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Medical Device Manufacturing: Gowning Procedure Harmonization Strategy

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ABSTRACT

Efficient and safe gowning procedures are an essential components of productive medical device manufacturing practices within a supply chain, but without standardized process for gowning existing and best practices being unique to respective firms, businesses will expose themselves to an abundance of risks if they do not focus on this topic. Specifically, a weak gowning procedure leaves firms susceptible to quality issues during production, safety concerns for employees, high unit costs of equipment, and many more serious consequences. Another issue arises through the fact that there is no common best practice for gowning in the medical device manufacturing industry, so one company's success with gowning procedures cannot be directly transferred to another due to unique needs for each business. This thesis will analyze how a leading player in the medical device manufacturing industry, Company A, manages their gowning procedures across their global sites as well as recommend how they can improve this specific area within their supply chain to benefit the firm as a whole. Six leaders from Company A were interviewed with a standard set of questions which were made to gain insight into Company A's current issues with gowning and areas for potential improvement. These interview results, along with data collected of gowning procedures at every global site were combined to provide employee driven recommendations. The results were compared with the limited academic research in this space and deliverables were made for company A based on these results, explaining ways they can improve their supply chain through change. The final recommendations for Company A focus on improved communication and the formation of a harmonized gowning procedure. The key takeaway from this project and thesis is finding ways to improve gowning procedures specifically for Company A, which will lead to many benefits for their overall supply chain.

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Chapter 1

Introduction

Medical Device Manufacturing Industry

An efficient supply chain consists of strong individual processes that are continuously improved. Each step in the process is important; however, for a plethora of industries, none may be as essential as manufacturing. There are certain factors that must be analyzed to create an efficient manufacturing process, such as cost, sustainability, and safety. However, the importance of safety and the effects it can have on the overall supply chain are often disregarded as a focal point of manufacturing.

The medical device manufacturing market generates nearly 50 billion dollars per year and is essential for the well-being of people across the globe (IBISWorld, 2023). Leaders in the industry face challenges producing these products through strict regulations and supply chain disruptions. It is important for a firm to establish standard operating procedures at plants to avoid these problems during production, as it is easy for one safety issue to disrupt a firm's entire manufacturing process moving forward.

This thesis centers around creating a standard gowning operating procedure within manufacturing plants for a major medical device manufacturer through establishing best practices specific to the industry. Site heads and sterilization experts from three different continents will be interviewed to gather data on their current practices. Redundancies and areas of potential harmonization across plants will be identified. There is a lack of research on manufacturing safety and quality assurance for firms that produce medical equipment. Hence, the goal of this thesis is to formulate a gowning harmonization plan in controlled manufacturing

environments that will improve efficiency within the overall supply chain of the company through the assurance of safety and quality during manufacturing procedures by establishing best practices. Although a single solution may not be applicable to all companies, general themes and findings can still be understood for potential improvements.

The thesis will follow the subsequent format: background, methodology, analysis, and conclusions and topics for further research. The background chapter will provide an overview of the current state and importance of the medical equipment manufacturing industry, while also defining the concepts of controlled manufacturing environments, gowning procedures, and best practices. The methodology section will describe the interview process and how data was collected to summarize current procedures at the medical device manufacturers sites. This part will also exemplify where the company is falling short on industry standards and where areas of improvement potentially lie. The analysis chapter will present a possible solution for the firm and the most important findings from the data collection stage, including results from the interviews and current state summaries of gowning procedures. The conclusion section will portray the importance of this research and how other companies adopt the key findings of this thesis to benefit their supply chains through efficient manufacturing practices that emphasize safety and quality. Lastly, the thesis will conclude with topics that can be further researched and built upon in the future.

