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FDA Regulation Impact on Early Stage Medical Device Innovation in Academia

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FDA REGULATION IMPACT ON EARLY STAGE MEDICAL DEVICE INNOVATION IN ACADEMIA

By

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Abstract

The commercialization of medical products at the university level is a multilayered and challenging process. One barrier to commercialization is the difficulty of meeting Food and Drug Administration (FDA) regulatory requirements. Regulations and standards are undoubtedly necessary to maintain the highest product safety levels, but it creates many obstacles. This paper will analyze how researchers involved with early-stage medical device innovation in a university setting deal with FDA compliance issues and the implications of this engagement for innovation. I conducted an exploratory case study of ten medical product development projects at the Rochester Institute of Technology (RIT). Overall, I found that FDA approval pathways were challenging for project participants to navigate without proper resources; approximately half of the projects indicated a lack of confidence in their knowledge of and/or progress towards meeting FDA requirements based on the resources available. I offer several suggestions regarding how RIT and other universities can reduce barriers to innovation caused by FDA regulation through actions, both internal and external to the university.

Chapter I: Introduction

Introduction

Universities often foster the creation of medical devices through their support of research and new ideas. Research centers and labs can support innovation, test theories, and devices without the market pressures that medical device companies experience. Medical technology is advancing quickly, as seen in the ever-growing healthcare market. Luckily, medical research in universities can pursue ideas and theories that may have a low chance of success. Their ability to take risks without the possibility of failure has allowed groundbreaking discoveries. When a medical product is created or discovered that the researcher believes is worth pursuing commercially, it moves forward for further testing, approval, and commercialization. Thus, it is essential for any life-changing medical product created in the university setting to have adequate commercialization compliance support. Without the proper permission, documentation, and resources, a life-saving technology may not reach the people that need it.

A medical device falls into a category of products that is overseen by the government. The department known for oversight within the government is the Food and Drug Administration (FDA). They are responsible for the approval processes that allow medical products to be on the market. Once a product is developed enough to be considered for FDA approval, the creator or university decides whether to pursue it. The decision to pursue commercialization and approval may seem like an easy decision; however, literature and research shows that the approval process at this level can be challenging, expensive, and hard to navigate (Gulbranson & Audretsch, 2008).

Commercializing a medical device requires compliance with FDA regulations, which is challenging to obtain and requires knowledge of the processes involved, as well as financial

resources. Most recommendations for improvement to universities to help with this process include changes to organizational structure or funding. As will be discussed in the literature review, few papers offer any specific advice relating to regulatory compliance or any case studies of successful models for overcoming university innovators' regulatory barriers.

Thus, the goal of this thesis is to take a more in-depth look at how FDA regulations impact early-stage medical device innovation projects at the university level. To do this, I performed exploratory case studies of medical products in different stages of development at one university. The interview questions targeted multiple aspects of their experience, such as regulatory and compliance resources, barriers to innovation, and the university's impact on project success. After presenting my findings and analysis, I discuss the implications of this research for university policy, FDA policy, and future research.

Chapter II: Background of FDA and Definitions

Medical device innovation is a critical component in the growing field of medicine and comprehensive care. Under the guidance of the Food and Drug Administration (FDA), the definition of a medical device is (O. O. Affairs, 2018)

> "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part or accessory which is: recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them, intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes."

Under this definition, there are many different types of medical devices, with varying degrees of intrusiveness or potential for harm. For example, a tongue depressor and a pacemaker are both considered medical devices, although one is less dangerous than the other. The variance in danger calls for a different level of regulation.

Device classifications are a way to categorize medical devices based on their risks and the regulatory controls necessary to provide a reasonable assurance of safety and effectiveness. (Center for Devices and Radiological Health. (2017)). Figure 1 shows the differences between Class I, II, and III devices. The examples of products range in simplicity and class based on the risk. The regulatory pathways are different based on the product's class, as described in the chart below.

Class	Risk	Examples	Safety / Effectiveness Controls	Regulatory Pathway
I	Low	Tongue depressor, hospital beds	**General Controls** - With Exemption - Without Exemption	**Self Registration** Or **510(k)**
II	Medium	Absorbable suture, blood pressure cuffs	**General controls** - With Exemption - Without Exemption **Special controls** - With Exemption - Without Exemption	• Most class II devices are approved under a **510(k)** pre-market notification submission. • Few devices of class II are approve under **PMA** • 10-15% devices require **clinical trial**
III	Highest	Implantable pacemaker, coronary stent	**General controls** **Special controls** **Pre-market authorization**	**Pre-market approval (PMA)** Almost all require clinical Data

Figure 1: Types of device classifications and the differences between them (Geete, 2016).

