

## **ABSTRACT**

HAYES, KATHRYN M. Analysis and Improvement of the Medical Textile Supply Chain in North Carolina. (Under the direction of Dr. A. Blanton Godfrey).

Medical textiles and biotextiles are intended to improve the overall health and wellness of a patient, whether it be temporarily or permanently. Because medical textiles and biotextiles fill the lives of healthcare providers, patients, and all of us, it is imperative that the quality and safety of these products is sound. To achieve this, the entire supply chain must be managed well. The prominence of large regulatory bodies such as the Food and Drug Administration (FDA) make it difficult for market entry into both the medical textiles and biotextiles industry. The purpose of this research was to understand and analyze the medical device industry supply chain for private medical textile companies across North Carolina and how quality is maintained throughout all process steps. This research will be valuable for new companies looking to enter this market. The literature review covered biotextiles and medical textiles, quality in the medical textiles and biotextiles industries, supply chain management, and the North Carolina medical textile and biotextile industry. Our research used a qualitative method through in-depth, semi-structured interviews with one representative from each of five medical device companies across North Carolina. We found significant similarities and differences across the supply chains of five medical device companies in North Carolina.

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Analysis and Improvement of the Medical Textile Supply Chain in North Carolina

by  
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## **BIOGRAPHY**

I was born in Würzburg, Germany in June of 1995 to my wonderful parents, Brian and Audrey Hayes. I grew up in Clemmons, North Carolina, a small town outside of Winston-Salem. I have one younger sister, Madison, who attends Elon University. I graduated from West Forsyth High School in 2013 and enrolled in the College of Textiles at NC State University. After graduating in 2017 with a B.S. in Textile Technology and working as a quality engineer, I decided to continue my career and focus on quality engineering and process improvement in the biotextile and healthcare fields. Aside from earning my Master of Science in Textiles, I will also receive a minor in statistics and a healthcare performance improvement certificate from the NC State Industrial Engineering department. In addition to graduate classes, I also worked as a graduate teaching assistant for the Lean Six Sigma class as well as an undergraduate entrepreneurship class.

In my free time, I like to run, cook, play piano, and hang out with family and friends – and with my three cats, Ollie, Stevie, and Layla. In June, I will begin a full-time position at COOK Medical as a medical device Quality Engineer.

My graduate school education at NC State has been very unique and extremely rewarding, and I am so grateful for the opportunities I have been given.

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# CHAPTER 1

## Introduction

The advantages that medical textiles and biotextiles reap is no secret. As its name suggests, a medical textile is any textile that provides a medical benefit (Dell, 2008). A biotextile works similarly, offering medical benefits specifically for inside the body (King, 2013). From bandages to surgical gowns and hospital sheets to artificial hearts, medical textiles and biotextiles fill the lives of healthcare providers, patients, and all of us. Because there is such a widespread impact, it is imperative that the quality and safety of these products is sound and the primary reason the industry has such strict regulations in place.

With the medical textiles and biotextiles markets quickly growing, many companies in the early stages of development are looking to the Wilson College of Textiles for expertise on supply chain management and for information on how existing medical device companies interact (Warner, 2014). Because of the sheer complexity of the medical device industry, it is not surprising that providing accurate, relevant, and helpful information can be a tough task. Additionally, it is imperative that high quality products are maintained throughout the manufacturing process, from raw materials to final customer, and that emerging companies are aware of the requirements necessary for producing safe and effective devices. Finally, little has been explored on how existing medical textile companies initially formed supply chain relationships when in the early stages of development.

With any medical textiles and biotextiles product, proper supply chain management goes directly with ensuring every step of the manufacturing process in producing high quality output. Even then, other steps along the way, such as transportation and handling logistics, can affect

how well quality is maintained throughout the process. It is important for companies to have the confidence that they are not only receiving quality products but passing them along as well.

### **Purpose of Research**

The purpose of this research was to understand and analyze the medical device industry supply chain for private medical textile companies across North Carolina and how quality is maintained throughout all process steps. This research will be valuable for new companies looking to enter this market.

The remainder of this chapter is organized into sections as followed: 1. Research Objectives, 2. Research Questions, 3. Significance, 4. Scope, 5. Limitations, 6. Definitions.

### **Research Objectives**

The following are the main research objectives used in this study:

**Research Objective 1:** Understand significant similarities and differences in supply chains for five different medical textile companies across North Carolina.

**Research Objective 2:** Determine how companies ensure quality as a product moves through the supply chain

**Research Objective 3:** Describe the supply chain for five different medical textile companies across North Carolina.

### **Significance**

This research aspired to provide a better understanding of the medical device supply chain, how companies interact within the supply chain, and how an effective supply chain model works to improve the quality of products. This research aims to fill any gaps in the research, particularly in the medical textile industry, and hopefully be advantageous to new companies

looking to begin their industry journey. A review of the relevant literature will be presented in Chapter 2 of this paper.

### **Scope**

The scope of this research is on medical textiles and biotextiles companies in North Carolina and their supply chain. In depth interviews were conducted with 5 different medical textiles and biotextiles companies. The companies are all based in North Carolina and manufacture products intended to improve the quality of care for patients and providers in the healthcare industry.

### **Limitations**

While this research aims to be thorough, there are factors that may limit the applicability to certain audiences:

- The sample size used for the case studies was limited (5) and a purposive sample of companies was selected and chosen to cover a broad spectrum of the industry. They were also chosen based on their willingness to participate in the study and prior company knowledge.
- Industry interviews were used in this research. The information provided in the interviews could be limited based on the participant. Additionally, only one participant was chosen per each company, meaning there could be risk involved with delegating one individual to speak on behalf of an entire company. These participants were very familiar with almost every aspect of their companies and include four founders or co-founders, two chief technical officers, a company president, and a company CEO. Several of these people had more than one title.

- Only North Carolina companies were chosen to participate; conclusions may not be appropriate to other regions of the United States or areas of the world.
- Only medical textiles and biotextiles companies were used for the case studies; conclusions may not be appropriate for other sectors of the textile industry, such as fashion and apparel.

### **Definitions**

Biotextiles: Structures composed of textile fibers designed for use in specific biological environments where their performance depends on their biocompatibility and biostability with cells and biological fluids (Gajjar, 2014).

Growth: Company is between 10 and 30 years old

Large Company: Over 200 employees

Mature: Company is more than 30 years old

Medical Textiles: Any textiles that provide a medical benefit (Dell, 2008).

Medium Company: Between 20 and 200 employees

Product: A manufactured device that serves a medical application, including uses for inside the body as well as outside the body

Small Company: Less than 20 employees

Start-up: Company is within 10 years of development

## **CHAPTER 2**

### **Review of Related Literature**

#### **Scope**

This chapter will provide a review of the existing literature on medical textiles and biotextiles, quality in the medical textiles and biotextiles industries, supply chain management, and the North Carolina medical textile and biotextile industry.

#### **Biotextiles and Medical Textiles**

##### *Biotextiles Definition*

A general definition for biotextiles has been developed by Dr. Martin King from the North Carolina State University Wilson College of Textiles: “Biotextiles are non-viable, permanent or temporary, fibrous textile structures created from synthetic or natural materials that are used either in an internal (inside the body) or external (outside the body) biological environment as a medical device for the prevention, treatment or diagnosis of an injury or disease, and as such, serve to improve the health, medical condition, comfort and wellness of the patient.” (King, 2013, p. xxxi). Biotextiles can also be thought as structures composed of textile fibers designed for use in specific biological environments where their performance depends on their biocompatibility and biostability with cells and biological fluids (Gajjar, 2014).

Biotextiles, similar to medical textiles, work to improve the health and wellbeing of the patient; however, these refer to a narrower range of products that are used inside the body or in contact with circulating blood/bodily fluids, and in turn need to have a more regulated environment than medical textile devices (King, 2013, p. xxxii). Due to this more regulated environment, virtually all biotextile devices are classified as ‘Class III’ products.

### *Medical Textiles Definition*

Medical textiles represent structures designed and accomplished for a medical application (Akter, 2014). Additionally, Dr. King effectively explains the difference between a biotextile and a medical textile, saying that medical textiles can be visualized as products that are used outside the body and are usually not in contact with circulating blood or open wounds, such as certain bandages, feminine hygiene products, diapers, or a cast. These can typically be found in a healthcare provider's practice. They can also be visualized as products that are found in an operating room, such as surgical drapes, gowns, gloves, hairnets, and bedsheets. The main intentions for medical textiles are to improve health and wellness, maintain comfort and hygiene, prevent or treat injury, avoid infection, or assist in rehabilitation (King, 2013).

The FDA has also added an important distinguishing factor to their definition of a medical device, defining it as “a healthcare product that does not achieve its purpose by chemical action or by being metabolized” (Syring, 2003).

### *Device Classes*

Medical textile and biotextile devices are each assigned to one of three device classes or risk categories: Class I, Class II, or Class III.

- Class I devices impose the lowest risk to the patient. These devices are not intended to support or sustain life or be substantially important to improving human health. Class I devices also receive the least amount of controls, and are typically only subject to general controls, such as adhering to good manufacturing practices. They must be registered with the FDA, but most Class I devices do not



have to go through a review process. Examples of Class I devices include surgical masks, stethoscopes, and hospital bedding.

- Class II devices are considered medium risk and require more controls than that of Class I devices. They might have special labels or be required to meet specific performance requirements. These devices, if used correctly, should somewhat enhance human health without causing injury or harm to the user. The FDA will go through a 510(K) process before market approval to ensure that the device is safe and effective for users. Examples of Class II devices include surgical gowns and powered wheelchairs.
- The final class includes devices that introduce the highest risk to the patient, Class III. Devices in Class III are typically those that can support human life and are important to prevention of harm in humans. They are usually implanted in the body and left for extended periods of time, making the safety and effectiveness of the device imperative. Because of this, Class III devices must undergo animal trials as well as clinical trials to ensure human benefit. These devices require pre-market approval as well as scientific review and are subject to the controls of Class I and II. Some Class III devices would be implantable pacemakers, artificial heart valves, and hernia meshes.

(Kramer, 2014 and King, 2013)

### *Applications*

Medical textile and biotextiles devices can be divided into two main applications: external and internal. External applications include non-implantable textiles, extracorporeal

devices (performed outside the body), and healthcare/hygiene materials. Internal applications consist solely of implantable devices (Onar, 2002).

Examples of common medical textiles and biotextiles products are shown in Table 1 below. Additionally, the device category (medical textile, biotextile), device class (Class I, II, III), device application (external/internal, non-implantable/implantable/extracorporeal/healthcare/hygiene), and device function are listed.

Table 1: Examples of common medical textile and biotextile devices

Source: Author

<b>Device</b>	<b>Category</b>	<b>Class</b>	<b>Application</b>
Bandage	Medical textile	I	External, non-implantable
Artificial heart valve	Biotextile	III	Internal, implantable
Surgical gloves	Medical textile	I	External, healthcare
Surgical gown	Medical textile	II	External, healthcare
Powered wheelchair	Medical textile	II	External, non-implantable
Vascular graft	Biotextile	III	Internal, implantable
Hernia mesh	Biotextile	III	Internal, implantable
Contact (eye)	Biotextile	II or III	Internal, implantable
Surgical suture	Biotextile	III	Internal, implantable
Defibrillator	Medical textile	III	External, extracorporeal
Diaper	Medical textile	I	External, hygiene
Artificial kidney	Biotextile	II	External, extracorporeal

### *Material Changes for Medical Devices*

Medical devices will likely undergo material changes as part of their product lifecycle. Because of the regulations in place involving changes in medical devices, the supply chain can be greatly affected by any sort of material change; therefore, proper knowledge on the change process is crucial (“Material Change”, 2015).

There are many reasons why a medical device manufacturer may want to make a material change after the original product has been granted a 501(K); below, Table 2 shows common events that may initiate a medical device material change.

Table 2: Medical device material change

Source: (“Material Change”, 2015).

Event	Description
Discontinuation of material	When a supplier or producer of a material shuts down the production of a specific material.
Policy change	When a supplier/producer or regulatory body restricts the use of a material in the medical device market.
Price change	When manufacturers seek out a new raw materials supplier because a price point has become too high.
Device improvement	When a manufacturer determines that a different material can be used in a device that will improve quality, function, or use; sometimes, a materials change will also allow a device to serve a broader range of applications.

Once it is decided that a device will undergo a material change, it is important for a company to decide if a new 510(K) should be submitted to the FDA. This can be a tricky decision to make, yet extremely crucial to the mandatory regulation of a device; therefore, the FDA has developed guidelines to assist manufacturers through the logic scheme they recommend to arrive at a decision on whether to submit a new 510(k) for a change to an existing device. The main flowchart (Figure 1 below) can be broken up into five smaller flowcharts, but for the purposes of this research, only the materials changes flowchart will be included. However, it should be noted that companies making material changes should also consider the other types of changes, such as labelling or specification changes, and their impact on the decision regarding submission of a new 510(K) (“Deciding When”, 2017).

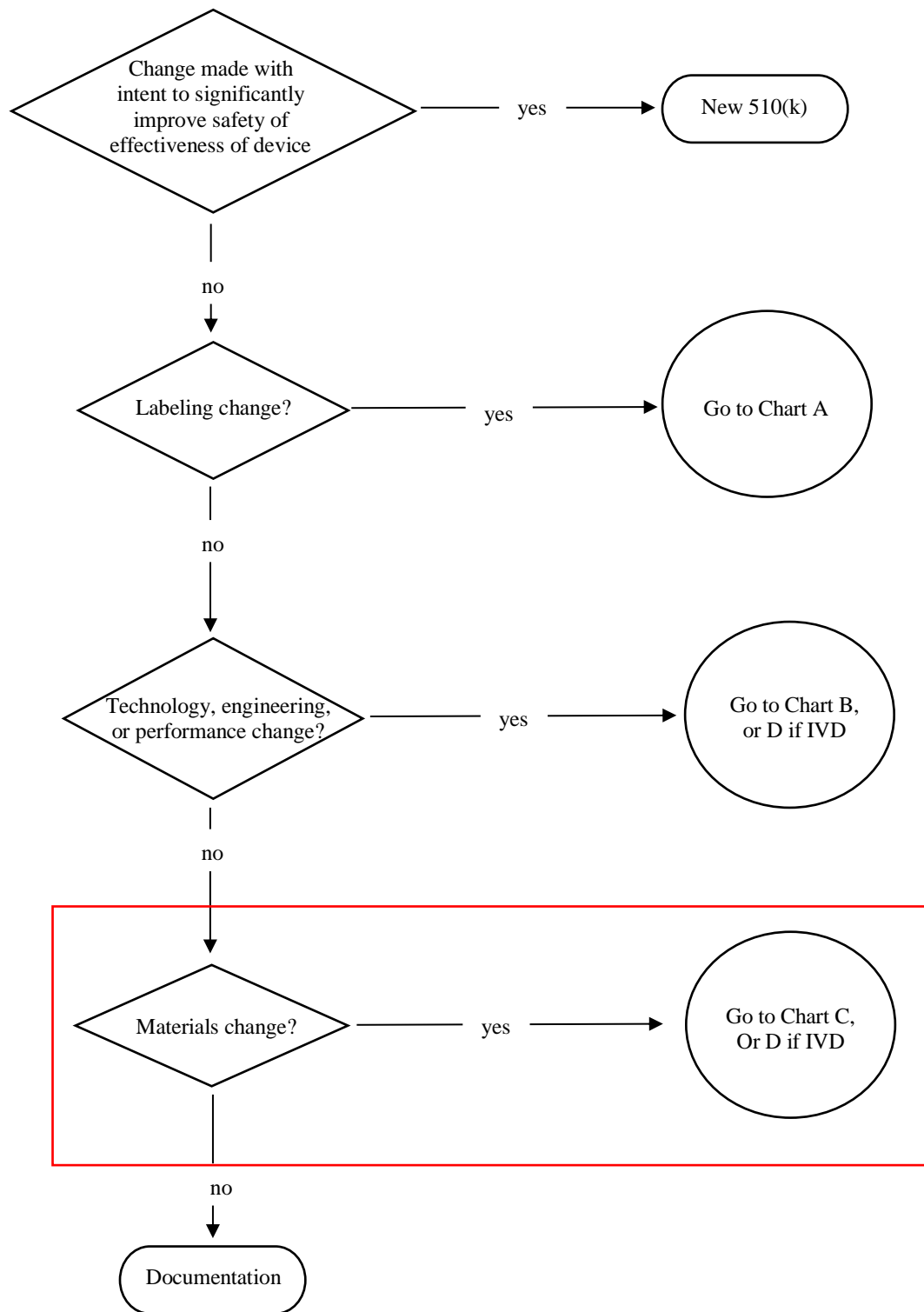


Figure 1: Main flowchart for submitting new 510(K)

Source: ("Deciding When", 2017).