Chapter 2

Background

Medical Device Manufacturing Importance and Challenges

The well-being of millions of people across the globe is reliant on the production of equipment and devices that aid in enhancing the quality of care, improving patient outcomes, and even saving lives. At the heart of this process are medical equipment manufacturers, who are the architects behind the development, design, production, and distribution of a massive array of tools crucial to efficient medical practices. Medical equipment manufacturers produce a wide range of different devices that all serve important purposes. For example, diagnostic equipment such as X-Ray, MRI machines, and CT scanners are made and utilized for imaging and identifying health conditions that could potentially alter people's lives permanently. Equipment is made for monitoring purposes such as glucose meters and blood pressure monitors, which are vital in tracking baselines of health. Therapeutic devices for treatments and surgeries are also manufactured in the form of infusion pumps or dialysis machines. Additionally, simple tools such as sutures, needles, syringes, or scalpels are made within the industry and are indispensable to best practices in healthcare during common procedures or even complex surgeries. To gain a better understanding of the market landscape, a breakdown of the product segmentation within the industry can be analyzed. In 2018, the most popular type of equipment manufactured were cardiovascular devices at 23.6 percent. The following were irradiation at 20.9, patient recovery and noninvasive devices at 17.8, neuromodulation and spinal devices at 11.8, and diabetes devices at 5.2. All other devices make up 20.7 percent (Nead, 2018). Manufacturers must ensure the precision and reliability of producing these many different products that can save lives and

keep people healthy, which requires an abundance of stringent standards and procedures that must be in place during manufacturing processes to maintain safety and quality within an essential industry that needs to constantly adapt.

Controlled Manufacturing Environments

Based on the type of medical equipment one is producing, there are different rules and regulations that must be followed in order to keep employees safe who are making them, maintain product quality and precision, and also to make sure it is safe for the end consumer to finally use. One of the most common measures taken at manufacturing sites to ensure this is that there needs to be specific areas within the plants designated as "Controlled Manufacturing Environments", or CMEs. A CME is an extremely regulated and monitored area within a manufacturing plant, specifically designed to maintain conditions necessary for the production of high-quality and safe medical equipment. This controlled environment takes many factors under consideration that are needed to produce the devices, such as, temperature, cleanliness, and air quality. Key components that go into ensuring these factors within CMEs are efficient cleanrooms, sterile environments, and proper employee training and attire for entering and exiting. Cleanrooms are specialized areas equipped with high-efficiency particulate air filtration systems to maintain extremely low levels of airborne particles. Based on what type of medical equipment is being produced, cleanrooms are classified into different categories based on allowable particle count, as some may need less than others. For devices requiring sterility, sterile environments are designated in the controlled manufacturing environments at sites to prevent microbial contamination. Different methods can be used to produce the sterile environment such as gamma irradiation or steam sterilization. Finally, another necessary

component of CMEs is proper employee training and attire. Strict protocols in controlled manufacturing environments regarding hygiene, how to enter and exit, and what pieces of attire need to be worn based on what is being produced will help immensely in preventing contamination from human sources and ensuring safety and quality in production.

After exploring the predominant factors that go into making a controlled manufacturing environment, it is important to understand what the purpose of CMEs are and what they help medical device manufacturers achieve. Firstly, CMEs help with quality assurance in equipment being made. They are able to reduce the risk of contamination, errors, and inconsistencies during the manufacturing process through the mitigation of outside particles by having a clean environment with strict standards. In turn, aiding in the maintenance of device purpose and integrity while also ensuring predefined standards and specifications of consumers are met. CMEs also make sure that manufacturing plants are meeting regulatory requirements that exist within the medical device industry. For example, regulatory bodies such as The Food and Drug Administration (FDA) and International Organization for Standardization (ISO)mandate specific manufacturing conditions to make sure products and the practice used to make them are safe and controlled manufacturing environments are designed to meet these conditions that are necessary for products to be approved to enter the market. Additionally, controlled manufacturing environments aid in minimizing contamination and risks that can cause health and safety concerns while manufacturing medical equipment, helping to protect both employees and consumers from contaminants that could compromise their safety. Contaminants that are limited are dust, microbes, and small particles, as even a small amount can ruin a product in the medical device industry. As a whole, it is apparent that CMEs help medical device manufacturers in

numerous avenues, but most importantly to assure quality and safety of equipment being made by limiting outside pollutants getting near products.

Gowning

Despite the abundance of benefits that stem from taking strict precautions within manufacturing plants through the formulation of designated controlled manufacturing environment areas, many firms disregard important aspects that go into efficient processes within them, leading to issues during production. One being what individuals who enter these CMEs wear in terms of gowning/attire while preparing to work on producing equipment. One of the biggest contaminators in a CME is people, hence, proper gowning of employees that work within the controlled manufacturing environments is essential and can lead to many benefits for a company's manufacturing practices along with the mitigation of issues.