Below are definitions of several terms that I use in this thesis. These terms explain the FDA, different approval pathways, and the difference between a medical device and equipment.

Definitions

510(k)- is a premarket submission made to the FDA to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent, to a legally marketed device (section 513(i)(1)(A) FD&C Act) that is not subject to premarket approval.
(510(k) Premarket Notification, n.d.)

Equipment: Medical devices requiring calibration, maintenance, repair, user training, and decommissioning – activities usually managed by clinical engineers. Medical equipment is used for the specific purposes of diagnosis and treatment of disease or rehabilitation following disease or injury; it can be used either alone or in combination with any accessory, consumable or other piece of medical equipment. Medical equipment excludes implantable, disposable, or single-use medical devices. (Medical Device – Full Definition, 2018)

FDA (Food and Drug Administration)- The Food and Drug Administration is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation. (O. O. Commissioner, 2018)

Medical device: article, instrument, apparatus, or machine that is used in the prevention, diagnosis, or treatment of illness or disease, or for detecting, measuring, restoring, correcting, or modifying the structure or function of the body for some health purpose. Typically, the purpose of a medical device is not achieved by pharmacological, immunological, or metabolic means. (Medical Device – Full Definition, 2018)

Predicate Device-A predicate device is a medical device that may be legally marketed in the U.S. and used as a point of comparison for new medical devices seeking approval through FDA's 510(K) premarket clearance pathway. The new device must be proven to be substantially equivalent in safety and efficacy to the predicate device in order to receive clearance. (Predicate Device: Greenlight Guru, (n.d.)).

Pre-market Approval - is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices. Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury.
(Premarket Approval (PMA), 2020)

Translational Research- the process of applying knowledge from basic biology and clinical trials to techniques and tools that address critical medical needs.
(What is Translational Research?, 2017)

Chapter III: Literature Review

The Food & Drug Administration (FDA) recently published a document that states the main objective of regulatory entities is "helping to ensure that innovation in product development continues, so that patients can get groundbreaking medical products while at the same time ensuring patient safety and that harmful medical devices do not reach the market (O.O. Commissioner, 2018)." However, a *Harvard Business Review* article (Minguillo & Thelwall, 2014) describe current innovation in healthcare as "unsuccessful." They discuss six forces that affect the success or failure of innovation: players, funding, policy, technology, customers, and accountability. It may not be that all of these are equally important in a university setting. In the following sections, I will thus focus on reviewing the literature on regulatory compliance and commercialization in universities in particular.

Commercialization in Universities

The costs associated with regulatory compliance are two of the most considerable burdens on innovation. As stated by Herzlinger (2006), "One problem is the long investment time needed for new drugs or therapies that require FDA approval. While venture capitalists backing an IT start-up may be able to get their money out in two to three years, investors in a biotech firm have to wait ten years even to find out whether a product will be approved for use." Innovation in universities is similarly challenged, and the difficulty of bringing a product to market is a risk that must be weighed. Unlike private firms, however, a university's number one goal is to research and explore new ideas, which may not include commercialization. If they are using resources to prepare something for commercialization, it must show promise; even if there

is a promise of success, however, the risk of failure may prevent the pursuit of commercialization.

Despite the risks of commercialization, there has been a steady increase in the desire for commercial outcomes from university research since the early 2000s (Ambos et al., 2008). While this increased push for the commercialization of new technology may bring increased risks, a healthy support system at a university can reduce this risk and help universities claim the benefits of commercialization, such as income and increased reputation.