The portion of the flowchart pertaining to materials change is circled in red. It has been expanded in Figure 2 below.

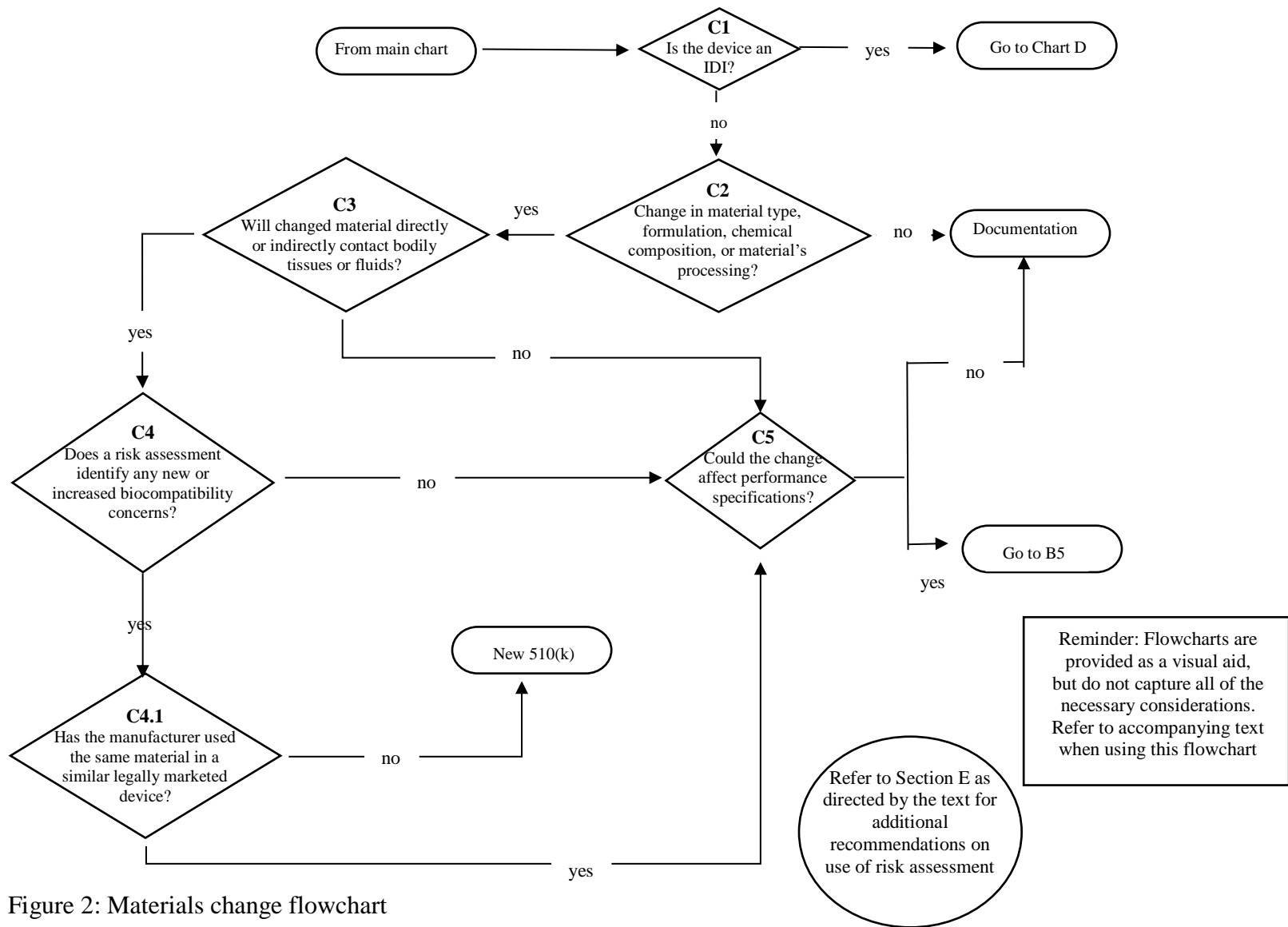


Figure 2: Materials change flowchart

Source: (“Deciding When”, 2017).

Notes: ‘**Chart D**’ refers to changes for *in vitro* diagnostic devices (IVD), which are defined as reagents, instruments, and systems intended for use in the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease. This chart is focused on non-IVD devices.

“**B5**” is a subsection of the ‘technology, engineering, and performance changes’ flowchart that asks if there are any other change in design (e.g., dimensions, performance specifications, wireless communication, components or accessories, or the patient/user interface).

The flowchart begins with the device type: if the device is an IVD, chart D will provide a more accurate decision model; for all non-IVD devices, continue to C2.

If the device is not an IVD, the next step is to determine if the device has had a change in material type, formulation, chemical composition, or material processing. A yes to *any one* of these changes will require continuation to C3. If none of these are applicable to the materials change being made, then only in-house documentation is needed. This may seem self-explanatory, but even the smallest change in material can alter the biocompatibility of the device as well as how the device is made and, therefore, should be evaluated on safety and effectiveness (“Deciding When”, 2017).

Moving from C2, which determined there is change in material type, formulation, chemical composition, or material processing, the next question to answer is if the changed material will directly or indirectly contact body tissues or fluids. If it will not, the follow up with C5, if the change will affect performance specifications. If it will not affect the performance, there is no need for a new 501(K), just documentation of the change being made. However, if the change affects the performance specifications, then a whole new process will be referred to.

If the changed material will directly or indirectly contact body tissues or fluids, a new risk assessment will need to be conducted to determine any new risks to the patient due to the material change. If no new risk is identified, it is appropriate to return to C5; however, new risks identified will require the manufacturer to analyze other existing products they have made and if the new material they wish to use has been used in any other legally marketed devices. A legally marketed device using same material they wish to use is acceptable and cycles back to C5, but if the material has not been used in another legally marketed device, a new 501(K) will need to be submitted.

Overall, the process to make a material change in a medical device product is very complex and thorough, and really attests to the high regulatory environment characteristic of the medical device industry as well as the focus on quality products.

### **Quality in the Medical Device Industry**

#### *Defining Quality*

The term “quality” can be quite difficult to define. This is because, naturally, everyone has their own unique interpretation of “quality” and what it means to them (Exemplar Global College, 2016). Fundamentally, a quality product could be defined as one that meets the expectations of the customer, however, this definition, though not incorrect, is too broad to be considered adequate (Pereira, 2008). Three of the most famous quality gurus, W. Edwards Deming, Joseph Juran, and Noriaki Kano have different views of the term. Deming defined quality as:

*“Good quality means a predictable degree of uniformity and dependability with a quality standard suited to the customer.”* (Chandrupatla, 2009).



Juran, on the other hand, more closely incorporates the views of the customer, defining quality as:

*“Fitness for use in terms of design, conformance, availability, safety, and field use.”*

(Monnappa, 2018).

Finally, Kano offered a unique view of quality, actually defining five key quality elements:

- *“Attractive Quality: Quality elements that when fulfilled provide satisfaction but when not fulfilled are acceptable.”*
- *“One-dimensional Quality: Quality elements that result in satisfaction when fulfilled and in dissatisfaction when not fulfilled.”*
- *“Must-be Quality: Quality elements that are absolutely expected (taken for granted when fulfilled) but result in dissatisfaction when not fulfilled.”*
- *“Indifferent Quality: Quality elements that neither result in satisfaction nor dissatisfaction, regardless of whether they are fulfilled or not.”*
- *“Reverse Quality: Quality elements that result in dissatisfaction when fulfilled and satisfaction when not fulfilled.”*

(Kametani et al., 2010).

Overall, for the medical device industry, it is imperative that quality not be looked at in terms of one aspect but instead seen as a multi-dimensional concept with many players involved. David Garvin, a Harvard Business School professor and author of *Managing Quality: The Strategic and Competitive Edge*, defined 8 dimensions of quality, shown in Table 3 below.

Table 3: 8 Dimensions of quality

Source: Adapted from (Garvin, 1988) with definitions applied to the medical device industry by the author.

<b>Dimension</b>	<b>Definition</b>
Performance	Is the device doing what it is intended to do within the defined tolerances? This is very important, as medical devices are manufactured with a specific performance in mind. Not only do manufacturers need to set performance requirements, but need to set requirements with their customers and suppliers about their performance standards. Performance should also include safety of product and product training.
Features	Does the product or service possess all of the features specified, or required for its intended purpose?
Reliability	Will the product consistently perform within specifications? This is closely related to performance, but over time using a certain process.
Conformance	Does the product or service conform to the specification?  Conformance is a critical element in medical devices, particularly with biotextile devices being used inside the body. Specifications should be validated and verified frequently to ensure specifications are still correct and effective for the device.

Table 3 (continued).

Durability	<p>How long will the product perform or last, and under what conditions? Durability is important when a medical device will be used for an extended period. For example, antimicrobial sheets need to go through laundering tests to ensure they are durable enough to withstand the frequency of wash cycles hospitals require.</p>
Serviceability	<p>Is the product relatively easy to maintain and repair? This can tie into customer complaints and proper communication between supply chain partners. If a nonconforming product is received, it should be easy to contact the manufacturer and request a new batch is sent and, in some cases, a corrective action is done to ensure the nonconformance does not continue to occur.</p>
Aesthetics	<p>Is the product properly labeled and appealing to the customer? It is not thought about often, but proper packaging and labeling choices for medical devices is very important. Not only does packaging serve an aesthetic importance, but packaging is important for safety. One concern is packaging in a way that the product will become nonconforming before reaching the next customer.</p> <p>Labeling is important to verify important specifications, such as sterilization or product life span.</p>

Table 3 (continued).

<p>Perception</p>	<p>Is the product maintaining a superior perception from the customer? For example, a device may be very high quality, but the doctor may misuse the device, leaving the patient with a poor perception of the device. This ties back to other dimensions of quality to ensure proper instructions, labeling, and device usage is conveyed.</p>
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These 8 dimensions are designed to help achieve quality more effectively and with the right goals in mind. However, these dimensions may not cover everything to consider, as quality is also dependent on the industry, situation, and type of contract or specification a company has.

*Quality Regulations and Compliance*

The growing number and sophistication of medical devices has introduced regulatory challenges (Sorenson, 2014). To help combat these challenges, in addition to good manufacturing practices (GMPs), FDA approvals, and 501(K)s, there are many other quality and compliance standards in place to ensure the safety and continuous regulation of a medical textile or biotextile device. From 2010 to 2015, about 50 percent of FDA device-surveillance inspections led the agency to require official action or voluntary action to correct quality system failures. This state of noncompliance suggests that manufacturers have struggled to meet regulatory requirements; therefore, it is important to be aware of the existing regulations and how they differ from each other (Fuhr et al., 2017).

One important regulation is the Quality System Regulation, or QSR, established in 1996. Prior to QSR, the main set of device regulations were the GMPs. These GMPs were focused on regulating the device manufacturing environment, such as the cleanliness and organization of the manufacturing floor and ensured that manufacturing was conducted at the appropriate temperature and humidity settings. However, due to significant device malfunctions, it was evident that these GMPs, though a great start to regulation, were not able to regulate such that devices did not fail. Considering this, the QSR took effect in an effort to have control over the device development process. The QSR required documentation of the design and development and statements that outlined the device benefit to the patient as well as how the device was able to meet those needs.

Ultimately, another level of quality assurance was added with the international standard known as ISO 13485 from the International Organization for Standardization. ISO 13485 is similar to QSR in that it put emphasis on design controls and put the task of creating and adhering to a sound quality system a main priority. Currently, the medical device industry is following ISO 13485:2016, the most up-to-date version of the standard.

Biocompatibility is another important standard that needs to be evaluated for certain devices. Biocompatibility is defined as the ability to perform with an appropriate host in a specific application (Gajjar, 2014). Since medical textile devices are typically in class I or II, they do not need to be tested for biocompatibility. However, all class III biotextile devices are used inside the body and therefore need another set of regulations for evaluating biocompatibility. ISO 10993 provides a series of standards that can evaluate the biocompatibility of biotextile devices. The industry is currently abiding by ISO 10993:2018.

For class II medical devices, a 501(K) will need to be submitted to the Food and Drug Administration. This is a premarket submission that establishes the device as safe and effective to be used. It also must prove that the device is comparable to another medical device already on the market and will be labeled in accordance to the FDA's labelling requirements (Gupta, 2016).

Similarly, class III medical devices also must go through a premarket approval process, though this process is more rigorous due to the nature of the devices. Because class III devices, as discussed above, are categorized as high-risk, life-sustaining devices, the premarket approval (PMA) process requires clinical study to demonstrate the safety and effectiveness prior to marketing approval (Gupta, 2016). Additionally, post-market surveillance is included in the FDA charter. Companies are required to have processes in place to respond and report to the FDA and any manufacturer's device-related deaths, serious injuries, or certain malfunctions. Figure 3 below illustrates an overall classification of medical devices and the degree of risk associated.

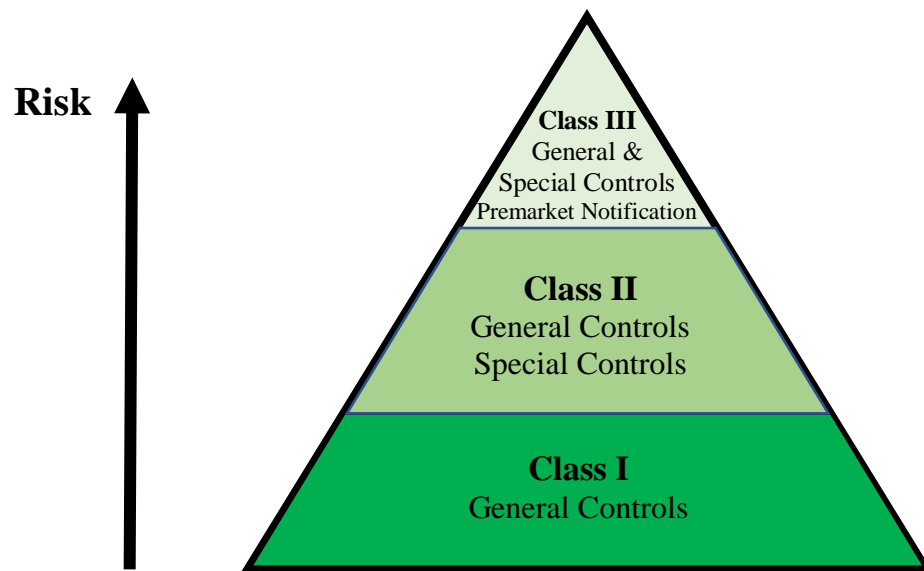


Figure 3: Medical device classes and risk associated

Source: (Morrison, 2015).

Some issues may arise when a device manufacturer is seeking a raw materials supplier. If the raw materials supplier is not a medical device manufacturer and does not adhere to medical quality standards, the situation can be a complicated one. It is important that the agreed upon raw materials do not change in composition or specifications, as changes in those areas this could cause safety and regulation problems. In cases like this, more frequent contact between the manufacturers, contracts, and validations are necessary for maintaining safety from both manufacturers (King, 2013).

One study written by Oliver et al. in 2017 explored issues regarding the global medical device supply chain through interviews with 34 companies. This allowed them to understand the challenges and initiatives regarding supply chain. Out of the 34 participants in the study, 6 were from the world’s top ten medical device companies. Though the study discovered medical device companies are making great strides in continuously improving their supply chain, there is still much room for improvement. One important finding came when the participants were asked about the biggest issues in their respective supply chains. Figure 4 below shows the percent of participants rating the category as a top or strategic priority.

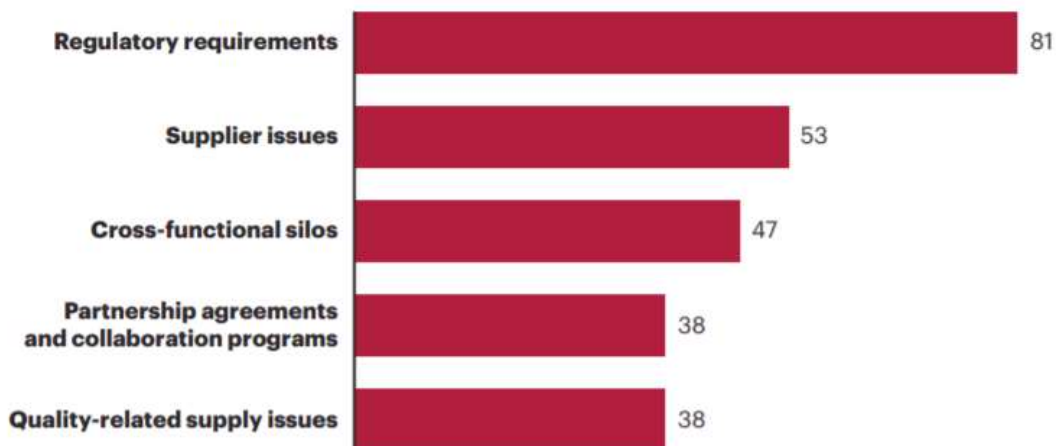


Figure 4: Biggest issues in medical device supply chain according to 34 companies.