In controlled manufacturing environment cleanrooms, there a several predominant types of gowning pieces worn to maintain cleanliness, adhere to quality regulations, and to prevent contamination. These main pieces are lab coats/coveralls, shoe covers/booties, face masks, hair covers, beard covers, and gloves. Each piece of gowning is selected and used at sites based on specific requirements of what type of equipment is being produced in the controlled environment and the level of cleanliness required for the manufacturing process. This level of cleanliness is generally determined by the ISO type. ISO types are requirements that explain how to implement, maintain, establish, and continually improve quality management systems depending on what type of product you are manufacturing. Cleanroom ISO classification can be validated by particle measurements with a benchtop or handheld particle counter. The cleanest classification is ISO 3, which is an environment that contains 1 particle per cubic foot. Lower

ISO classifications such as ISO 4 or 5, have a higher level of cleanliness required than ISO classification 3. The least rigorous classification is ISO 8, which is an atmosphere containing 10,000 particles per cubic foot. Consequently, each classification has a set of requirements that must be followed, including proper gowning attire within controlled manufacturing environments, as improper gowning procedures are the most common source of cleanroom contamination (TerraUniversal, 2022).

These requirements then need to be communicated to employees effectively through a common procedure. The gowning procedure in a cleanroom is a detailed process designed to ensure that individuals entering the controlled environment are properly attired with step-by-step instructions on how to do so. Hence, firms in the medical device manufacturing industry need to spend time meticulously crafting a standard operating procedure at their sites in order to avoid serious consequences for both their company and consumers that could stem from inefficient protocols and communication techniques. Humans carry an astonishing billions of microscopic particles that can easily be shed by their hair, skin, or clothing. Hence, procedures that include unsuitable attire or missed steps in the gowning process will lead to contamination and cleanroom shutdowns rapidly.

Best Practices

Establishing a suitable and harmonized cleanroom gowning procedure within a medical device manufacturing site's-controlled manufacturing environment is crucial to maintaining the integrity of products and ensuring the safety of customers and employees at a firm. Therefore, it is important to find and establish the accepted best practices for gowning in CMEs, so that procedures can be modeled after it for the medical device manufacturing industry specifically.

Best practices are commonly accepted strategies within a specific industry that companies model their processes after. These guidelines will aid a business in formulating an operating framework and influence their decision making. No matter what these practices exemplify, procedures need to be harmonized and communicated to all employees and affected stakeholders. Without harmonized procedures across a firm and efficient communication processes will be inefficient and subpar to industry standards, along with employees being confused on how to correctly operate. Every individual company will have their own unique best practices for gowning procedures in CMEs, but general recommendations can be given to other firms based on the best practices that will be established for the medical device manufacturing industry.

Chapter 3

Methodology

Company Background

The company at the center of this research will remain anonymous for confidentiality reasons. For this thesis, they will be referred to as Company A. Company A is a major player in the medical device manufacturing industry and is a subsidiary of a Fortune 500 firm. They are headquartered in The United States but own fourteen manufacturing plants for developing their products across the globe. Company A has a vertically integrated supply chain with unique practices at each of their owned sites.

Project Scope

Company A is currently striving to analyze their processes for gowning individuals within controlled manufacturing environments in order to improve both safety and quality during manufacturing. Constant miscommunications, stakeholders being on different pages, and ambiguity in procedures due to unique practices at each site have prompted Company A to seek solutions as a precautionary measure before they are negatively impacted. The goal of this project is to collect data from key stakeholders through a structured interview process and to formulate a summary of current procedures from internal documents in order to recommend best practices for gowning in their controlled manufacturing environments to make manufacturing more efficient and reduce risks through efficient gowning procedures across all their sites. Then, the impact of a harmonized plan will be captured, specifically on how the alterations of current practices can change safety, quality, and potentially costs. As a whole, Company A is striving to

formulate the most efficient processes for gowning attire and procedures in CMEs in order to benefit the company, employees, and end consumers through a harmonized plan that does not exist currently.