The promise of income and increased reputation has driven support for more commercialization of technical innovation at universities (Ambos et al., 2008). Policymakers also support this trend for more innovation because it increases competitiveness in the market. They often have specific initiatives and incentives to encourage more universities to participate in medical device innovation (Ambos et al., 2008). However, while it is mutually beneficial to commercialize university research, it is not always easy. One issue is that different stakeholders involved in innovation may have different motives. For example, universities have education and research as the primary motivation, while players in the market have patient care, competitiveness, and profit as their motivations (Marantz et al., 2010). In addition, poor knowledge management, cultural differences, and bureaucratic struggles can hamper commercialization efforts (Siegel et al., 2003). Pober et al. (2001) argue that contributing to the low rate of commercialization, or translation, from universities is the fact that process can vary from case to case and, as a result, is not straightforward or consistent. Also, the authors recognize the need for continued research and collaboration, even following the commercialization of technology. This type of continued support is a burden that universities cannot bear (Pober et al., 2001).

There is some evidence that universities can overcome these challenges and see success in commercialization. There are many reasons for this, but most experts agree that it takes additional structures at the university level to achieve smooth commercialization. An example of this is the University of Michigan. They have attempted to create a model for this through their partnership with the Wallace H. Coulter Foundation (Pienta, 2010). This partnership resulted in a center that helps build structures and change the university culture to better support collaboration between the university faculty and professionals in the medical field. As explained on the Coulter Translational Research Partnership Program website, the center is described as follows (About the Program, 2016):

> The U-M Coulter Translational Research Partnership Program is a commercialization fund that seeks to accelerate the development of university technologies into new products to improve health care. The program funds 5-7 projects per year for an average of over $100,000 each. Each project must involve a collaboration between UM faculty from any college of engineering department and a practicing clinician from a clinical department. Each project aims to generate a new medical device, surgical tool, diagnostic assay or other biomedical tool and is mentored by a team of industry experts to guide projects to the point of start-up, partnering with industry, and/or follow-on funding.

Minguillo and Thelwall (2014) found that these new infrastructures appear to have the most success in having positive interactions between universities and the market. Another type of enabling structure is a proof-of-concept center. University researchers struggle to obtain funding during the early stages, and a proof-of-concept center bridges that gap by providing researchers with appropriate funding (Gulbranson & Audretsch, 2008). With that said, creating these new structures takes a certain amount of time, resources, and effort that many universities simply cannot afford.

Regulatory Compliance

The overall success of the product can not be achieved without compliance with the FDA and other regulatory bodies. Compliance with the FDA is challenging and requires both knowledge of the regulatory process and a high amount of resources. This leads to more commercialization success at the large company level than the university level (Schwartz & Macomber, 2017). As just discussed, most recommendations of improvement to universities include changes to organizational structure and/or funding. Noticeably absent from the literature, however, was any mention of specific recommendations relating to assistance with regulations or the compliance of devices.

Medical devices vary significantly in their use, risk, complexity, and other characteristics. Understanding how individuals at universities handle the burden of compliance for such a range of products should be researched and understood. It was surprisingly difficult to find information detailing success case studies or a model for overcoming regulatory body barriers for university innovators. Throughout the literature review, there were examples of successful medical innovations, yet not nearly enough recommendations for becoming successful in the stages where compliance is necessary.

Thus, while the literature discusses how universities have found success in medical device innovative efforts through culture change, increased funding, and new structures, it is unclear how these universities have achieved regulatory compliance success. It is evident that a university must show a genuine interest in growing the success of innovation in order to grow their program. However, what they need to do to provide support for regulatory compliance remains unclear. The potential of university medical research could be endless, but the lack of understanding in compliance processes is holding back many institutions. Therefore, the gap of

information found in this literature review shows that universities need a greater understanding of the regulatory barriers to commercializing their medical device innovations.

Research Question:

The literature review addresses commercialization in universities and regulatory compliance. As shown in the literature review, commercialization is an increasingly common goal for university-based medical device innovation. The literature review shows a large gap in our knowledge of how regulatory compliance impacts medical device innovation at the university level and how universities can help with respect to compliance issues. Thus, in this thesis, I ask: *How does FDA regulation impact early-stage medical device innovation projects at the university level?* In particular, three specific sub-questions are looked at:

1. What sources of information did the project use to learn about compliance standards for FDA regulations?
2. What barriers to innovation have the project owners faced with regard to regulatory compliance and how did they overcome these barriers?
3. How do the information sources and barriers impact the product design and ultimate project success?

Chapter IV: Methodology

Data Collection

Access was a deciding factor in choosing to focus on the RIT population's medical products and research. It would have been challenging to contact other universities to access their staff, students, and research while keeping anonymity. Remaining within RIT gave a more focused study and decreased the possibility of delays or issues. Also, RIT is an exciting institution to analyze because it is very active in medical innovation. Still, it does not have an associated medical school to conduct trials at or implement the innovation.