Source: (Tribe et al. 2017).

Many participants (81%) claimed that regulation is the main source of concern in the medical device industry. Furthermore, in 2016, the Food and Drug Administration issued 39 major medical device recalls, a number that can attest to the high concerns around regulation and compliance with medical devices (Tribe et al., 2017).

### *ISO 13485*

ISO 13485:2016 *Medical Devices – Quality Management Systems – Requirements for regulatory purposes* is an internationally agreed standard that sets out the requirements for a quality management system specific to the medical devices industry. ISO 13485 is designed to be used by organizations throughout the life cycle of a medical device, from initial conception to production and post-production, including final decommission and disposal. Additionally, it helps an organization design a quality management system that establishes and maintains the effectiveness of its processes (ISO 13485, 2016). Though certification to the ISO 13485 standard is not a requirement for medical device companies, certification does offer many benefits to companies involved in any stage of medical device development by providing evidence that they:

- Demonstrate compliance with regulatory and legal requirements
- Ensure the establishment of QMS practices that consistently yield safe and effective medical devices
- Manage risk effectively
- Improve processes and efficiencies as necessary
- Gain a competitive advantage

Source: (ISO 13485, 2016).



## *ISO 9001*

Similar to ISO 13485, ISO 9001 2016 is an International Standard that gives requirements for an organization's quality management system (QMS). ISO 9001 provides a set of requirements that, if effectively implemented, will give a company confidence that their supplier can consistently provide products and services that meet your needs and expectations and will comply with applicable regulations.

ISO 9001 covers a wide range of components that make up supplier quality including:

- Commitment to quality
- Customer focus
- Adequacy of its resources
- Employee competence
- Process management
- Quality planning
- Design of the products and services it provides
- Review of incoming orders
- Purchasing
- Monitoring and measurement of its processes, products and services needed to ensure conformity
- Processes to resolve customer complaints
- Corrective actions
- Requirement to drive improvement

Source: (ISO 9001, 2016).

ISO 9001 also provides requirements for a customer's purchasing process that include topics such as:

- Requirements regarding the purchasing information that you should
- Specific approvals that might be needed to confirm that the supplied products and services meet your requirements, and any monitoring or inspections that you might require at your supplier's premises

Source: (ISO 9001, 2016).

Overall, ISO 9001 is a great tool to demonstrate that a supplier is managing their business so that they can achieve consistent quality products.

It is vital that companies have quality management systems in place and can prove the quality of their product meets or better yet, exceeds standards and expectations. Just as the medical device market is growing, the number of regulations and standards being updated or implemented is also growing and are important to the overall success of any medical device company.

### *Supplier Quality*

The selection of component suppliers has long been regarded as one of the most important functions to be performed by a purchasing department (Weber, 1991). However, the process of choosing a raw material supplier is not as easy one, as various criteria should be considered in the decision-making process. A 1966 study performed by G. Dickson utilized a questionnaire sent to 273 purchasing agents and managers across the U.S. and Canada. The questionnaire, which had 170 respondents, asked participants to describe the important criteria when purchasing raw material supplies. Table 4 below summarizes the questionnaire results.

Table 4: Ranking of the importance of 23 criteria for vendor selection (out of 170 responses)

Source: (Dickson, 1966).

<b>Rank</b>	<b>Factor</b>	<b>Mean rating</b>	<b>Evaluation</b>
1	Quality	3.508	<b>Extreme importance</b>
2	Delivery	3.417	
3	Performance history	2.998	
4	Warranties and claim policies	2.849	
5	Production facilities and capacity	2.775	<b>Considerable importance</b>
6	Price	2.758	
7	Technical capability	2.545	
8	Financial position	2.514	
9	Procedural compliance	2.488	
10	Communication system	2.426	
11	Reputation and position in industry	2.412	
12	Desire for business	2.256	
13	Management and organization	2.216	
14	Operating controls	2.211	
15	Repair service	2.187	
16	Attitude	2.120	
17	Impression	2.054	
18	Packaging ability	2.009	
19	Labor relations record	2.003	
20	Geographical location	1.872	
21	Amount of past business	1.597	
22	Training aids	1.537	<b>Slight importance</b>
23	Reciprocal arrangements	0.610	

From Table 4, it is apparent that quality of products being sent by the supplier are of extreme importance and therefore appropriate measures should be put in place to ensure this demand is met.

Additionally, supplier selection will be influenced by the nature of the company. For example, for high commoditized and mature medical devices, cost is the primary consideration in supplier selection; for less commoditized and newly developed medical devices such as implantable devices, quality is much more important than cost because both physician and patient desire a good service life from the device (Hsu, 2010).

### *Purchasing Controls*

Medical devices are unique because they include a wide range of product types and services in their design and assembly, for example, raw materials, components, sterilizers, calibration, and laboratories. Additionally, there is a wide range in risk associated with supplied products and services. This means that the same supplied product may have a different risk based on its end use, or that the same supplier may have different risks for different supplied products. Due to the wide range in risks associated with medical device supplies, the FDA has implemented purchasing controls that intend to ensure that device manufacturers select only suppliers who have the capability to provide quality products and services (Cabassa, 2015).

There are two types of medical device suppliers:

- Internal: the supplier is in-house, or under the same quality system and it audited internally
- External: the supplier is not housed under the same quality system

Not only should the supplier establish quality requirements, but the manufacturer should establish procedures to ensure all received materials or services are conforming to specified requirements.

### **Supply Chain Management**

Proper supply chain management is critical to any business looking to form a competitive advantage. Supply chain management activities include: purchasing, in-bound transportation, quality control, demand and supply planning, materials handling and inventory control, order processing, production planning, scheduling, warehousing, distribution, shipping, outbound transportation, and customer service (Taylor, 2003). Simply put, it is the range of activities involved in a product's lifecycle, from raw materials to final customer, and should be executed in a cost-effective and efficient manner.

Global Value Chains (GVCs) encompass the full range of activities required to bring a good or service from conception, through the different phases of production (provision of raw materials, input of various components, subassemblies, producer services and assembly of finished goods) and delivery to final consumers, and, finally, to disposal after use. GVC analysis provides a holistic view of global industries, both from the top down (how a firm will govern their supplier networks) and from the bottom up (how these business decisions can add value to the industry) and are highly focused on the sequences of value-added activities (Gereffi & Fernandez-Stark, 2011).

#### *Medical Devices Global Value Chain*

A report written by the Duke University Center on Globalization, Governance & Competitiveness provides an excellent overview of the medical devices global value chain. The

authors of the study, Bamber and Gereffi, provide one of the first detailed chain maps for the medical device industry aimed at providing a comprehensive map that covers the sector as a whole rather than limiting this to a particular product line (Figure 5) (Bamber and Gereffi, 2013).

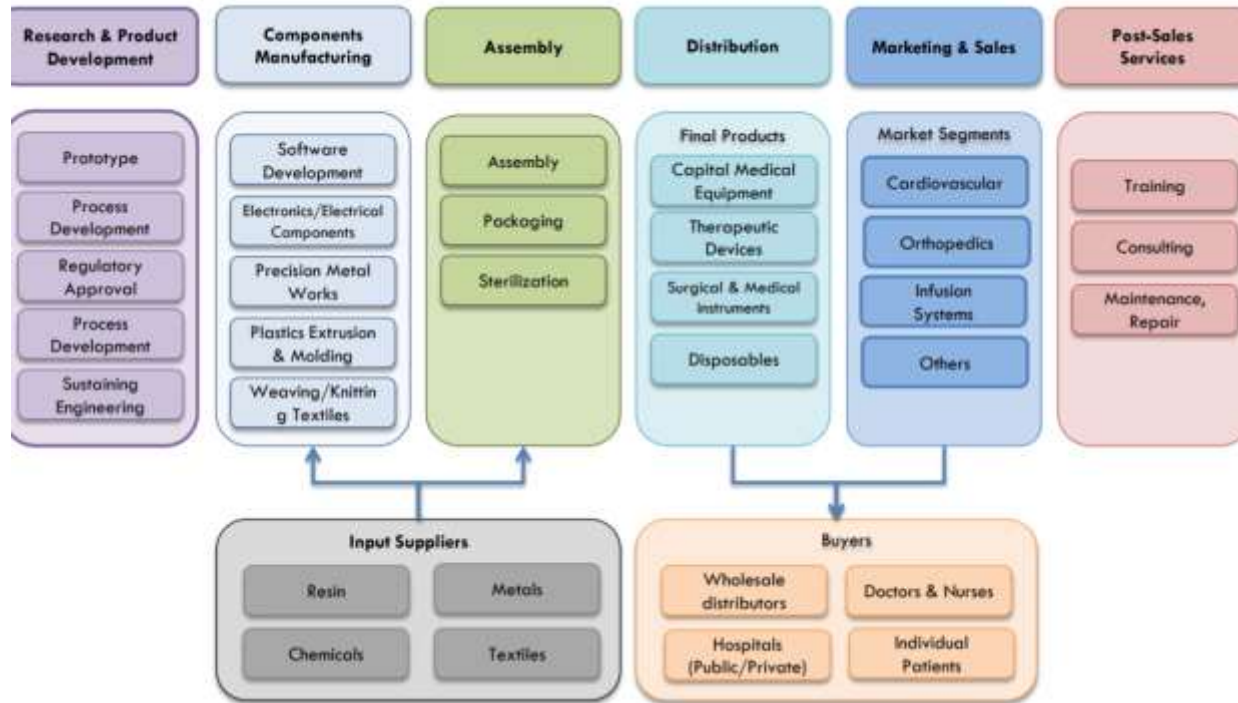


Figure 5: Medical device global value chain

(Bamber and Gereffi, 2013).

Each segment will be discussed further based on Bamber and Gereffi’s report.

The authors define the highest value segment in the medical device global value chain as research and product development. In this stage, new products are conceptualized, prototypes are produced and tested, and potential manufacturing capabilities are assessed. The product is then registered for regulatory approval in the desired market. This step alone can take up to six years, depending on the risk category of the device and clinical trials required, and the total time for a new device to come to market can be as long as eight years (Bamber and Gereffi, 2013).

The production segments, which are defined in Figure 5 as components manufacturing and assembly, are typically the lowest value-added segments of the chain. Components manufacturing refers to the ways a product component is created, such as software development, knitting or weaving, or extrusion and molding. Assembly steps include packaging and sterilization. Input suppliers come into play here, as the component manufacturing and assembly almost always require outside sources, such as chemical coatings, metals, and textile products (Bamber and Gereffi, 2013).

The next step in the chain involves choosing distribution channels for the final product and figuring out a market segment to sell in. Medical devices producers may distribute through wholesale distributors or directly to their end clients via internal distribution centers. End clients are typically hospital or clinic administrators or direct retailers selling directly to the patient themselves, typically with products like bandages, gauze, and medical tapes. Distribution channels depend on the type and value of particular products. Lower-value products tend to be distributed through wholesale distributors, while high-value products are likely to be sold directly to hospital administrators (Bamber and Gereffi, 2013).

Finally, a distinguishing addition to the medical device value chain compared to other sectors, is post-sales services. This includes product training, typically for Class III devices that have to be used properly in the body, as well as thorough maintenance plans for products such as MRI machines or CT scanners (Bamber and Gereffi, 2013).

## **The Medical Device Industry**

### *United States*

The United States medical instrument and supply manufacturing industry is defined as:  
*“An industry that primarily researches, develops and produces nonelectronic medical, surgical,*

dental and veterinary instruments and apparatus, such as syringes, anesthesia apparatus, blood transfusion equipment, catheters, surgical clamps and medical thermometers.” (Curran, 2018b).

In 2018, the US medical instrument and medical supply market had \$93.6B in revenues, a 3.3% increase from 2017 revenues. The drop in annual profit in 2014 was due to new and heavy quality regulations implemented by the FDA as well as a shifted focus towards extending product lines instead of researching and developing new products; however, because of favorable demographics (aging population and high overweight population in US), the industry is forecasted to hit \$100B in revenues by year 2023 (see Figure 6 below).

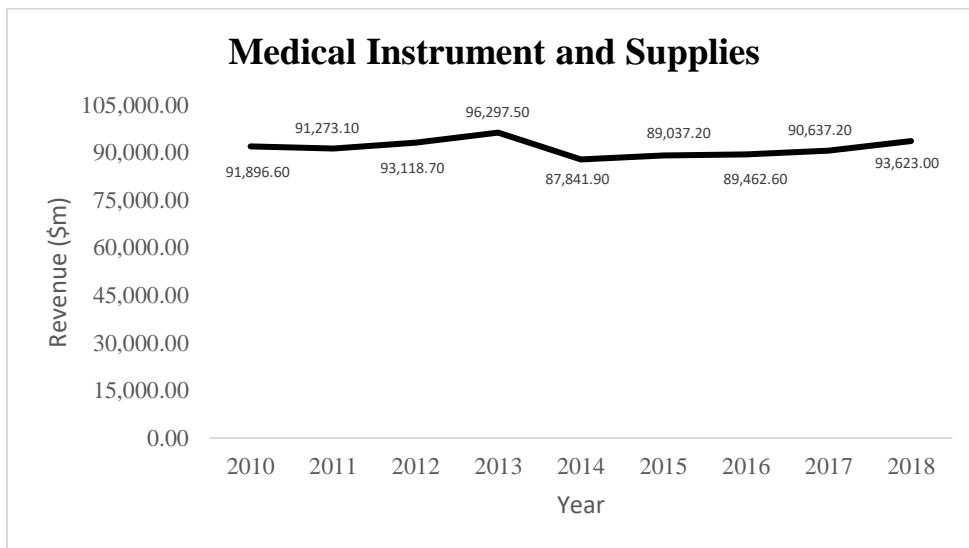


Figure 6: Medical instruments and supplies manufacturing in the US, 2010 – 2018

Source: Adapted from (Curran, 2018).

Though competition in this industry is considered medium due to moderate entry barriers mandated by government regulations, the industry is beginning to utilize technological advancements in its favor. Excellence in design, high product performance, quality of services and competitive pricing are among the key factors affecting competition for medical instruments and supplies, while patient well-being is a large driver in the healthcare sector. Johnson &



Johnson, Stryker, Becton, Dickinson and Co. (BD), and Boston Scientific are leaders in this industry, combining for approximately 25% of the market. Though entry barriers exist, the number of medical instruments and supplies establishments has grown by approximately 400 establishments over the last 3 years, see Figure 7 below.

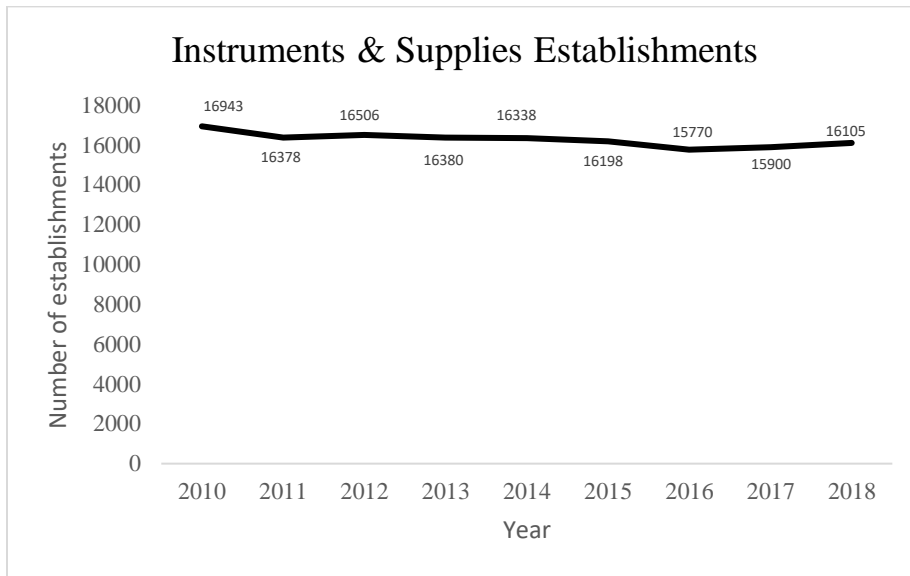


Figure 7: Medical instruments and supplies establishments in US, 2010 – 2018

Source: Adapted from (Curran, 2018).