The project's initial step is to request documents from sites that mapped out what current procedures look like for gowning individuals in controlled manufacturing environments within Company A's plants. This was completed by reaching out to site heads and explaining the project scope and how the data will aid in the process. Then, these procedures will be summarized to analyze how they can be improved and altered to establish best practices in the industry in order to ensure safety and quality. Areas where Company A is falling behind on industry standards will also be noted as avenues of potential improvement. For documents requested from sites where the predominate language is not English, translations will be done through Google Translate. Then, after mapping out the current state through these summaries, interviews can be conducted in order to gain an understanding of why these procedures exist and how they can be changed in order to benefit Company A based on the goals and vision moving forward of those affected by these procedures daily.

The ensuing list is a breakdown of the different roles held by the interview subjects who were asked questions regarding the project:

- Site Quality Head from North America
- Site Quality Head from Latin America
- Site Quality Head from Europe
- Site Quality Head from Asia
- Platform Lead Sterilization
- Global Supply Chain Quality Manager

The interviews with the subject listed lasted about thirty minutes each. The diverse viewpoints by site location and experiences allowed an abundance of information to be collected. All of these interviewees were asked the same standard set of questions, which were split into three main categories as follows:

I. Introduction

- What is your job title and primary role at the site?
- Where is your site located and what is produced?
- How many people work at this site?

II. Current State Facts and Reasoning

- What are the current procedures for gowning in controlled manufacturing environments step by step?
- What is each gowning piece of equipment that needs to be worn by an individual in controlled manufacturing environments?
- How long have these procedures been in place and how often are they changed?
- What is the ISO type in the controlled manufacturing environments?
- What are the different areas in the plant dedicated to putting on gowning equipment?
- What are the regulations, preferences, or product requirements that affected your procedures and equipment worn?
- Are there any requirements solely required at your site or for the products your site produces?

- Have there been any production quality issues that stem from gowning procedures?
- Have there been any health concerns or employee safety issues due to gowning procedures?

III. Moving Forward

- Do you believe current procedures need to be altered in any way for improvement, if yes, what are the benefits of these changes?
- Do you or your employees at the site have any specific goals or desires for gowning procedures moving forward or changes you wish would occur?
- In what ways do you think a harmonized gowning procedure would be beneficial and how would you recommend steps forward to achieve this?

These questions were created with the advice provided from one of Company A's site heads that believes gowning procedures need to be improved due to a lack of harmonization currently. These questions will help with succeeding on the project scope goals as well as to provide valuable insight on how to improve Company A's current CME gowning procedures. The introduction questions serve to give an understanding of who is being interviewed and what types of products are manufactured at their plant because it is important to know where and what equipment are being made in order to formulate specific procedures that may be required for certain devices. The main purpose of the questions within the current state facts and reasoning section is to understand why current procedures exist, if it is important to change current practices based on their experiences working directly at the site, and to understand any issues that may have occurred in the past due to gowning operations. Additionally, hearing the procedures directly from an individual that works at the plant will also reveal the process in

greater detail than what is found solely in the procedure summary documents and give this research the time to ask specific questions for each step. The final section of questions will provide an understanding of if leaders and individuals working at Company A believe a harmonized plan is desired and what benefits will come from it. Also, these questions will reveal any other changes or goals desired that can be implemented in current procedures so that best practices can be established for creating the harmonized plan.

There also are additional questions that naturally become brought up during the interviews based on responses received. These answers will also be noted and stored for future reference if they reveal to be important to the research project. All interviews will have notes taken during them which will be analyzed thoroughly alongside the procedure summaries for the analysis stage to provide a final recommendation of best practices for a harmonized gowning procedure. Common trends, themes, and goals will be revealed from the responses during the interview stage which will also aid in developing the final recommendation for Company A. They key pain points in current procedures will also be revealed from each stakeholder interviewed, which will aid in formulating a procedure that is applicable across all sites for Company A.

The final analysis stage will include conducting additional research using reliable articles and internet sources to gain a better understanding of efficient gowning procedure concepts that can be applied to the final recommendation for Company A, by learning from best practices that can be applied across the industry. The combination of current state procedure summaries that come directly from each global site, in-depth interviews with key stakeholders, and external research will provide the knowledge necessary to formulate an improved gowning operating

procedure for Company A's manufacturing site CMEs. This improved gowning procedure will also be harmonized and standardized to meet the requirements and needs of all individual sites.