Snowball sampling was the method used to recruit possible products (Johnson, 2014). I reached out to past and present department heads in the Kate Gleason School of Engineering to create a list of potential research contacts. The potential products needed to meet specific requirements to participate in the study. The products needed to be created on the Rochester Institute of Technology campus, be classified as a medical product and be recognized by RIT as a university project. The products were chosen to represent a wide range of innovation types. Once the devices were selected, the contacts received an email asking for participation in the study; all contacts responded and agreed to participate.

After connecting with all contacts, selecting ten medical device projects ranging from beginning stages to commercialization took place. All products and subjects remain confidential to keep any intellectual property concerns to a minimum. Due to the COVID-19 lockdown and quarantine, the interviews could not be held in person and instead were on ZOOM during the Spring and Summer of 2020. All of the meetings were recorded and placed in a private drive with the interviewees' consent. The meetings were transcribed word by word to allow for direct quote use.

After gathering information about each project, I created tables to assign a coded number and compare their basic details such as device class, owner, and function. Doing so kept the anonymity of the products while also keeping the product list consistent. After the general product details were analyzed, I created tables that contained more specific information to compare the resources used for compliance and regulatory data. The resources varied based on the type of product. The transcripts were analyzed to pull out direct quotes of the barriers faced by project owners. The most prevalent barriers described in the transcripts were examined and further analyzed. Lastly, the impact of university policy and regulation was analyzed for the specific project types and explained further.

Due to the patterns seen across the projects, I decided to split the data and tables apart into three sections. The three sections are labeled *Sponsored Projects*, *Research Projects*, and *Individual Projects*, to be defined later. After dividing the sections and splitting the tables, I also created three subheadings for each section. The three subheadings for each product are labeled as *Information Resources, Primary Barriers Encountered,* and *Impacts* to organize the findings.

Chapter IV: Analysis of Data

Overview of Projects

Table 1 shows the ten products chosen for the thesis. For anonymity, the products received a corresponding number used throughout the analysis and a basic description. The basic description is an indication of the complexity and risk of the product. For example, an implantable device is riskier than a modeling device. The risks described in the class column correlate with the basic description and can aid in understanding the product. The goal of the project states the end result the owner intends to reach. Commercialization means the project was intended to be commercialized from conception. Research with intent to market means the owner's primary goal is basic research but is willing to commercialize with a successful product. Lastly, basic research means there is no intent to commercialize the product.

Table 1: Description of the type of product, product FDA class, and the goal of the product project. See definition sections for explanation of the categories.

Product	Type of Product	Class	Basic Description	Goal of Project
1	Device	I	External health monitoring system	Commercialization
2	Device	III	Implantable device	Research with intent to market
3	Equipment	I	Assistive equipment	Commercialization
4	Equipment	I	Modeling device	Basic research
5	Device	I	Assistive equipment	Commercialization
6	Equipment	I	Biological prototyping device	Commercialization
7	Device	I or II	Investigative Autonomical Tool Used During Physical Exams	Commercialization
8	Device	III	Technological Advancement for Assistive Devices	Basic research
9	Device	III	Life-Sustaining Internal Device	Research with intent to market
10	Device	I or II	Personal Protective Gear	Commercialization

At least half of the products are Class I products, the lowest risk class, while three of the products were Class III. I also classified the projects as being focused on either devices or equipment to give the reader a better understanding of their function. A device is used in the prevention, diagnosis, or treatment of illness or disease or for detecting, measuring, restoring, correcting, or modifying the structure or function of the body for some health purpose. In contrast, equipment is used for activities usually managed by clinical engineers. Medical equipment is used for the specific purposes of diagnosis and treatment of disease or rehabilitation following disease or injury (*Medical Device – Full Definition*, 2018). Out of the ten products, seven are classified as devices, while the other three are equipment.

As seen in Table 2, the product's origin is an indicator of the type of support it has from the university. A *research product* originates in a research lab. The university, along with external research grants, financially supports the project and RIT staff are the project leaders. *Sponsored Projects* originate from clients internal or external to the university and are run by students; while the university does not fund them, students can use available resources at RIT. Participants in Research and Sponsored Projects would acknowledge the role the university played in the case of a successful product. Lastly, *Individual Projects* are those recognized by RIT but do not use RIT funds and would not recognize RIT as a stakeholder of the project. The findings in Table 1 and 2 show that all Class I, or the lowest risk projects, fell under Sponsored Projects and were run by students, while three out of the four Research Projects were Class III. Three of the Research Projects were done in collaboration with external companies.