### *North Carolina*

The North Carolina medical device industry combines two of the state’s leading sectors: textiles & nonwovens and life sciences. North Carolina boasts the largest concentration of nonwovens companies, users and suppliers in the nation and is highly specialized in innovative engineered fabrics. The life sciences industry in North Carolina is growing more than three times as fast as the national average, making it one of the world’s largest and most mature life sciences clusters as well as the largest biological product manufacturing industry in the U.S. (EDPNC, 2017).

Table 5: North Carolina industry statistics

Source: (EDPNC, 2017).

	<b>Textile &amp; Nonwovens</b>	<b>Life Sciences</b>
<b># of Companies</b>	600+	700+
<b># of Jobs</b>	175,924	70,622
<b>Top Companies</b>	Berry Global Kimberly-Clark Unifi Hanes Gildan Glen Raven Avol Nonwovens	Pfizer Merck Novo Nordisk PPD LabCorp. Biogen IQVIA

Table 6: North Carolina industry sub-sectors

Source: (EDPNC, 2017).

<b>Sector</b>	<b>Textile &amp; Nonwovens</b>	<b>Life Sciences</b>
Sub-sectors	Automotive/Transportation Home & Office Furnishing <b>Medical/Hygiene</b>	Human Therapeutics Research & Testing Agriculture <b>Medical Devices &amp; Diagnostics</b>

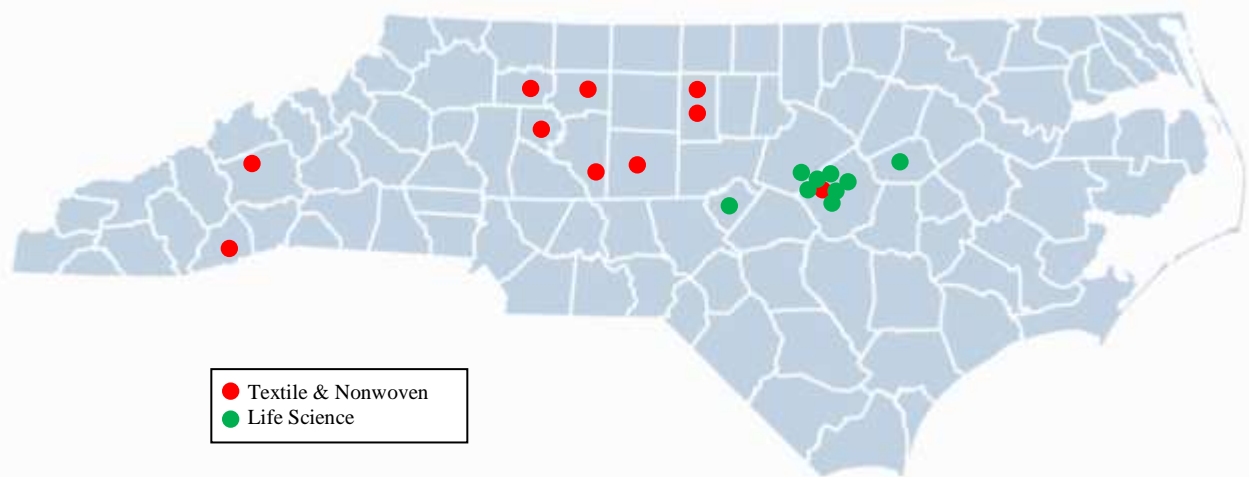


Figure 8: Top textile & nonwoven and life science companies across North Carolina

Source: Author

### *BTEC*

One facility that is boosting the way future employees are educated in the bio industry is NC State University's Golden LEAF Biomanufacturing Training and Education Center (BTEC). BTEC provides hands-on educational opportunities to develop skilled biotech professionals, as well as customized short courses tailored to meet the needs of specific companies. BTEC simulates a biomanufacturing pilot plant facility capable of producing biopharmaceutical products and packaging them in a sterile environment. One of the main goals of the center opening was the potential to help attract new biotech companies to North Carolina and assist the development of new technologies for production of value-added biopharmaceuticals.

With four top research universities, the nation's only college devoted entirely to textiles, and the largest research park in North America, North Carolina offers an excellent foundation for new entry companies looking to join the medical textiles or biotextiles industries.

## **CHAPTER 3**

### **Methodology**

#### **Purpose of Research**

The purpose of this research was to understand and analyze the medical device industry supply chain for private medical textile companies across North Carolina and how quality is maintained throughout all process steps. This research will be valuable for new companies looking to emerge in this market.

#### **Research Objectives**

**Research Objective 1:** Understand significant similarities and differences in supply chains for five different medical textile companies across North Carolina.

**Research Objective 2:** Determine how companies ensure quality as a device or product moves through the supply chain

**Research Objective 3:** Describe the supply chain for five different medical textile companies across North Carolina.

#### **Summary of Research Method**

1. Formulated three research objectives
2. Selected candidates to perform in-depth interviews
3. Performed 5 in-depth interviews (March – April 2019)
4. Used NVIVO software to perform textual analysis and answer research questions

The following sections will provide an in-depth description of the research design used.

## **Research Design**

### *Qualitative Research Method*

This research utilized primarily qualitative methods obtained through in-depth interviews to answer the research questions. Qualitative research focuses on understanding a research query as a humanistic or idealistic approach. It is used to understand people's beliefs, experiences, attitudes, behavior, and interactions (Pathak, 2013). Qualitative research also generally requires some form of qualitative interviewing which encourages the interviewee to share descriptions of phenomena while leaving the interpretation or analysis to the investigators (Dicicco, 2006). Additionally, Creswell (2009) states that qualitative studies introduce a level of exploration into the meaning that individuals or groups ascribe to a social or human problem. Because this research sought to explore meaning and perceptions to gain a better understanding of the medical device supply chain and its focus on quality, in-depth interviews utilizing open-ended questions was chosen as the best fit method to answer the research questions.

### *In-depth Interviews*

An in-depth interview, hereon referred to as IDI, is a qualitative data collection activity characterized by a skilled interviewer engaged in a probing conversation with a suitably knowledgeable interviewee. It is versatile across a range of study topics, adaptable to challenging field conditions, and excellent for not just providing information but for generating understanding as well (Guest, 2013).

Listed below are specific defining characteristics that are important to IDIs and how they connect to this study.

- **Conducted One-on-One:** A one-on-one interview allows the researcher to focus solely on the contents of the participant's responses, including tone and body language. A one-on-one interview is also important to this research, as some information provided may be confidential or sensitive to the company participating.
- **Open-Ended Questioning:** The use of open-ended questions in an IDI is highly important, as they are intended to lead a conversation about the topic at hand. The questions should be designed to maximize opportunities for detailed, discursive, and thorough responses. Because these interviews were the primary source of data collection in this research, the need for well-scripted and conversation-leading questions was highly important.

**Use of Inductive Probing:** Inductive responses are could be considered the most important aspect of IDIs. They allow the researcher to interpret the responses in a way that can be linked directly back to the research objectives and where an IDI produces the meanings, insights and causal chains that provide the richness of qualitative data (Guest, 2013). The questions written for this research were aimed to allow the participant to elaborate and expand on the supply chain in from all aspects.

In order to analyze and understand the supply chain for various medical textile companies across North Carolina, IDIs were conducted with five medical textile device companies across North Carolina. These IDIs provided crucial information to the researcher regarding specific company experiences; with this information the researcher was able to address the four research

objectives defined. This information would not have been obtained without interviews with a representative from each company.

### *Semi-structured Interviews*

Interviews are often categorized as structured, semistructured, unstructured, or informal. Semistructured interviews were utilized in this research, as the goal of this interview type is to seek to address a number of predetermined questions or topic areas. Semistructured interviews are used when the researcher's goal is to compare the participants' responses while simultaneously seeking to fully understand their unique experiences (Mills et al., 2010). Additionally, an important characteristic of a semistructured interview is the freedom for the researcher to follow trajectories in the conversation outside of the predetermined questions (Cohen & Crabtree, 2006).

### *Company Selection and Descriptions*

The selection of cases is an essential part of the research design. In contrast to survey research, interview research samples are ideally selected strategically rather than randomly (Mills et al., 2010). Due to the descriptive nature of the research objectives, multiple cases with similar characteristics were studied separately. The number of selected cases depends on the type of research objectives. In qualitative multiple-case studies the recommended range of samples is from four to 15 (Mills et al., 2010). This study looked at five cases.

The five companies selected to participate vary in size (small, medium, large; See “Definitions” pg. 4) and product type (biotextile, medical textile; See “Definitions” pg. 4). A brief description of each company is provided below.

**Company A:** Company A is a small, privately-owned medical textile company that has been in existence for approximately 10 years. It manufactures antimicrobial fibers and filaments for businesses in the healthcare, home, military and industrial markets and improves on existing antimicrobial textile solutions by embedding silver salts into fibers.

**Company B:** Company B is a small, privately-owned medical device company that creates bed linens using silver embedded fibers for antimicrobial healthcare benefits.

**Company C:** Company C is a large, privately-owned medical textile company that is a leading innovator in value-added nonwoven fabrics for the global medical market. They specialize in reusable and single-use products including bed sheets, towels, drapes, and hospital gowns.

**Company D:** Company D is a small, privately-owned biomedical company that is focused on utilizing chitosan, a biopolymer sourced from crustacean shells, for clinical use as an implantable biotextile devices.

**Company E:** Company E was a small, privately-owned medical textile company that was successful in commercially producing antibacterial and antiviral surgical masks and disposable cleaning wipes but was never able to receive FDA approval for their devices and, therefore, closed its doors in 2013.

### *Interview Process and Data Collection*

Interviews were conducted via phone, skype and in-person at the participants company location. That way, any supporting material needed could be more accessible. Initial contact emails were sent out on 14 January 2019 to explain the topic of research and inquire about an interview (See Appendix C). These inquiry emails were sent to one representative of each



company with job titles varying from: supply chain manager, chief technology officer, product management coordinator, president, and CEO. The sample of interviewees chosen for an IDI should be fairly homogenous and share critical similarities related to the research question (Dicicco-Bloom, 2006). Though the job titles of the participants selected for this research vary, all participants are strongly associated with the supply chain operations of their represented company.

NC State Institutional Review Board for Human Subjects (IRB) granted permission to interview participants on February 27, 2019 (See Appendix A). Following approval, interviews were conducted beginning early March and concluding late April. Prior to the interview, the participants were asked to read and sign (in person or electronically) a consent form outlining the purpose of research, risks, benefits, confidentiality associated with the research, and consent to participate (See Appendix B). General questions about the company were asked at the beginning of the interview; however, prior company research was important to understand the participant answers to the fullest.

The interview questions were drafted and sent for critiquing by a field expert and upon edits, seven research questions were formulated, shown below in Table 7. All companies were asked the same seven research questions with slight variations in the questions from company to company based on their products and position in the supply chain. The questions were intended to relate back to the supply chain of the company, how it interacts with other companies, and how it ensures quality in all products. The interviews were all recorded after verbal approval. The recorded interviews were then transcribed by the researcher and the transcriptions were used for textual content analysis. The responses from each question were analyzed separately across all cases. The interviews lasted anywhere from 30 minutes to two hours.

Table 7: Interview Questions

#	Interview Question
1	What are some challenges your company faced when entering the medical device supply chain?
2	How did you company overcome these challenges and how long did it take?
3	What are some of the tools out there, if any, that assisted your company when entering the supply chain and looking for supply chain connections?
4	When entering the supply chain, what criteria are typically set for looking for raw materials/supplies and suppliers? How have these criteria changed over time?
5	How does your company go about identifying and selecting new suppliers? How do they assure the quality of materials and supplies purchased? How do their customers assure the quality of the products they are receiving?
6	How does your company modify their supply chain models for various products or customers?
7	How does your company feel their supply chain plays a role in the improvement of patient and provider wellbeing?

### Methodology Limitations

Qualitative research through in-depth interviews provides the appropriate information needed to answer the research questions. However, Atieno (2009) describes a couple of limitations to qualitative research when using in-depth interviews:

- The aim of qualitative analysis is a complete, detailed description. No attempt is made to assign frequencies to the linguistic features which are identified in the data
- Qualitative data findings cannot be extended to wider populations with the same degree of certainty that quantitative analyses can because the findings of the research are not tested to discover whether they are statistically significant or due to chance.

(Atieno, 2009).

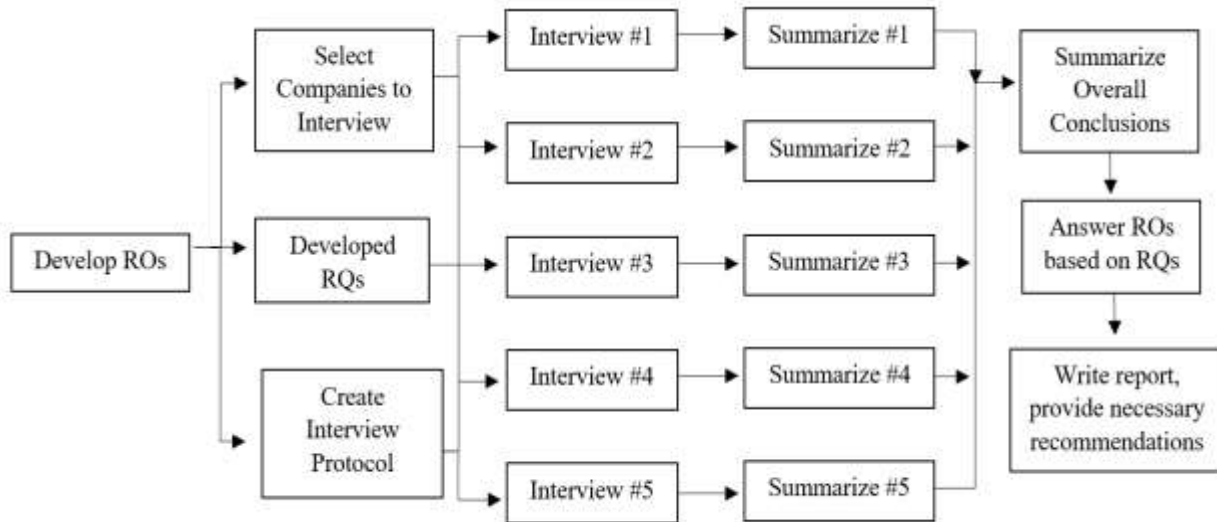


Figure 9: Flow of interviews

Source: Author

## **Data Analysis**

The purpose of data gathering in qualitative research is to provide evidence for the experience it is investigating. The evidence is in the form of accounts participants have given of the experience; it is the ideas and thoughts that have been expressed by the participants (Polkinghorne, 2005).

The data from the interviews were analyzed after transcription. The five interviews were transcribed by the researcher and then analyzed using NVivo 11, a qualitative data analysis software. NVivo is used for the organization and analysis of text, image, audio, and video data and enables the quantification of qualitative data. A word frequency count query and a word cloud were developed in NVivo to help provide support when answering the research objectives and to identify overall themes in the interviews. Textual comparisons were done by the researcher by identifying similar phrases of words across the transcripts.

## **CHAPTER 4**

### **Case Study Summaries**

#### **Company A**

Company A is a small, privately-owned fiber and yarn manufacturing company that has been in existence for approximately 10 years. It manufactures antimicrobial fibers and filaments for businesses in the healthcare, consumer, home, military and industrial markets and improves on existing antimicrobial textile solutions by embedding silver salts into fibers. Interestingly enough, the antimicrobial textiles produced by Company A are registered as a pesticide; this classification is what allows A to make any sort of claims about the products ability to kill bacteria.

The participant being interviewed (Participant A) is the President and CEO and has been with the company for about 6 years. Participant A comes from a pharmaceutical background and has worked in pharmacy administration, drug development, and pharmaceutical quality control, stating that having a pharmaceutical background was paramount when deciding to join Company A.

#### *Challenges*

When Company A decided to begin their journey as a healthcare product company, their biggest challenge was the decision of whether or not to submit for FDA approval on their product. Participant A explains that, though the raw materials they use are approved by the Environmental Protection Agency (EPA) as a pesticide, the perception towards using a ‘pesticide’ in the healthcare world can be worrisome and unpredictable. Participant A described the challenges that obtaining FDA approval can bring, such as seeking predicate devices to file

against and the lower margins that medical textile products have as opposed to medical devices. Currently, FDA approval is not high on the priority list, but the company is frequently monitoring other FDA approved medical devices and textiles just in case a similar product is released, and the approval can be used as a predicate device.