Chapter 4

Analysis

Results

Once the documents of gowning procedures were collected from each site and interviews concluded, data could be analyzed to get a strong understanding of current gowning process issues. Additionally, themes for how Company A could improve their procedures for gowning emerged. Company A has fourteen manufacturing sites for their medical device products that span across North America, Europe, and Asia. Each site has a unique gowning process for their controlled manufacturing environments, but all were found to be following regulatory and product requirements efficiently. The products produced at each site varies, which contributes to the differences in gowning due to unique requirements of each product. The differences were found in several areas. The main being types of gowning equipment used, the order of steps in the procedure, and the rooms at each site dedicated to putting on the gowning equipment. The products Company A produced are sutures, staples, skin adhesives, skin closure systems, surgical cutters, and ligatures. This lack of standardization identified during the procedure summaries for gowning processes revealed key issues that were discovered during the interviews. On key issue found is that there is a lack of communication between plants. Employees and key stakeholders such as suppliers constantly travel between plants and every time, they are hit with a new gowning procedure they have to follow, which causes confusion as they are unaware of what the correct procedures are at the foreign site. This is dangerous because following procedures incorrectly and having to learn on the spot with brief training can result in contamination or particle infiltration. Also, there is no transparency or communication between plants on the topic

of gowning procedures and it was revealed that sites do not even have access to procedures from other manufacturing plants, making them unable to learn from each other's best practices or be prepared for site visits. Additionally, issues exist during audits of procedures from regulatory agencies. Individual audits, which are time consuming and can be stressful to the firm, have to be completed at each individual plant instead of just at one due to the lack of procedural harmonization. Hence, if changes are required, they will have to be implemented carefully at each individual plant due to their unique practices instead of efficiently all at once. Another issue is that there is an abundance of suppliers for gowning pieces because each site has different gowning equipment in terms of what is worn and materials of the pieces. With a diverse supplier base that sites order from in small amounts the unit costs of gowning equipment rise as economies of scale cannot be leveraged by ordering in bulk. Lastly, a common problem found among the plants is with the speed of the gowning procedures. The steps currently are time consuming and lots of the plants do not house enough space to accommodate the employees to move through the gowning process in an efficient manner. The comments summarized here are just a portion of the information collected but outline the main themes Company A is facing problems with. The commonalities in issues found between the procedure summaries and interviewees led to the following recommendations being developed.

Improving Communication

To address the issue of a lack of communication of procedural information between manufacturing sites, communication channels were developed for Company A. A Microsoft Team's Page was made as a central communication point. This page included gowning procedural documents from each site, summaries developed of procedures at each site, and a message board

to exchange ideas and information. The page is accessible by all quality heads at each site, and they are able to open up accessibility to the page for any stakeholders they would like such as employees, suppliers, or auditors. Hence, for the first time, Company A had a communication channel solely dedicated to gowning procedures. There are many benefits that will stem from this improvement in communication. One of the key findings from the interview process was that there needs to be more informational visible from other sites so that best practices and strategies that are working at another location can be learned from and implemented. The procedure summary documents can also be utilized to quickly learn how gowning pieces differ at each site. The communication channel will also be beneficial as it can serve as a place to discuss changes in procedures from audits. When a procedural inefficiency is found during an audit at one site, it can then immediately be communicated to other global location within the message board. Hence, giving site leaders time to adjust their practices beforehand. Another advantage is that if a site leader or employee needs to visit another site, they can look at the procedure documents within the Team's page and be prepared far before they even arrive in terms of how to be efficiently gowned. This will minimize any risk of contamination or particle infiltration from people that are unfamiliar with the intricacies of foreign gowning procedures. This communication channel will overall aid in mending many issues identified with current gowning procedures, but there were still other problems that existed that could be addressed to improve current procedures at Company A.