Table 2: Range of products chosen based on origin, collaborator, and project owner.

Product	Origin	Collaborator	Project Owner
1	Research Project	Company	Staff
2	Research Project	Company	Staff
3	Sponsored Project	N/A	Student
4	Sponsored Project	N/A	Student
5	Sponsored Project	N/A	Student
6	Sponsored Project	N/A	Student
7	Sponsored Project	N/A	Student
8	Research Project	N/A	Staff
9	Research Project	Company	Staff
10	Individual Project	N/A	Student

Research Projects

As stated earlier, the research products exist in a research lab and run by RIT staff. All products in this section are devices that are used directly by medical staff (i.e., pacemakers, artificial hips) rather than equipment that is often managed by engineers (i.e., patient monitors). This section will look at the resources for compliance, barriers experienced by project owners, and the impact of these resources and barriers on ultimate product design and project success.

Information Resources

The design process for a typical medical product begins with an idea and ends with commercialization. To create a successful medical product, each stage of innovation relies on knowledge gained from various resources. Without knowing the proper design and safety requirements, a medical device can not reach the market and be successful. Based on its device class, each product needs to meet different design and testing criteria for the chosen FDA pathway. The impact of good or bad information sources can affect the outcome of the ability of a product to comply with regulatory requirements, as well as choices in the design itself. Low-

quality information is more likely to harm the product, while a high-quality source will help the product advance through the innovation process. Common compliance information needs include device classifications, approval pathways, design criteria, necessary documentation, and testing requirements documents.

Table 3 details the resources used to gather information on regulatory standards in the Research Projects. Six primary sources provided the information on FDA guidelines for products. These sources are design standards (such as ISO, IEEE), expert consults, other established companies, customers, a general internet search, and looking at existing technology. A consistent theme in the interviews was how information about regulatory requirements for a specific product was difficult to come by. Across the ten devices, most researchers obtained their knowledge through different sources.

Table 3: Resources used to gather the FDA process and design criteria for research products.

Product	Origin of Support	Design Standards	Expert Consult	Company	Customer	Internet	Existing Technology
1	RIT/ Company	X	X	X			
2	NIH/RIT/ Company		X	X	X		
8	Company/ NIH/RIT			X			X
9	RIT		X			X	X

All four of the Research Projects, headed by RIT staff, were able to connect with experts or have a relationship with companies. A range of other resources was used as well, although not the same extent as experts and companies. Having information sources backed by experienced companies and institutions outside of RIT provided an adequate level of confidence in the quality of information and expertise. The experts seem to be available through RIT connections, as well

as external connections gained through the personal researcher's network developed over their career. The experts used by the researchers are not shared across others in the university. There is typically a high degree of confidence about the quality of data through expert consultants and companies with prior experience. Thus, these projects have access to reliable information on FDA compliance.

Product 1 is a low-risk device, as shown in Table 1. The owner of the device believes the device has the potential to be successful and is pushing the product to market. The owner of the project started a company to support any of the product needs. This company is specifically dedicated to the success and commercialization of the product. The interviewee stated that "the company is taking it through the FDA. That is expensive to do, and there is expertise that is required to do it. The company has an FDA consultant who understands how to go about doing those filings with the FDA."

Translational research, as defined previously, is specifically designed to improve health outcomes. It uses an integrated team of experts who are focused on translating useful information from laboratories to doctors' offices and hospitals and is a "bench to bedside" bridge ("What is Translational Research?," 2017). The translational pathway of research to commercialization is not common at RIT; with limited past translated products to use as a model, innovation at RIT is challenging. The interviewee believes going through the FDA approval process is extremely uncommon on campus. The interviews indicated that this lack of experience could harm the translational process. The limited knowledge of the university showcases the lack of resources available to entrepreneurs, engineers, and collaborators to commercialize innovation. Luckily, the company created to assist the product has hired experts, and the product will have the resources needed to move forward.