### *Successes*

Fortunately, Participant A was able to speak to some of the successes the company experienced in its early stages of company development. The first, and arguably the most important success according to Participant A, was seeking a raw materials supplier with EPA approval very early in the supply chain development process. EPA approval early on ensured that materials were at a higher quality level than a non-EPA approved material, and it directly affects the quality of the product that Company A passes on to their customers.

Company A only has one raw materials supplier for their silver and copper embedded fibers and filaments. They were able to secure this supplier within a year after creating the company and have remained loyal since.

### *Supply Chain Management*

When searching for potential customers or partners, Company A's biggest resource comes from networking. Not only do the employees utilize their personal networks, but the company attends conferences and trade shows to build networks and they even take advantage of existing partners in other countries to exploit their markets. Participant A stressed that the company only seeks high end partners that care about quality and provide pure ingredients to use in their antimicrobial products. As much as Company A stays aware of new manufacturers

coming into the country that are appealing, they are not aggressively seeking new partners, as they are quite satisfied with the partners they have now. A ‘tricky’ aspect when searching for suppliers, Participant A mentions, is simply size differences – since Company A is quite small, there is some level of difficulty when approaching larger, more prominent potential partners. However, that’s when a strong network, as mentioned before, becomes essential.

Company A’s antimicrobial fibers and filaments go into a variety of products. Though their healthcare market is the largest, they also sell to home, military and industrial markets. It may seem that the quality and quality regulations would be the same for their different markets, but that is not actually the case. Participant A explains that the amount of silver and copper they infuse into the finished good will differ depending on if the final product will be used for medical purposes. More silver and copper is used in the medical products, and more quality testing is involved throughout the supply chain of the medical products. The company requires the final product manufacturer to send a sample of the finished good so they can test it for appropriate levels of silver and copper, and occasionally as an added level of quality checking, they will send the sample off to a third-party testing lab for more in-depth analysis. If there is not enough silver or copper, Company A will send the sample back with the analysis results and ask for an explanation. Typically, the samples pass, but when asked how often the company has to send a failed sample back, Participant A exclaimed, “More than you’d like to imagine! More than I would have liked to imagine!”

It became quite clear that Company A is very thorough with ensuring the quality of the products they are receiving from their suppliers, but they take it one step further by encouraging their customers to test the products they are receiving from Company A. This allows for multiple



quality checks throughout the manufacturing process and is a reminder to Company A of the product end-use. Table 8 highlights the numerous quality checks that are performed and when.

Table 8: Quality tests done at Company A

<b>Quality check activity</b>	<b>When</b>
Absence of nanoparticles	Raw materials
Appropriate silver and copper content	
Have someone from Company A present when making fibers	During fiber extrusion process
Test beginning, middle, and end of fiber run to ensure consistency and uniformity	After fiber extrusion process
E. coli	On all finished samples
AATCC 100	On all finished samples
Elemental analysis	On some finished samples
Performance testing characteristic of fibers being substituted	On all finished samples
Laundering tests	Once to provide evidence

Quality control begins from the very first step of production with specifications on the absence of nanoparticles in the raw material batch. This was an important specification to include because nanoparticles are present in other materials that this raw material supplier produces.

Most quality testing is performed on the finished good sample that the customer has sent back to Company A. They will run an E. coli test as well as an AATCC 100 test, which is an antimicrobial test for textile materials. AATCC 100 test method will check the antimicrobial efficacy of antimicrobial agents, whether incorporated into the threads of the fabric or applied to the surface of the textiles. Additional elemental analysis is conducted at a third-party laboratory, but this is typically only done if Company A has reason to believe there are incorrect amounts of silver or copper based on the results of the E. coli and AATCC 100 tests.

It is vital that the antimicrobial aspects of the product are present at the appropriate levels; it is also necessary that the product perform like a typical textile product. For example, if Company A decided to substitute some percentage of polyester fibers with their silver and copper fibers, they need to ensure it still performs like regular polyester, aside from the antimicrobial benefits, so they also run typical textile tests, such as tenacity and pack tests. Participant A stressed that this was not something they have been doing since they began the company, but something they have learned throughout the years and make it a point to do now.

An important aspect to consider when using Company A's product in a hospital setting is the stringent and frequent laundering cycles. Knowing this, Company A measured laundering 50, 75, and 100 times using hospital specific laundering cycles and verified that there was no loss of antimicrobial activity and that the appropriate levels of silver and copper were still present.

### *Improvements*

Overall, Company A has an excellent mindset for producing quality products and can ensure that quality products are not only being received from their suppliers but sent to their customers with the same level of quality. When asked about what dimension of quality they could most improve on (e.g. adherence to specifications, timeliness, packaging, labeling, communication), Participant A had three areas that the company would like to focus on: timeliness, ease of ordering and shipping internationally, and adherence to specifications...the first time around!

## **Company B**

Company B is a small, privately-owned, 115-year-old textile company that was reestablished after closing its doors for twelve years. Previously the largest blanket and linen manufacturer in the world, the revived company now focuses on online retail of bed linens and antimicrobial bed sheets. It is important to note that Company B considers themselves a sales and marketing company – at this point in time they have no manufacturing processes. The antimicrobial fibers and filaments used in Company B’s bacteria-killing bed sheets are produced by Company A, whom they partnered with in 2017. The healthcare textile market is new to Company B, but they believe the partnership with Company A as well as their established reputation of producing high-quality linens projects a bright future for them.

The interviewee, Participant B, is the President and has extensive experience in the home textile industry. Participant B also served as chairman of a prestigious textile board. Together, Participant B and B’s business partner hold over 80 years of experience in R&D, sales and marketing, manufacturing, and quality assurance in the textile industry, setting the stage for great management of Company B.

### *Challenges*

The main challenge Company B faced when entering the healthcare market was the high cost of their antimicrobial sheets compared to regular hospital sheets. Company B thought that hospital purchasing staff and clinical staff would be willing to pay slightly higher prices if it meant a cleaner, safer environment, but they were unaware of the control that commercial laundering companies have on the products that are used. Participant B goes on to explain that about 80% of hospitals use commercial laundering companies – who charge by the pound.

Company B's antimicrobial sheets weigh about 25% less than the typical hospital sheet, which would in turn cut revenue for the commercial launderers. To make matters worse, a large hurdle arose when an interested hospital cancelled a contract due to disagreements with the launderer, which sent the company into a tailspin that they are still recovering from today. Until Company B can reduce their prices by ramping up inventory, they are not sure how to convince launderers of the benefits their products offer but are committed to finding a way. Participant B brings up a phrase often heard in the textile industry: "this is the way we've always done it and how we will continue to do it", commenting that this market is difficult to change, but products like these are important to the growth of the industry.

### *Successes*

One of the key successes that has benefitted the whole company was the creation of proprietary products. With four product patents, Company B was able to combine their fitted sheet technology with Company A's antimicrobial fibers to create a patented antimicrobial fitted linen.

Additionally, the company has extensive clinical data to validate the antimicrobial claims that they are making. Because the product is not registered as a medical device, there is no need for FDA approval, but successful clinical studies accepted by the FDA prove that their product is beneficial. They are now planning a clinical trial that will take place in a hospital to hopefully begin within the next year. The product has also been endorsed by two medical doctors.

The most gratifying success, according to Participant B, comes from the "wonderful and heartwarming" reviews that customers leave about the product. They provide the extra boost

needed to get through challenging times and help show the company that this is a worthwhile endeavor.

*Supply Chain Management*

When Company B decided to stray outside of the home textile market and into the healthcare market, the most helpful resource was their network. Since both founders come from the textile industry, their combined networks are large and diverse, allowing them to connect with trusted and knowledgeable industry leaders. They were able to connect with Company A through their network; a second supplier they found through a manufacturing catalog that offers reputable and “cream of the crop” manufacturing options. Before selecting them, Company B made sure to visit the facility and analyze the capabilities the supplier had to offer.

Company B only has two suppliers, and they have used them since they reopened the company. Participant B believes that limiting the number of suppliers to two helps with quality assurance of products – quality is easier to control and there is less of a chance for error.

Company B strives to carry on the high level of quality that Company A has built by providing quality checks of their own. Table 9 below outlines the various checks that Company B has implemented and when they occur.

Table 9: Quality checks done at Company B

<b>Quality check activity</b>	<b>When</b>
Someone from Company B in factory during production	During yarn and sheet manufacturing processes
Product specification testing (denier, dimensions)	At yarn manufacturer
Front, middle, end samples from each production lot	At sheet manufacturer
Send finished good sample to Company A for elemental testing	After sheet manufacturing process
Limiting the number of suppliers	N/A
Supplier integrity	Always

For Company B, quality control begins by having an employee present during the manufacturing of the yarn and antimicrobial sheet. This step goes hand-in-hand with one of their biggest quality focuses which is supplier integrity. They monitor this by frequently communicating with the suppliers and focusing on not only the products they can make but the attitudes and work environment they offer.

The yarn manufacture will check to make sure all specification that Company B has given them are met, including aspects such as denier, dimensions, and strength tests. Similarly, the sheet manufacturer tests random product samples from the front, middle, and back of the sheet for every production lot. Company B sends a sample of the finished good to Company A so they can perform elemental analysis tests. This ensures that the sheet has the specified amount of silver and copper fibers.

Finally, as discussed before, Company B has limited the number of suppliers they work with. They have found that this helps them monitor product quality at various levels more frequently and accurately.

### *Improvements*

The biggest and most ongoing improvement the company can make is reducing their production time. Currently, the whole process can take up to 150 days, not only because manufacturing is in China but because the process itself is time consuming. Company B believes that, with time, they will be able to reduce the 150-day turnaround time, especially when they begin to ramp up production.

## Company C

Company C is a large, privately-owned medical textiles company that has been in existence for a little over 30 years. Initially a traditional textile manufacturer, the company has slowly evolved into an engineered materials business with a focus on woven and nonwoven products. Company C offers products for many different markets, with the medical market being a large segment of their business. Products include antimicrobial pillow covers, surgical gowns & drapes, wound dressings, and low-lint towels. Their therapeutic bed sheet that aids in the treatment of bed sores and eczema is the only patented, FDA cleared bedding available in the market. Company C was the first ISO-qualified textile supplier in the USA and is still currently ISO 9001 certified. They have obtained FDA clearance on most of their products and have done over 12 clinical trials involving more than 12,000 patients.

The interviewee (Participant C) is the Chief Technology officer and the Vice President of Business Development. With degrees in textile technology and polymer science from NC State, Participant C fit in quite well with the company when hired about 20 years ago. Participant C has a vast amount of experience in developing fabrics, marketing, customer relations, and sales. Participant C's role involves meeting with hospital staff to market products, overseeing clinical trials, manufacturing logistics, and management of other departments. Simply put, Participant C's hand is in almost every step from initial concept to distribution and sales. Because Participant C is involved with all aspects of business, he/she provided great insight into the management of the company as well as the quality laced throughout.

## *Challenges*

A huge challenge for Company C, and arguably many other medical textile companies, has been educating the right people about the benefits of the products they offer. Participant C explains that when they approach a hospital there are two groups they are interested in: the supply chain experts and the clinical experts. However, neither of these groups understand textiles, like fiber selection or composition method (woven vs. nonwoven). When you demonstrate a new product that provides better healthcare, but increases the budget, it is difficult to have buy-in. Most of the time, purchasers are buying textiles as a supply item, and the challenge becomes educating them on why the antimicrobial sheet is worth spending more on.

An overall challenge characteristic of the healthcare industry is understanding the intricate layers of the healthcare system and where a product will make the greatest impact. Figuring out how to maneuver within the system becomes vital in succeeding in the industry.

## *Successes*

Company C has seen many successes during their 30+ years in business. During the early stages of the company, they were able to complete a lot of the backwork that has helped with the development of their products. This included traditional textile testing to show the differences in using a cotton fabric and a fabric made from continuous filament yarns. This helped the company prove that their products could not only be medically beneficial, but act as a regular textile as well.

The 12+ clinical trials the company has been able to complete is seen as a great achievement. The clinical trials provide the evidence needed for a skeptical hospital buyer or clinician to really see the product benefits. Participant C comments, “If you come prepared and



have all the right data the light will go on pretty quickly,” speaking to how the company has been able to overcome the challenge of product education.

The company has also seen success when adapting to the changing healthcare industry. Nowadays, people can choose to be in the comfort of their own home instead of going to a hospital. This has opened a new market segment in the home care market, where the company has tweaked their antimicrobial sheets to fit different bed sizes and endure a different type of wash cycle. It also required them to make a few changes in their supply chain to look towards medical equipment distributors rather than hospitals.

Finally, Participant C offered a unique example to show how the company is really working to expand the benefits that each product offers. In the maternity ward, new mothers typically wear the same gown as all other hospital patients. They were complaining that they were ratty old gowns and they didn’t look good in pictures with their newborns. Company C saw this as an opportunity to not only create an antimicrobial maternity gown to help with safety, but to create a unique and beautiful gown that mothers can feel good wearing. The gowns are now being used in hospitals local to the company. “If you pick the right materials, a product can have a lot of benefits, not just health,” concludes Participant C.

### *Supply Chain Management*

When Company C was searching for hospitals to market their products to and participate in clinical trials, they were able to use a resource close to home: a nurse that works at the company. The nurse’s network helped them get a foot in the door with various local hospitals who they still used today. They were also able to connect with the largest cut and sew manufacturer for hospitals who they have as a partner now.

Table 10: Company C quality check activities for therapy bedsheet

<b>Quality check activity</b>	<b>When</b>
Yarn type, yarn denier, weave type – all based on outlined specifications	Before fabric is manufactured
Packaging verbiage can be backed by clinical data	Final packaging
Laundering tests	Final product
Wear tests	Final product
Clinical trials	Final product
Using FDA registered suppliers	N/A
Requesting overseas manufacturer keep some supply in the United States	N/A
Supplier availability	N/A
ISO 9001 Quality System registered	All the time

The fabric raw materials supplier that Company C has been using for many years now is not involved in the medical field at all, they are actually a clothing manufacturer. To combat this, Company C has developed a detailed and extensive list of specifications and tests to ensure the material will be suitable for a medical application. Participant C notes that specifications are almost always met, and when they are not, there is a great corrective actions system in place. The raw material plant is also FDA registered, which was a big plus that drew Company C to them.

Another aspect that they request from one of their main suppliers is that they maintain a supply of yarn in the United States, so they do not have to wait for an overseas shipment. This allows them to be unconstrained by location but still maintain timeliness during production.

Company C has tried to become more innovative in their supply chain by choosing partners that are more entrepreneurial rather than traditional textile manufacturers. Participant C comments that the textile industry has a reputation for being slow to welcome changes, so partnering with a smaller, entrepreneurial company can be great for the evolution of the company.

Since Company C has many different markets, they have to pay close attention to how they advertise their medical textiles versus their standard home textiles. The most noticeable difference between their markets is the amount of regulations and clinical trials they have associated with the healthcare portion. They also must alter the language they use on the packaging and when selling the products.

### *Improvements*

Participant C feels the company could always be working to improve their timeliness. Even though they have some methods in place to speed up time, like requesting overseas suppliers keep a domestic supply, they struggle with very full production lines that can sometimes cause delays.

### **Company D**

Company D is a small, privately-owned biotextile company (< 20 employees) that has been in existence for approximately four years. This company focuses on utilizing chitosan, a biopolymer sourced from crustacean shells (shrimp shells), for clinical use as an implantable biotextile devices. Company D has been granted a patent that protects their processes used to make biomedical products as well as the products themselves. They are in the very early stages of development but were just granted the first round of funding and would now like to move forward with the development of the company.

The participant being interviewed (Participant D) is the co-founder and the Chief Scientific Officer. Participant D comes from a chemistry background, specifically polymer and fiber chemistry, and has a strong interest in the conversion of biopolymeric materials, such as chitosan, into medically beneficial fibers and films. Then, these fibers and films can be made into

wound dressings, like powders, bandages, and sponges. Participant D is considered an expert in chitosan, and the hemostatic advantages that chitosan offers has kept Participant D interested in this research field for over 35 years.

Before beginning the interview questions, Participant D provided useful information about the chemistry of chitosan. Currently, there are laparoscopic surgeries (surgeries that utilize multiple incisions in order to insert ports to pass instruments through) that cannot be performed due to the uncontrollable bleeding that occurs because of the incisions. Chitosan research is not new or recent, and it is known to the scientific world that chitosan can work as a hemostatic agent to control and even stop bleeding. However, chitosan, because it is derived from crustacean shells living in dirty water, has a chemical contamination issue that is very expensive to make sterile. These contaminants are called endotoxins, and they can be very dangerous in the body, so the FDA has extremely strict regulations on chitosan and the endoscopic compounds associated. These strict regulations as well as the high price of the decontamination process have pushed many people away from creating products made from chitosan. Company D has developed a process to effectively decontaminate and sterilize the chitosan so it can be made into filaments and films as well as an endotoxin free hemostatic device. Participant D was very excited about the opportunities that clean chitosan brings, not only to the biomedical markets, but to other markets as well.