Harmonization Strategy

The main issue discovered during the interview process was that there is a lack of harmonization in gowning procedures with control manufacturing environments across the

global sites. The reasoning was that the lack of standardization causes issues with confusion od protocols during visits, raises unit costs from suppliers, the process takes too long at certain sites, and makes the audit process inefficient. A standard gowning procedure can also alleviate other issues and cause efficiencies across additional areas. For example, ensuring a standard of safety and quality during manufacturing and reducing the most common source of contamination, people. Additionally, it was revealed from multiple site quality heads during the interview process that there have been contamination issues with hair in the past. Hence, plants need to decide on an efficient manner to fix this issue while also maintaining regulatory compliance. These issues and potential areas for improvement can be addressed by developing a standard gowning procedure that is harmonized across all global sites. Therefore, a gowning procedure was made that combines the most efficient practices from sites operated by Company A in terms of gowning pieces worn and equipment used in the changing rooms. Each step chosen and piece of equipment worn has been efficient in terms of both safety and quality assurance as communicated by site quality leaders at Company A. The best practice plan will also strive to improve the speed of the gowning process and to be implemented at all global sites in order to gain the ability of utilizing a common supplier of equipment worn to reduce costs. The recommended harmonized gowning process is as follows:

Step 1) Prior to entering the CME changing rooms all outer clothing must be removed.

Step 2) Enter changing room and step on tacky mat to remove shoe contamination.

Step 3) Put on disposable mask and ensure that it covers both the mouth and nose.

Step 4) Put on disposable hairnet and make sure all hair is under the net. Additionally, put on beard cover if applicable and make sure all hair is covered underneath.

Step 5) Put disposable shoe covers over outer shoes and ensure entire sole is covered.

Step 6) Wash and dry hands before continuing to reduce any further external contaminants.

Step 7) Put on reusable lab coat and make sure all parts of your body are covered by the garment.

Step 8) Put on disposable gloves and make sure no skin is exposed between the lab coat and gloves.

Step 9) Gowning process is now finished, and employees can exit into the controlled manufacturing environment.

In addition to the best practice plan above that list out each piece of gowning equipment worn and order of the steps, there are suggested additional requirements to be standardized across all sites. To prevent outer clothing from becoming a contaminant which was a problem revealed during the interviews, certain clothes will be restricted. The clothing items chosen are velvet, suede, fur, fringes, torn fabrics, or pompoms. These specific articles or clothing have a greater risk of materials being exposed with the gowning equipment chosen or can even have pieces fall off while working in the CME, hence they will not be allowed. Additionally, no open toed shoes are allowed as it can cause safety risks for employees. There are also other specific types of outer shoes that cannot be worn due to best practices in the medical device manufacturing industry, as communicated during the interview process. These types are high heels, polished leather, synthetic mesh, shoes with mesh, shoes with embordering, and shoes

with glitter. None of these will be allowed in this harmonized process. Additionally, best practice requirements were made for more specific employee conduct prior to entering the gowning areas. Employees will be prohibited from wearing makeup, nail polish, artificial eyelashes, and jewelry. This is a further measure to ensure quality and safety during production. As a whole, this harmonized gowning process will improve Company A's manufacturing practices in many ways. Confusion during site visits will be mitigated, common suppliers can be found to reduce unit costs due to the commonality in equipment, and the speed and efficiency of the process is ensured due to proven steps from existing and successful procedures from other sites have been chosen.

Next Steps

Now, it is up to leadership at Company A to effectively execute and implement the recommendations provided through this thesis project. Also, it is essential to note that the suggestions developed are specific to the needs of Company A and should not be directly applied to other companies within the medical device manufacturing industry. This project will serve as a catalyst for quality leaders at Company A to enact positive changes in the gowning process for controlled manufacturing environments. Company A also needs to decide whether they will move forward to implement the harmonized gowning procedure. Based on data collected from both the procedure summaries and interviews the best practice gowning plan made along with the formation of key communication channels dedicated exclusively to gowning procedures can be utilized as avenues to further improve safety, quality, and efficiency in the manufacturing process if they are chosen to be utilized. Continued monitoring of procedures and gowning processes will be required for Company A to remain a leader in the medical device

manufacturing industry. Additionally, constant improvements are necessary to stay competitive in this dynamic industry.

