But if you're just directly contracting suppliers, and your parts are directly coming to HIC, then those challenges are not relevant, it's only when you have an entity. And then basically to produce you have to transfer costs. Yeah. And then you when you want to sell, and if you so you have to get it back to the HIC entity, and then all that. So that it's not easy. And that also like, especially for a startup like us, in the HIC, a lot of like taxes, and a lot of things are very easy. And in LMIC, that's not like compliance and taxes is not that easy. So when you do something, if you want to have your own place, so you have to go through that whole process, have service providers who will do your compliances on your accounts, and all that, you have to set up that call system, so and all that overhead, will also only make sense if you are manufacturing at a certain scale. Not in

the manufacturing world. We also don't deal with the government people. Th customs when we are doing import is when we run into these issues. That's when after going through endless documents still not happy. In our experience its mainly in import export. You can minimize it but there will always be a surprise. That is not just in India, Something u see in LMICs. Importing things into a country is challenging. Sometimes there are rules that are difficult to follow. Even if we follow everything and still run into problems. I know that it is simply seen as a place to make money. People are willing to pay you money and that it is a big deal. It is build in. Here in HIC I have no clue how and where it happens. That's build differently in HIC countries.