Product 2, a Class III device, is still being used on animals, which limits the involvement of the FDA. When the researcher plans to move forward, their path will include collaboration with a larger company to assist in human testing and gaining FDA approval. The cost and time associated with testing a Class III device can be overwhelming for a university with limited experience. The interviewee believed that "most academics do not have any experience with that [FDA testing and approval]. It is very different from the majority of what we do for our research and how we write proposals. Usually, people would partner with companies." Based on the researcher's experience, collaboration with a larger company seems to be the most efficient way for a Class III technology to be translated.

Product 8's project leaders have possible plans to commercialize their Class II product. The progress of the product has not yet reached a point that requires the attention of the FDA for compliance. However, early consideration of FDA requirements could help avoid problems later on. Understanding different approval pathways and compliance standards could lead to changes that pay off later. The researcher already has plans to work with a multinational company for further testing and translation of the product once the product is ready for an FDA pathway. This company has experience with similar products and believes this is the best way to advance.

Product 9, a Class III device, is not going to be commercialized. Their project was a response to the COVID-19 pandemic, and their efforts proved to be fruitless as they did not have the resources to continue. Before the COVID-19 pandemic led to a partial shut down of university activities, the project members explored the FDA approval process through self-research and outside collaborators. The interviewee explained, "the problems that we were tackling there were not any regulations that would have hindered us, and if there were any

regulations, we were letting our partners make those decisions." The resources used for approval of this project would not have come from the university but outside consultants.

In sum, three out of the four Research Projects planned to use the help of companies, and the other used expert consultation through external collaborations. The Research Projects gathered information from additional sources, such as companies and consultants. Collaboration with companies has extreme advantages, such as knowledge, staff, and funding. Working with the company gives a researcher the freedom to continue working on their work at the university, yet both parties can benefit. Based on the research, there are few currently known disadvantages for company collaboration. For university innovators with little experience, a company can be the difference between success or failure.

Experienced Barriers

Lack of Knowledge

At RIT, researchers are responsible for many of the products that may result in a commercial product, but they can also experience barriers that stunt their possible successes. There are many things about regulation and compliance that researchers don't know and can not learn at the university. Luckily, the researchers in this study tended to have enough resources outside of the university to overcome this barrier.

One of the specific barriers experienced by the researchers was a lack of knowledge of documentation procedures. The FDA requires not only documentation for the final product, but also the process of developing the product. This can include design, test results, and other process steps. However, there is little to no standard documentation process to assist researchers in commercialization. A researcher stated,

> "We don't have documented procedures that define the way we do product development. We don't do a good job with documenting the design. We don't do a good job with documenting the way that we produce it. We don't have procedures for the way that you make them, and we don't have procedures for everything you test in a quality system where we take all of that data, and it's documented for every device. What that means is, if I produce the devices out of the university and we get all these great results from this study, which is a five-year study, I can't actually use it to submit to the FDA. We have to do it again. It still has value, because it can show with technology like this, you can reduce hospitalization rates. You just can't use that data to file with the FDA to be able to claim that you can use it to achieve that result."

This statement shows the importance of understanding the required documentation process. This lack of knowledge can cause a great deal of rework, and this particular researcher needed to start a company to redo some of the development work in order to create the necessary documentation.

Lack of Resources

To overcome their minimal expertise on regulatory compliance, the Research Projects also needed human and financial resources. University settings are helpful in research; however, they do not provide the resources a company does to further the product on the path to commercialization. To overcome this barrier, researchers with a marketable product may create a company. An interviewee explained the added that the money and expertise a company brings may be necessary for success. Hiring full-time experts that can be devoted to the project is beneficial. This researcher explained how they "started a company to commercialize it. That company is taking it through the FDA. That is expensive to do, and there is expertise that is required to do it. The company has an FDA consultant who understands how to go about doing those filings with the FDA." Without specialized FDA experts at the university, this researcher pursued another way to gain advice and help.

Although starting a company seems like the best way to pursue commercialization and approval, it can be a challenging path with hefty expenses. A researcher explained that they felt there was no other way to bring their product to market other than partnering with a company or starting one. He explained that starting a company is "really expensive, and we don't have the NIH funding to help you get through that process, but most academics do not have any experience with that. It's very different from the majority of what we do for our research and the way that we write proposals. Usually, people would partner with companies."