Chapter 5

Conclusions

Completing an open ended project like a thesis is a challenge that takes both time and thorough analysis. To improve their current gowning procedures and processes, Company A will have to make changes to their existing practices, which is never an easy task due to all the stakeholders affected. Focusing on improving communication and implementing best practices in the manufacturing steps of production will lead to positive results and companies should focus on making these changes. When thinking about best practices in the medical device manufacturing industry, there is never just one sole solution. Gowning procedures specifically are tailored to the custom needs of an individual corporations manufacturing needs and best practices will vary by scenario. Due to minimal research and findings in this space, companies are left experiment and try out methods that work for them while also looking to constantly adapt to challenges. Like this thesis did with Company A, businesses need to listen to employees and key stakeholders on where issues lie and address them immediately to cause change. Companies must enact changes that improve efficiency, safety, and quality continuously to maintain operational efficiency and to survive in sectors of high competition.

Topics For Further Research

This case study can be replicated on other firms within the medical device manufacturing industry and results can be compared. Comparisons can be made for the strategy of harmonization of gowning procedures and the actual step by step process that ends up being formed. With minimal research in the space currently, it is hard to find how gowning procedures within controlled manufacturing environments in the medical device manufacturing industry

differ between firms, and how these differences affect both safety and quality within a manufacturing site. Additionally, the research can be extended for steps after a harmonized gowning procedure is implemented. Data can be collected on how long it takes to gown after the changes, how the per unit cost of equipment is affected, and how much contamination is limited due to the change. Also, it would be beneficial to see if a harmonized plan results in a consolidated supplier base and the potential monetary benefits of it. Hence, it is clear the opportunities to build upon this project are plentiful and can provide many tangible benefits for firms within the medical device manufacturing industry.

BIBLIOGRAPHY

14:00-17:00. (n.d.). *ISO 9001:2015*. ISO. Retrieved March 22, 2024, from https://www.iso.org/standard/62085.html#:~:text=Its%20requirements%20define%20how%20to

Amazon.com : Disposable Caps Hair Nets, Salon Spa Food Service 100 Pack 21" White : Beauty & Personal Care. (n.d.). Www.amazon.com. Retrieved March 22, 2024, from https://www.amazon.com/Lifesoft-Disposable-Treatments-Individually-Wrapped/dp/B07PSFDT6W

IBISWorld - Industry Market Research, Reports, and Statistics. (2019). Ibisworld.com. https://www.ibisworld.com/united-states/market-research-reports/medical-device-manufacturing-industry/

McKesson Disposable Bouffant Surgical Caps at HealthyKin.com. (n.d.). Www.healthykin.com. Retrieved March 22, 2024, from https://www.healthykin.com//p-3703-mckesson-disposable-bouffant-surgical-caps.aspx?gad_source=1&gclid=CjwKCAiA6KWvBhAREiwAFPZM7suF2t-1DulrCavxOuXYbgddupt9qRZVpz7ljAOTZ6G2KcwaH9Ad2BoCseMQAvD_BwE

Medzell. (n.d.). *Disposable Beard Cover*. Medzell. Retrieved March 22, 2024, from https://www.medzell.net/product/disposable-beard-cover-masks-and-related-kits/

Nead, N. (n.d.). *Medical device manufacturing: Best practices, applications and regulations*. Protolabs Network. Retrieved March 22, 2024, from https://www.hubs.com/knowledge-base/medical-device-manufacturing/#best-practices

Reusable Cleanroom ESD Safe Lab Coats. (n.d.). Elimstat.com. Retrieved March 22, 2024, from https://elimstat.com/products/cleanroom-esd-safe-lab-coats/

STRONG Nitrile Exam Gloves - 200 Per Box - Powder Free. (n.d.). STRONG Manufacturers. Retrieved March 22, 2024, from https://strongmanufacturers.com/products/strong-medical-nitrile-exam-gloves-powder-free

The Business Case for Medical Device Quality. (2013). https://www.mckinsey.com/~/media/mckinsey/dotcom/client_service/public%20sector/regulatory%20excellence/the_business_case_for_medical_device_quality.ashx

U.S. Medical Device Manufacturers Market | Industry Report, 2019-2025. (2019). Grandviewresearch.com. https://www.grandviewresearch.com/industry-analysis/us-medical-device-manufacturers-market