### *Challenges*

Company D is still very early in development but has identified that the main challenge so far has been procuring funding for the development of the company. Participant D noted that both D and the two partners have a good understanding of the regulatory issues, writing

proposals, and how to develop the process. Their challenge now is building test machinery and testing instruments.

### *Successes*

According to Participant D, the trick to maintaining the company so far has been the team. With three equal partners, there is much opportunity for disagreement, but not in the case of Company D. Everyone gets along, knows their role, and contributes equally. Additionally, because of their interdisciplinary backgrounds, the trio has a large combined network, which Participant D recognizes has been a huge reason they were able to begin the company and start getting suppliers and customers on their radar.

Participant D also mentions that they utilized their resources well. Instead of having to outsource to a private company to use their machinery, Company D was able to use the NC State Nuclear Engineering Department's resources for their initial concept testing. This helped save money and time.

### *Supply Chain Management*

Since Company D is still in its infancy, a full supply chain has not been developed yet, but they are actively searching for suppliers and customers. Company D is currently evaluating various chitosan manufacturers, specifically looking for companies that are using shrimp shells and that are domestically located. Recently, they have begun receiving samples from different chitosan companies that they will analyze; they believe they are about a year out from actually finalizing a chitosan supplier(s).

When Company D evaluates the chitosan they receive, they have a list of criteria they are looking for, shown in Table 11 below. Even when they finalize a supplier, this will likely be part of the criteria they will continue to use.

Table 11: Quality measures used to evaluate potential chitosan suppliers

<b>Quality Check Criteria</b>	<b>Method</b>
Number of endotoxins present	2 Analytical methods using FDA standards
Molecular weight of chitosan	N/A
Sugar ratios	Titration
Time, temperature, pressure compatibility	Testing in the plasma machine

Because of the strict FDA endotoxin regulations, Company D is measuring the presence of endotoxins using two analytical methods that meet FDA standards. Location is important to them as they begin to receive samples from potential suppliers, as they are also concerned with the cleanliness of the water that the crustaceans are retrieved from. Other ordinary chemical standards that Company D is looking for is the molecular weight of chitosan, the sugar ratios, and the compatibility of the chitosan with time, temperature, and pressure settings that the cleaning process uses. More quality specifications will be outlined when the company begins to make final products.

### *Improvements*

Participant D believes that, even though the company is very young, there still could be some initial improvements made, particularly with project prioritization, meaning earlier prioritization behind which products would be going to the market first and the timing behind each one. Because Participant D and his partners are in academia and have started Company D

on the side, they tend to think more about pure science behind the product rather than the commerce side of the business.

Though Participant D never showed much interest in starting a company (and had plenty of opportunities!), D believes the opportunities that Company D presented are different, and that this time the three partners decided to take the risk and that “everything just clicked.” Though the future of Company D is unknown, the founders seem to have a firm grasp of not only the scientific aspect of the products, but the knowledge it takes to start and grow a business.

### **Company E**

Company E was a small, privately-owned medical textile company that was in existence for about seven years (2006 – 2013). The company was successful in commercially producing antibacterial and antiviral surgical masks and disposable cleaning wipes but was never able to receive FDA approval for their devices and, therefore, closed its doors in 2013. The surface treatment that Company E created to coat the devices and kill bacteria was light activated, which was a great achievement, but became the major hurdle to FDA approval due to the ineffectiveness of the devices in a dark hospital operating room. Even though Company E is no longer operating, it offers many success stories and is an excellent testimony to the difficulties presented when starting a medical textile company.

The participant being interviewed (Participant E) was the head scientist and was the lead on developing the chemical coating that was applied to the devices. Participant E also served on the Board of Directors and Chaired the Board. Participant E’s chemistry background and current research in the forensics and surface modification areas provided a great knowledgebase for the development of this company.

### *Challenges*

Company E's major challenge that ultimately led to its closing was the inability for the products to become FDA approved. Additionally, the FDA requires validation and verification of all process steps as well as raw materials, which was timely, costly, and tedious. Eventually, all processes were approved by the FDA, but the final products were still not approved for U.S. sale.

Participant E spoke some to the difficulties of predicting an accurate timeline for the development of the antimicrobial coating. For example, the company predicted about six months for creating the prototype, which was completed in less than a day. Another challenge arose when trying to teach manufacturing workers how to make Company E's products properly, especially when the workers were following standard operating procedures for other products.

### *Successes*

When talking to Participant E, it was evident that Company E had many successes that company members were proud to have accomplished. The first major achievement was when they made their first successful prototype in only a single day. Another came when they were finally able to apply their antimicrobial treatment to fabrics at a commercial scale. Not only was Company E able to commercially produce their products at an overseas manufacturing facility, but they were also able to recreate the manufacturing in the United States which was an important success factor for the company.

Unfortunately, the many successes of Company E were unable to keep it from closing, clearly attesting to the strict control the FDA has over seemingly successful companies.



### *Supply Chain Management*

Company E's basic approach when seeking potential suppliers was willingness. Participant E explains that, with a small company, many supplier inquiries go unnoticed, and the select few that take the time to listen and show interest are ones that are usually chosen. Because Company E was so small, they needed a convincing story with strong evidence to support the antibacterial claims of their products in order to assure suppliers that it was worth their time. An additional assurance boost came when the company was featured on CNN.

After agreeing on the selected raw materials suppliers, all of whom Company E used during their time as a company, many protocols and tests had to be created to assure the quality of the materials they were receiving. Though the size of Company E restricted their ability to request testing be done by each supplier, they were equipped with a large test facility that allowed them to quality test at various stages of manufacturing. Unfortunately, the distributors Company E had lined up never received any product due to the FDA's lack of approval.

### *Improvements*

A major improvement theme that Participant E discussed was communication. Participant E felt that communication with suppliers, the FDA, and even internally could have been much better, and might have contributed in part to the reason FDA approval was not granted. In terms of communication with suppliers, the antimicrobial chemical finish was synthesized at a pharmaceutical plant by someone untrained in the process caused Company E unnecessary expenses. When discussing communication with the FDA, Participant E believes the reason FDA approval was not granted was because of the way the FDA application was filed. Ambiguous wording and incorrect filing definitions done by poor and untrained management caused the

FDA to classify the device as a Class II device, which has stricter regulations and extensive clinical trials. Participant E thinks that if the FDA had classified the device as a Class I, the company would still exist.

## CHAPTER 5

### Discussion and Conclusions

The following chapter analyzes the five company summaries from Chapter 4. It will address the three research objectives and provide future research recommendations as well as concluding remarks.

**Research Objective 1: Understand significant similarities and differences in supply chains for five different medical textile companies across North Carolina.**

The five companies studied vary in size as well as product type. Overarching similarities and differences identified through textual understanding are presented in Table 12 below and will be discussed in detail. (Note: if three or more companies shared a commonality, it was considered a ‘similarity’; if two or fewer companies shared a commonality, it was considered a ‘difference.’)

Table 12: Overview of similarities and differences across five companies

<b>Similarities</b>	<b>Differences</b>
FDA challenges and difficult market penetration	Company D is solely a licensing company
Networking used as a supply chain-building tool	Company C is involved in many other markets
Timeliness as a needed improvement	Traditional textile companies entering medical markets
Lack of discussion on price	Classification language used for medical textiles and biotextiles is different

## *Similarities*

### *FDA challenges and difficult market penetration*

The most anticipated similarity between all five companies was the presence of the FDA. Inherent to the industry, the FDA has a hand in every medical product that will make it onto the market, and depending on what class of medical device, those regulations can be quite difficult and timely to work around.

Companies A and B found an interesting way to work around the FDA requirements for a medical textile product by registering their silver and copper filaments and antimicrobial sheets with the EPA, making them a pesticide. However, this adds some challenges when making accurate claims on their products, as the FDA also must approve any claims made about a medical device. Currently, Company A and B are keeping their eyes open for a similar medical textile that they could use as a predicate device for FDA approval, which will reduce time and higher chances of gaining approval.

Though Company C has FDA clearance on almost all of their products, the process was not an easy one. Many years' worth of clinical trials and product testing are required to be granted clearance, but Company C believes the time spent in the earlier days of the company was worthwhile. FDA clearance is easier now that they know the process, time and money requirements, and have many predicate devices to file against.

Currently, Company D feels they are too early in development to apply for FDA clearance, but would like to begin the process in the next year. Because they have patents on their process and future products, FDA clearance should not be as difficult. Company D has always kept the FDA in mind, as they are currently using two FDA standards to test their chitosan.

The biggest FDA challenge was seen at Company E, whose inability to be granted FDA clearance was one of the primary reasons the company ultimately shut down.

Figure 4 seen in Chapter 2 (pg. 22, also seen in Figure 10 below) ranked supply chain issues for 34 large medical device companies across the world. It can be seen that 81% of companies claimed regulatory requirements is the main source of concern in the medical device industry. Even at large, global companies, regulatory requirements are difficult to work around.

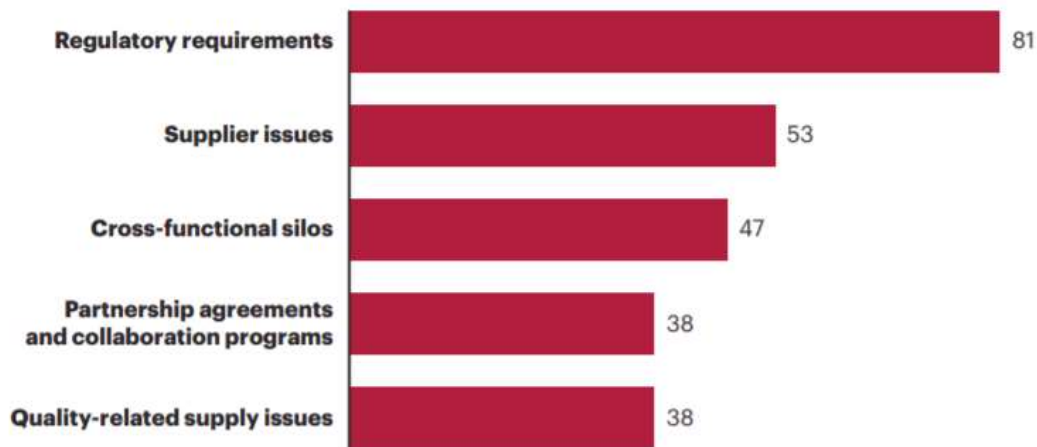


Figure 10: Biggest issues in medical device supply chain according to 34 companies.

Source: Tribe et al. (2017).

Because of the FDA's strict presence in the medical textile and biotextile markets, it is difficult for market penetration, especially for small start-up companies and companies creating a new market segment for themselves. The process is time consuming and tedious, but it is apparent that FDA clearance is almost mandatory for a successful company. Company C's success with the FDA was made by being thorough, dedicated, and always having the clinical data to back the device.

### *Networking used as a supply-chain-building tool*

One theme identified by all five participants was the way by which their companies identified and selected existing and new suppliers. All mentioned the main ‘tool’ they utilized was their network. They each recognized that previous work experience and strong industry connections helped form key relationships that played large roles in initial company development. Networking as a supply chain resource is likely characteristic of smaller businesses in early stages of development, as the process of approaching a larger and more prominent company will usually result in rejection.

### *Timeliness as a needed improvement*

Participants A, B, C, and D all felt timeliness was an area of their company that could use improvements. In particular, Company B is currently operating at an approximate 150-day turnaround time due to their utilization of an overseas supplier. Company C is also working to reduce their production times, but for a different reason. Because they manufacture so many product types, their production line is usually running at full capacity, and a slight hiccup in the process can cause significant delays. Company C does, however, also utilize an overseas supplier, but has been able to keep transport times short by requesting their supplier have a domestic supply always available. A suggestion for Company B may be to approach their supplier and request that some supply is always available at a closer and more convenient location to help improve their long turnaround times.

### *Lack of discussion on price*

An interesting finding from the interviews was the lack of any discussion about pricing. Revisiting the table of important criteria for vendor selection see in Chapter 2 (pg. 26, also seen in Table 13 below), price is seen as a considerably important factor, yet only Company B discussed product pricing in any detail (Company C mentioned it but did not express any concerns about price). Company B expressed the high price of their antimicrobial sheets as one of their major challenges to market entry, as many hospital supply purchasers are not willing to raise their budget without sufficient evidence as to why the product is worth more.

The lack of concern at any other company about pricing is interesting and could be attributed to the characteristics of the medical textile and biotextile industries, and arguably the healthcare industries, where no price is too high if it means improving lives.

Table 13: Ranking of the importance of 23 criteria for vendor selection (out of 170 responses)

Source: (Dickson, 1966).

Rank	Factor	Mean rating	Evaluation
1	Quality	3.508	Extreme importance
2	Delivery	3.417	
3	Performance history	2.998	
4	Warranties and claim policies	2.849	
5	Production facilities and capacity	2.775	Considerable importance
6	Price	2.758	
7	Technical capability	2.545	Average importance
8	Financial position	2.514	
9	Procedural compliance	2.488	
10	Communication system	2.426	
11	Reputation and position in industry	2.412	
12	Desire for business	2.256	
13	Management and organization	2.216	
14	Operating controls	2.211	
15	Repair service	2.187	
16	Attitude	2.120	
17	Impression	2.054	
18	Packaging ability	2.009	
19	Labor relations record	2.003	
20	Geographical location	1.872	
21	Amount of past business	1.597	
22	Training aids	1.537	Slight importance
23	Reciprocal arrangements	0.610	

### *Differences*

*Company D is solely a licensing company*

One notable difference can be seen with the logistics of Company D compared to the other four companies. Company D, though very early in development, is planning on licensing their chitosan-cleaning technology to a larger, well-known medical device company. They are



not interested in manufacturing, marketing, sales, or distribution and once the scientific portion of their invention is sound, they will pass it forward. This is likely due to the fact that the founders of Company D are all still in academia which takes up most of their daily time.

#### *Company C is involved in many other markets*

Company C's involvement in a number of different markets sets them apart from other traditional medical textile companies. Some of their other fabric markets include industrial, commercial and home. The wide range of products they have allows them to be versatile and creative when developing new products, and they are also able to share raw materials for the different markets. The main difference comes into play when they begin testing the raw materials – the materials for medical textiles will have stricter specifications, more regulations, and the company will alter the language they use to cater towards a clinical audience.

#### *Traditional textile companies entering medical market*

Company B was the only company that was formerly a traditional textile company. Their recent entry into the medical market with their antimicrobial sheets has been challenging due to the regulations for manufacturing and selling a medical device. For traditional textile companies looking to emerge into the medical textile market, it is important to have awareness for the regulatory bodies that are involved in the medical industry and how they will affect product development. Company B was fortunate enough to form a great partnership with Company A, who was already EPA registered, and were able to grow their business some with Company A. However, Company B will soon be conducting clinical trials on their sheets in hopes to eventually become FDA approved.

*Classification language used for medical textiles and biotextiles is different*

It was interesting to hear the different classification languages used between the companies. Company A was quick to mention that their silver and copper infused fibers and filaments could not be called a medical device or a biotextile because they were not FDA approved. Company B reiterated that, though the antimicrobial sheets are a textile product with a medical benefit, they were not actually classified as a medical textile. Company D had a similar story, since they have created a process to clean chitosan but will not actually be manufacturing a device, they do not classify themselves a biotextile company. However, this chitosan-cleaning process will lead to fibers and films that will eventually be created into a biotextile for internal use.

**Research Objective 2: Determine how companies ensure quality as a device or product moves through the supply chain.**

As a device moves through the supply chain from process to process and factory to factory, it can be difficult to guarantee that quality will be maintained within each step. Thinking back to the 8 dimensions of quality explained in Table 3 of Chapter 2 (pg. 17 – also a brief version shown in Figure 11 below), four of the five companies interviewed shared various ways they monitor and measure quality, shown in Table 14.

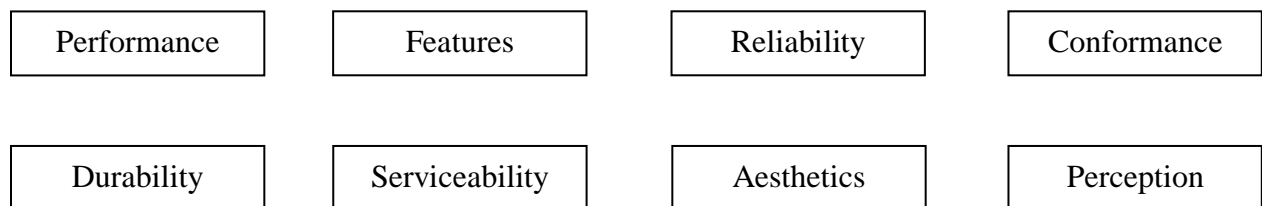


Figure 11: 8 Dimensions of quality

Source: (Garvin, 1988).

Table 14: Quality control activity for four companies and the corresponding quality dimension

	<b>Quality control activity</b>	<b>Quality Dimension</b>
<b>Company A</b>	Absence of nanoparticles	Conformance
	Appropriate silver and copper content	Conformance
	Have someone from Company A present when making fibers at supplier's location	Perception
	Test beginning, middle, and end of fiber run to ensure consistency and uniformity	Conformance
	E. coli test	Conformance
	AATCC 100 test	Performance/ Conformance
	Elemental analysis	Performance/ Conformance
	Performance testing characteristic of fibers being substituted	Performance
	Laundering tests	Durability
<b>Company B</b>	Someone from Company B in factory during production at supplier's location	Perception
	Product specification testing (denier, dimensions)	Conformance
	Front, middle, end samples from each production lot	Conformance
	Send finished good sample to Company A for elemental testing	Performance/ Reliability
	Limiting the number of suppliers	Perception
	Supplier integrity	Perception
<b>Company C</b>	Yarn type, yarn denier, weave type – all based on outlined specifications	Conformance
	Packaging verbiage can be backed by clinical data	Features/ Aesthetics
	Laundering tests	Durability
	Wear tests	Durability
	Clinical trials	Performance
	Using FDA registered suppliers	Perception
	Requesting overseas manufacturer keep some supply in the United States	Serviceability
	Supplier availability	Serviceability
	ISO 9001 Quality System registered	Perception
<b>Company D</b>	Number of endotoxins present	Conformance
	Molecular weight of chitosan	Conformance
	Sugar ratios	Conformance
	Time, temperature, pressure compatibility	Performance
<b>Company E</b>	N/A	N/A

One interesting finding about the quality dimensions in the table above is regarding Company D, who, as mentioned in RO1, is solely a licensing company with no manufacturing, marketing, or distribution. The quality dimensions at Company D are all conformance and performance dimensions, meaning they are only concerned about how the product (chitosan pellets) conforms to their set specifications and performs to their set standards.

From Table 14, it is apparent that these four companies are not only focused on the quality of their products, but also try to incorporate other dimensions of quality other than adherence to specifications. They incorporate durability tests to ensure the product not only works but can work for a long time. They incorporate perception quality checks so that outside sources can see integrity in the company. They also include serviceability in terms of their suppliers, which shows they are partnering with reputable suppliers. Many of these dimensions are easy to overlook because meeting specifications is very important, but non-measurable or hard to measure quality dimensions should always be included to produce a well-rounded and successful medical device company.

**Research Objective 3: Describe the supply chain for five different medical textile companies across North Carolina.**

In order to describe the supply chains of the five companies, a simplified linear process map was created for each company following the flow of material and product, see Figures 12, 13, 14, 15, and 16 below.

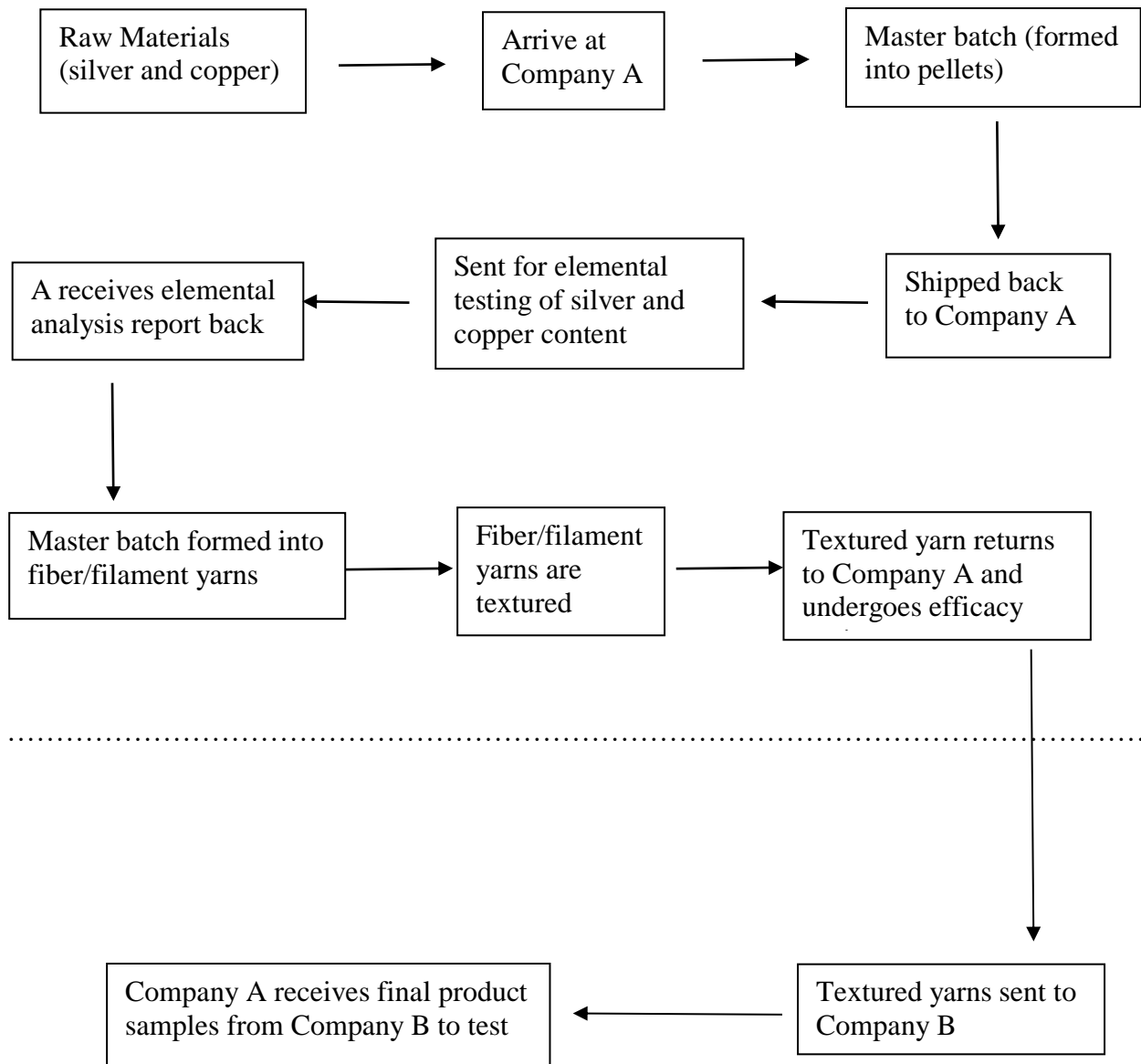


Figure 12: **Company A** process map

Note: Dotted line represents the handoff from Company A to Company B.

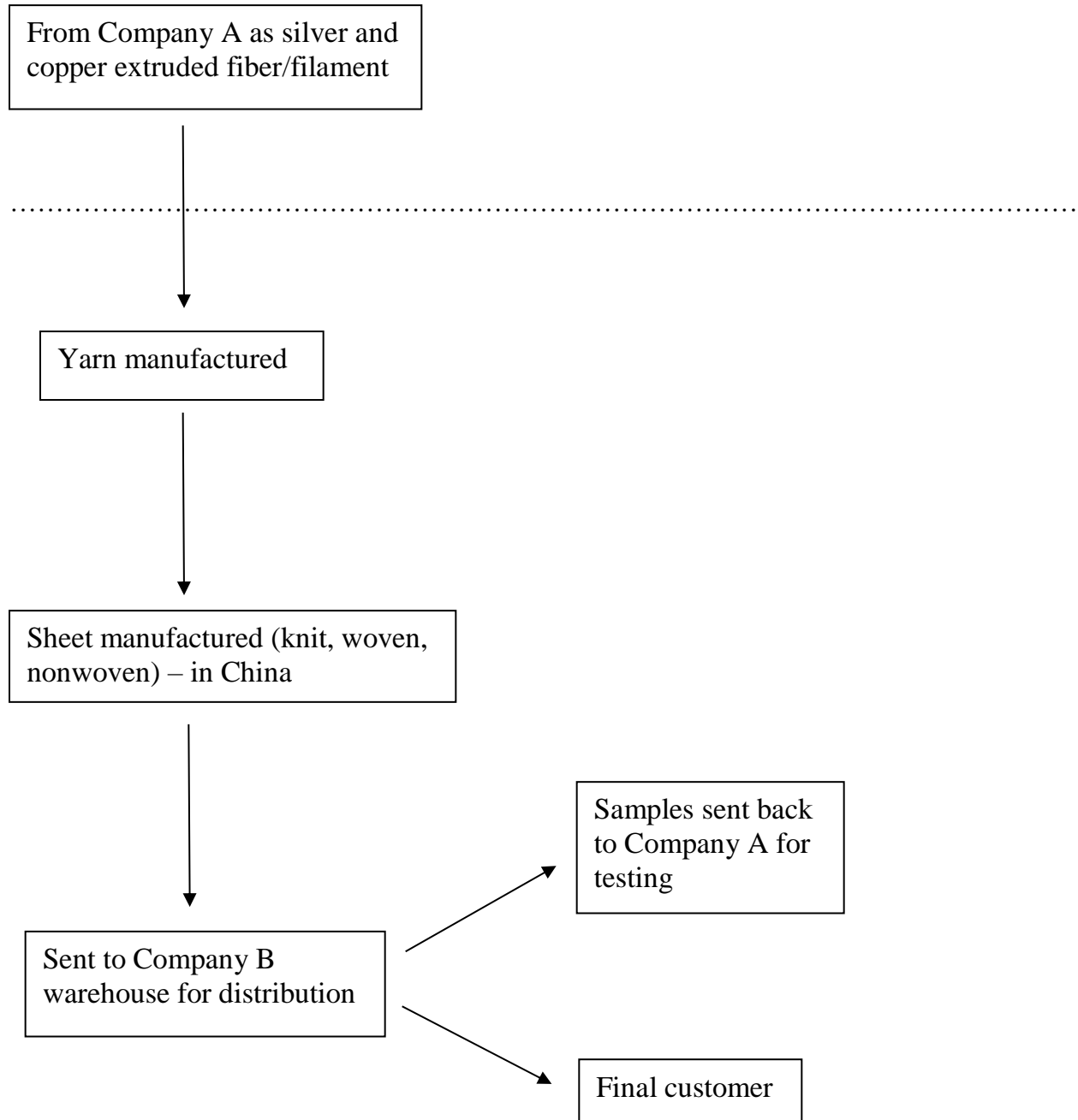


Figure 13: **Company B** process map

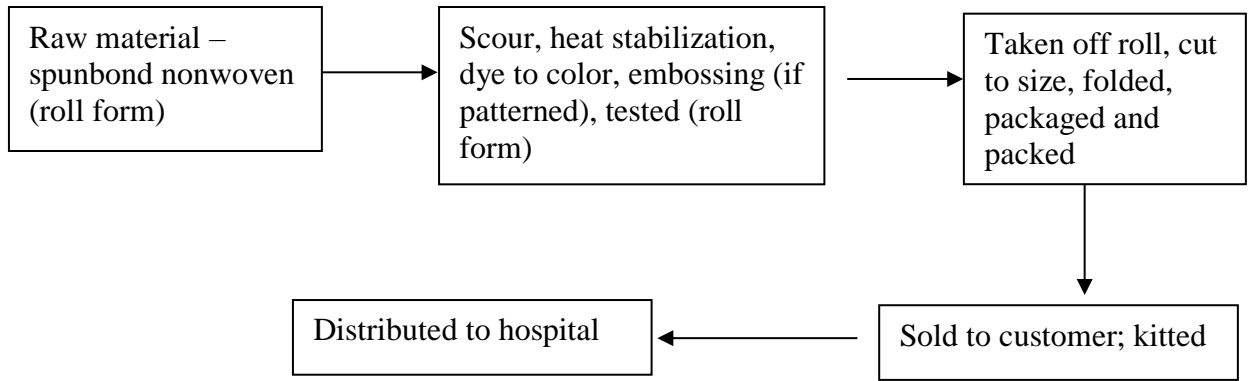


Figure 14a: **Company C** process map for **disposable** medical product

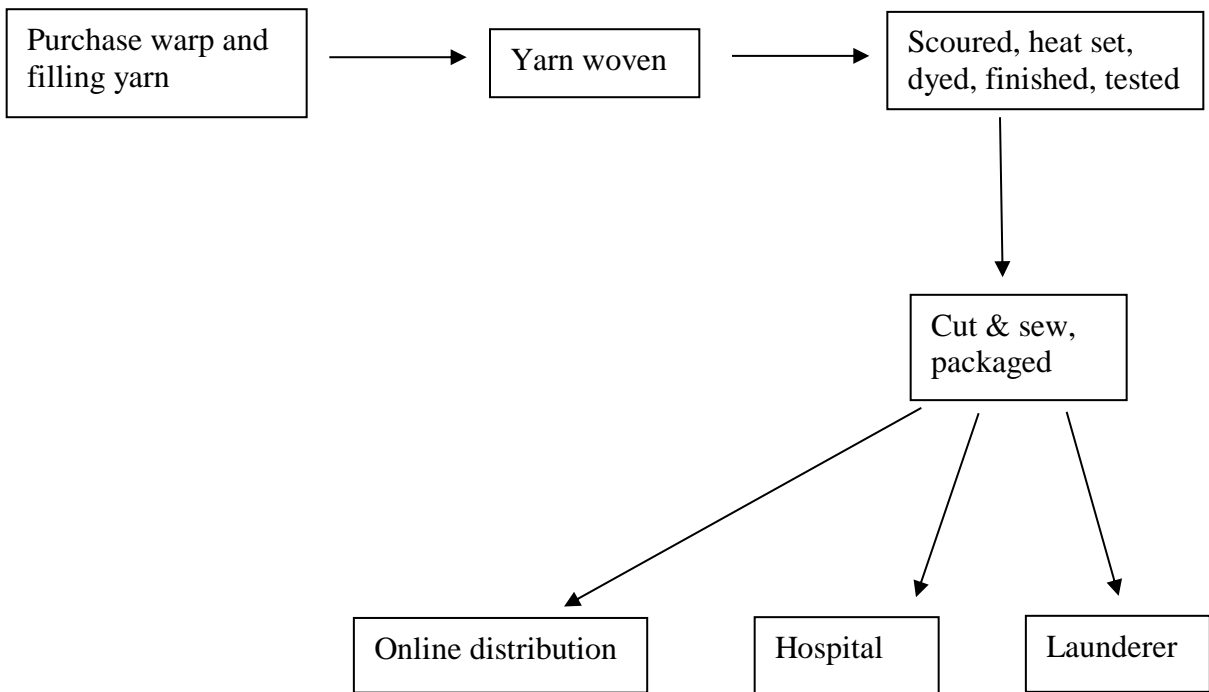


Figure 14b: **Company C** process map for **reusable** medical product

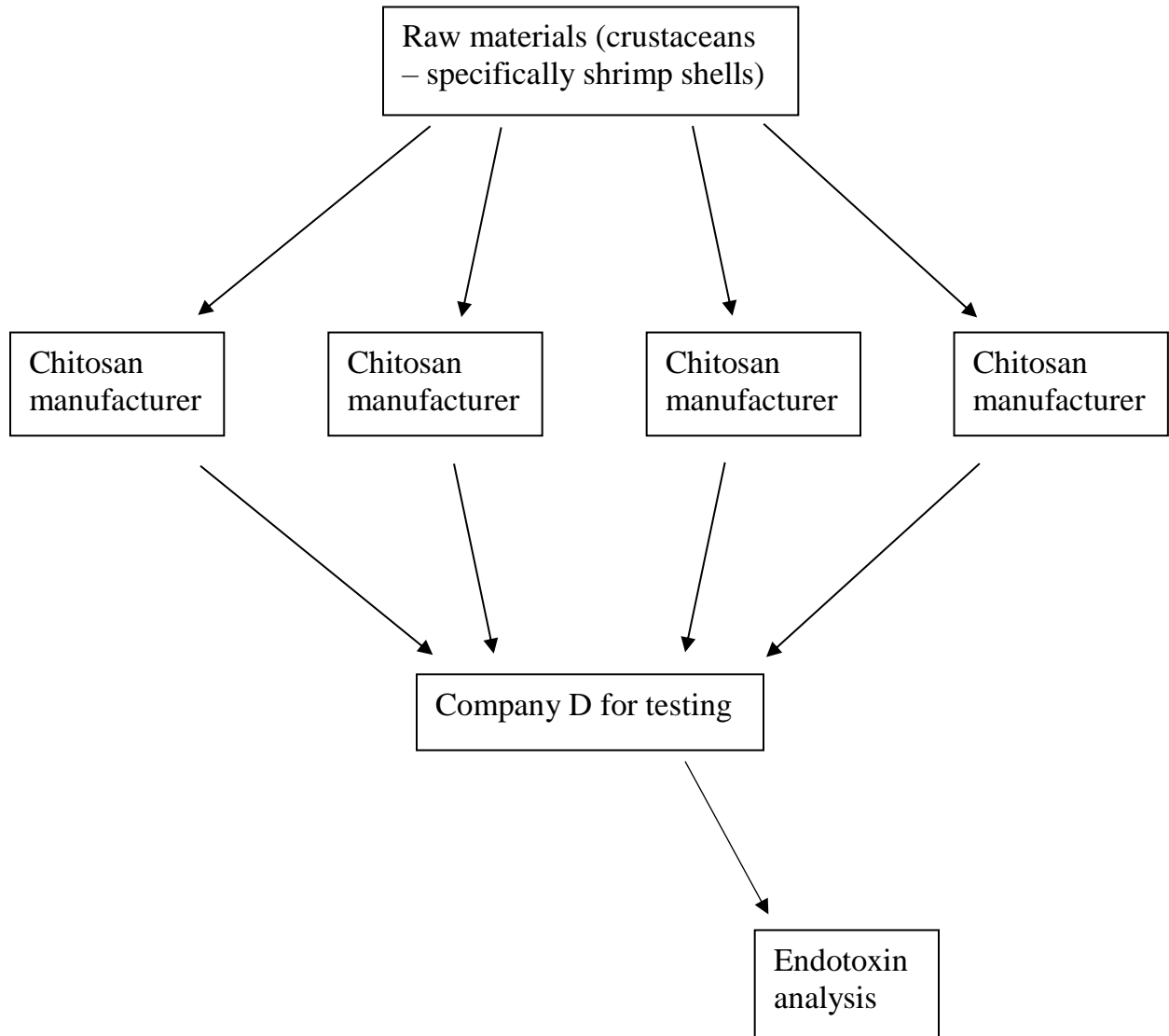


Figure 15: **Company D** process map



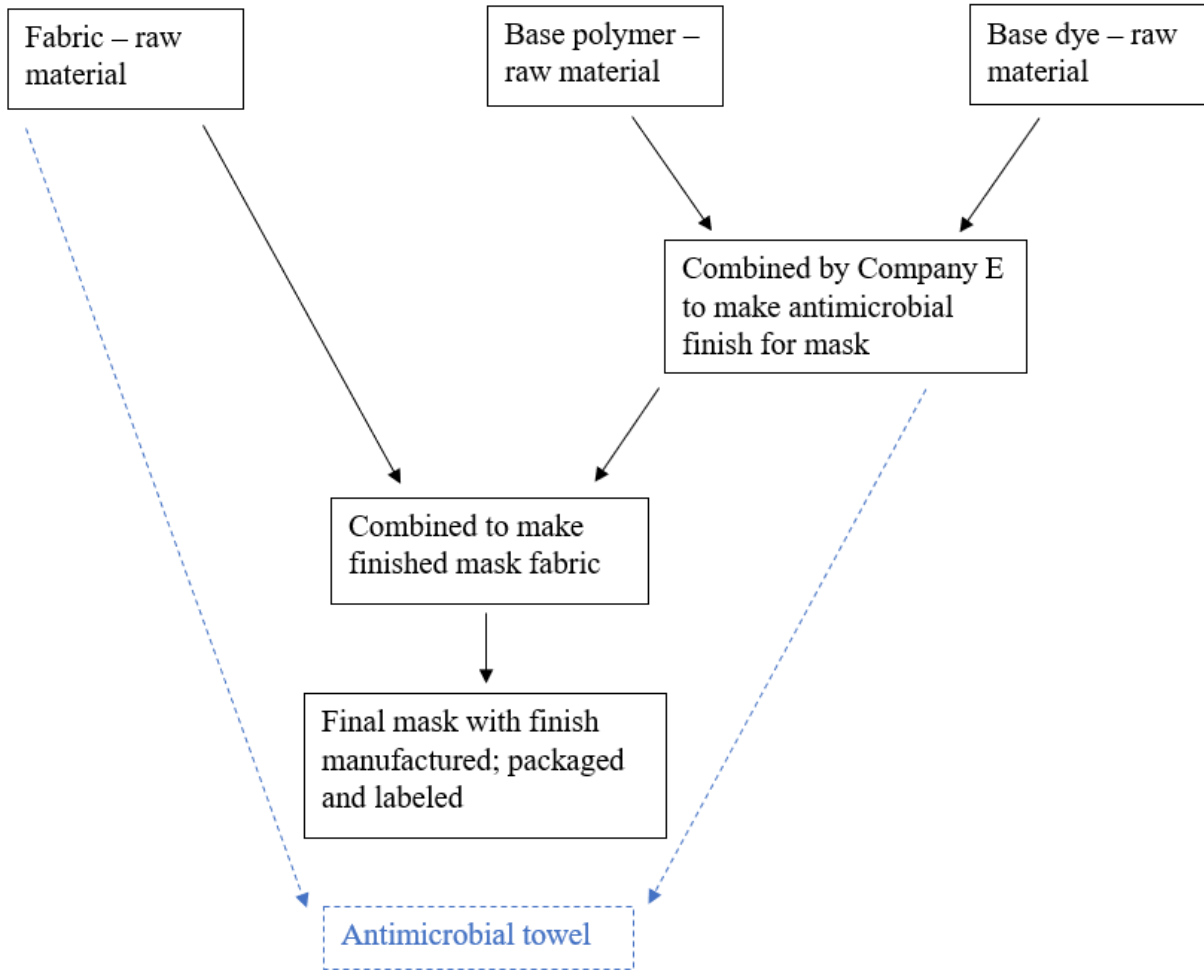


Figure 16: **Company E** process map

Though the five process maps do differ in shape and process steps, they all follow a generally flow throughout. This is likely because each of these companies, with the exception of Company C, are only manufacturing one product.

## **Conclusions**

The purpose of this research was to understand and analyze the medical device industry supply chain for private medical textile companies in North Carolina and how quality is maintained throughout the supply chain. In-depth, semi-structured interviews were performed on five private medical textile device companies in North Carolina. The five companies were chosen because they all create a product that provides a medical benefit, and after textual analysis of the interviews, the research objectives were answered.

The five companies shared similarities across a few different areas. The main similarity found was the sheer challenge that entering the medical device industry poses due to strict regulations, most notably by the FDA. Companies recognize these stringent regulations as the reason for difficult market entry and, for one company interviewed, FDA challenges ultimately caused the company to close. Other similarities were also found, such as the utilization of a strong network to build supply chain relationships, the need to improve on timeliness, and the lack of product pricing as a discussion point.

Though the chosen companies were all small, privately owned medical device companies in North Carolina, there were some noticeable differences in the characteristics of each company. The main differences were seen when discussing the way each company classified themselves. Classification terminology is important in the medical device industry, as companies have to be

FDA registered to make certain claims about their products. There were also differences in the backgrounds of the companies and market positioning.

Four of the five companies shared the various ways quality is maintained throughout the development process. Each quality check was then associated to one of eight dimensions of quality. With the exception of one company, who is solely focused on licensing a process, they demonstrate many of the dimensions of quality throughout processing, which speaks to well-roundedness of each.

Finally, process flow maps of each company were created to help describe the supply chain process. Though each of the companies vary in product made, the process maps show an overall linear flow, likely since the companies are small and focused on one or two products.

For companies looking to enter the medical textile or biotextile supply chain, the biggest hurdle is very likely going to be the stringent regulations. However, with the proper management, industry connections, patience, and thoroughness, market entry can be successful. FDA clearance is tedious and time-consuming but taking the extra time to do it correctly will ultimately provide a much larger pay off.

### **Future Recommendations**

1. Since only five companies were chosen to participate in this research, a larger sample of similar companies should be explored for relationships in the future, given more time and resources.
2. Additionally, a survey sent to privately-owned medical textile and biotextile companies may be useful in collecting more information across a larger range quicker than performing in-depth interviews with each company.

3. It would be interesting to explore how the results of this research reflect similarly-regulated industries, such as the automotive and aircraft industries.
4. Re-evaluating the supply chain for the four existing companies (A, B, C, D) after a few years would provide great insight to how these companies are developing over time.

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## APPENDICES

## Appendix A: IRB Approval Form

NORTH CAROLINA STATE UNIVERSITY  
INSTITUTIONAL REVIEW BOARD FOR THE USE OF HUMAN SUBJECTS IN RESEARCH  
SUBMISSION FOR NEW STUDIES

Protocol Number 16621

*Project Title*

Analysis and Improvement of the Medical Textile Supply Chain in North Carolina

*IRB File Number:*

*Original Approval Date:*

02/27/2019

*Approval Period*

02/27/2019 -

*Source of funding (if externally funded, enter PINS or RADAR number of funding proposal via 'Add New Sponsored Project Record' button below):*

none

*NCSU Faculty point of contact for this protocol: NB: only this person has authority to submit the protocol*

Godfrey, A. Blanton: Textile & Apparel, Technology & Management

*Does any investigator associated with this project have a significant financial interest in, or other conflict of interest involving, the sponsor of this project? (Answer No if this project is not sponsored)*

No

*Is this conflict managed with a written management plan, and is the management plan being properly followed?*

No

*Preliminary Review Determination*

*Category:*

Exempt d.2

## Appendix B: NCSU Consent Form

### North Carolina State University INFORMED CONSENT FORM for RESEARCH

Title of Study: Analysis and Improvement of the Medical Textile Supply Chain in North Carolina

Principal Investigator: Kathryn M. Hayes Faculty Sponsor (if applicable): Dr. A. Blanton Godfrey

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#### **What are some general things you should know about research studies?**

You are being asked to take part in a research study. Your participation in this study is voluntary. You have the right to be a part of this study, to choose not to participate or to stop participating at any time without penalty. The purpose of research studies is to gain a better understanding of a certain topic or issue.

You are not guaranteed any personal benefits from being in a study. Research studies also may pose risks to those that participate. In this consent form you will find specific details about the research in which you are being asked to participate. If you do not understand something in this form it is your right to ask the researcher for clarification or more information. If you would like, a copy of this consent form will be provided to you. If at any time you have questions about your participation, do not hesitate to contact the researcher(s) named above.

#### **What is the purpose of this study?**

The purpose of this study is to examine and understand the supply chain for various medical textile companies across North Carolina, how they interact, and how they work to improve the lives of patients and providers.

#### **What will happen if you take part in the study?**

If you agree to participate in this study, you will be asked to answer seven open-ended interview questions. The interview will take a few hours and it will be audio recorded for transcription and verification purposes only.

The researcher would like to observe your related processes and take notes while at your location. The researcher would also like to review a few documents on the growth of the company; e.g., annual reports, financial statements if possible, to assist the understanding of the growth of the company over time. The duration depends on the selected processes.

#### **Risks and Benefits**

There are minimal risks associated with participation in this research. There are no direct benefits to your participation in the research. Your participation will help us to get a better understanding of the medical device industry supply chain. Moreover, the results will help us to identify better variables to model successful medical textile supply chains and how they better the lives of patients and providers.

#### **Confidentiality**

The information in the study records will be kept confidential to the full extent allowed by law. Data will be stored securely in password-protected files in a NC State University computer and secured storage area. No reference will be made in oral or written reports which could link you to the study.

#### **Compensation**

You will not receive anything for participating in this study.

#### **What if you have questions about this study?**

If you have questions at any time about the study itself or the procedures implemented in this study, you may contact the researcher, Kathryn M. Hayes, kmhayes3@ncsu.edu, 336-413-7600.

#### **What if you have questions about your rights as a research participant?**

If you feel you have not been treated according to the descriptions in this form, or your rights as a participant in research have been violated during the course of this project, you may contact the NCSU IRB Office via email at [irb-director@ncsu.edu](mailto:irb-director@ncsu.edu) or via phone at 1.919.515.4514.

**Consent To Participate**

"I have read and understand the above information. I have received a copy of this form. I agree to participate in this study with the understanding that I may choose not to participate or to stop participating at any time without penalty or loss of benefits to which I am otherwise entitled."

**Subject's signature** \_\_\_\_\_

**Date** \_\_\_\_\_

**Investigator's signature** \_\_\_\_\_

**Date** \_\_\_\_\_

## Appendix C: NCSU Initial Email Draft

Dear \_\_\_\_\_,

My name is Kathryn Hayes and I am currently working on my Master of Science in Textiles and minoring in statistics at North Carolina State University under Dr. A. Blanton Godfrey. As part of my graduate research, I am interested in performing case studies on select companies in order to obtain qualitative information. More specifically, I would like to examine and understand the supply chain for five medical textile companies across North Carolina, how they interact, and how they work to improve the products as well as the lives of patients and providers. My undergraduate background is in medical textiles and a main focus of my graduate career has been on quality improvement in healthcare, so I believe this research is a great marriage of my interests and education background. Moreover, little has been explored on how existing medical textile companies interact and how they initially formed supply chain relationships when in the early stages of development, and I would like to fill that gap in the research.

I am contacting you because I believe your company would be valuable for me to include in my study. I believe the information you can provide will be beneficial in my research and I would love to gain more insight on your supply chain and how it is managed.

The interview would consist of 7 open-ended questions and would take ~2 hours. It could be conducted over the phone or skype, but preferably in-person (I am more than willing to travel!). I would like to conduct the interview within the next month due to my thesis deadline requirements. The results of the research would be made available to you at the conclusion of my thesis.

Thank you so much for your consideration and please inform me on your willingness to participate in this research!

Very Sincerely,  
Kathryn Hayes

## Appendix D: NCSU Interview Protocol

### Interview Protocol

**Title of Study:** Analysis and Improvement of the Medical Textile Supply Chain in North Carolina

**Principal Investigator:** Kathryn M. Hayes

**Faculty Sponsor:** Dr. A. Blanton Godfrey, Textile and Apparel, Technology and Management Department, Wilson College of Textiles

**Interview Location and Time:** The location will be determined later, upon agreement between the researcher and each participant. It is most likely that the interviews will be conducted either personally off-campus, via Skype, or via phone. The participants will be contacted in advance via email to schedule a time for interview.

**Number of Participants:** Five, each will be interviewed separately.

Hi, my name is Kathryn Hayes and I want to begin by thanking you for agreeing to meet with me to answer a few questions. The purpose of this study is to examine and understand the supply chains for various medical textile companies across North Carolina, how they interact, and how they work to improve the product as well as the lives of patients and providers. Before we move forward with our interview, I am obligated to give you this consent form which includes the necessary information about this study. Please take as long as you need to read it thoroughly and sign the bottom of the paper if you are willing to participate in this study.

(Collect the consent form)

As mentioned in the consent form, I'm going to audio record this interview and transcribe it later for data analysis. All the information will be kept confidential and identifying information will not be used for the publication of my thesis. There are minimal risks associated with participation in this research. The approximate interview time is a few hours based on our conversation followed by some data collection for further information. In this interview you will be asked questions about seven areas of your company's supply chain:

1. What are some of the challenges your company faced when entering the supply chain? How did you overcome these challenges and how long did it take?
2. What were some of the things you felt your company did successfully when entering the supply chain?
3. What are some tools out there, if any, that assisted your company when entering the supply chain and looking for connections?
4. When entering the supply chain, what criteria did you set for looking for raw materials/supplies and suppliers? How have these criteria changed over time?
5. How do you go about identifying and selecting new suppliers? How do you assure the quality of the materials and supplies you purchase? How does your customer assure the quality of your products? Do you have examples of some innovations you have made to managing supply chains?
6. How do you modify your supply chain model for various products or customers?
7. What part does your supply chain play in the improvement of patient and provider wellbeing?

However, during the interview if more questions arise, they will be addressed. With this introduction, I'm going to start our interview.

(Begin audio recording the interview, starting with question one)

(End audio recording when the interview is finished)

Thank you for much for your time. If it is OK, I will contact you again in the future if I feel I need more information or would like to schedule a follow-up meeting.

Sincerely,  
Kathryn Hayes