Partnering with companies can be a mutually beneficial path as long as both parties have enough confidence in each other in order for the collaboration to work. Most companies will not risk resources for a product without a proven need or a high possibility of success. There is also no specified process for collaborating with a company and it can be challenging for a researcher that does not have experience building this type of relationship. Other researchers are lucky enough to have personal connections to information sources such as other universities, companies, or consultants. One researcher explained how they gathered information and where they got it from in the following quote.

> Well in our case, we did have some input and insight from people that have medical device experience in developing and working with regulatory agencies so people that have worked in industry for a while, so I would classify them as consultants. In some cases, one of the consultants was unpaid and a personal connection. Another case, the U of R actually has a translational research center you may know of. So they actually have staff that are there to help you with that. So they are able to point us to some documents, but in the end we had to interpret them ourselves because they were not experts in exactly what we wanted to do. But it did give us some direction in where we wanted to go."

A large issue encountered by researchers is a lack of resources and funding. A lab usually employs or allows students to work in a lab for financial compensation or experience. Students in research labs looking to gain experience in their designated field usually perform the tedious

tasks of documentation and other clerical tasks for FDA approval. These tasks are often seen as busy work and not given the proper care or attention they should. Even with the research assistants able to do little work on documentation, it is nowhere near the necessary amount needed for FDA approval submissions. Lack of funds and resources leads to products not reaching their full potential or using an external company. The lack of funds for one project during COVID-19 halted their progress. As explained by one person: "as our supplies dwindled, the financial security of the university came into play and so we weren't going to be able to purchase tens of thousands of dollars of material." In this case, the lab's work ended due to the considerable lack of resources.

Lack of Motivation

Another barrier might be the researchers' own motivation to commercialize the technology. Some researchers are not interested in commercializing the product on their own but are open to building a device with the potential for commercialization to be pursued by a company collaboration. These researchers aim to prove that the product is helpful and useful in the medical field; however, they are not interested in anything more. A researcher's main objective is to discover the technology, not sell or approve products. One creator at the university explained his feelings on discovery and innovation as, "when it comes to regulation, makers in general don't pay attention to it. Because they're not thinking about commercializing it, or they're not going to be using it on people. So the safety's not safe there." One person indicated that the developer wants the product to fulfill its potential but is not interested in the process to get it further than a lab. They said, "that's one where we right now are trying to follow some of these ASTM standards to make sure whatever data we do collect would be meaningful to someone that then wanted to actually spin it out or scale it up."

Impact

A common consideration for owners of the Research Projects was how to be impacted the least by compliance and regulation, as rework and wasting time is not desirable. Three out of four device projects collaborated with companies that help to optimize the commercialization process. The interviewees mentioned changing their devices to avoid setbacks. Based on the expertise of collaborators and the possibility of changing the function of a device, work can be done to lessen the impact of regulation and compliance. Some interviewed also believed that the timing of their consideration of FDA regulations for regulation had an impact on the ultimate product design. In some instances, early compliance consideration can change the entire project. When talking to the interviewee of Project 1, he began describing the effect of the FDA regulations as, "It made us decide not to do a [certain product function]." He went on to say, "At the early stages of design, we made that decision so that it would relieve the burden on us to begin doing human subject testing." With this change, the project would use a cheaper and quicker FDA approval pathway when the time comes to apply for FDA approval.

Alternatively, sometimes a necessary design change may not happen because consideration for compliance did not occur until the project's end. A product could miss compliance criteria or lack the necessary testing. Another interviewee said, "What that means is, if I produce the devices out of the university and we get all these great results from this study, which is a five-year study, I can't actually use it to submit to the FDA." It is important to note that it is not always the owner's fault, but it points to the need for a better understanding of the best time to consider compliance and regulation.

Sponsored Projects

As stated earlier, Sponsored Projects are run by students, not funded directly by RIT, and use RIT resources. This section will continue to look at the resources for compliance, barriers experienced by project owners, and the impact each had on the sponsored products.

Information Resources

Products 3, 4, 5, 6, and 7 were Sponsored Projects and relied on a student team-based approach to development. Within the teams, specific members were responsible for gathering the compliance information.

Table 4: This table showcases the different resources used by the students at RIT.

Product	Design Standards/ Sponsor	Expert Consult	Personal Knowledge	Customer	Internet
3	X	X			X
4			X		X
5	X		X		X
6					X
7	X			X	X

For these projects, most of the information resources were found through internet searches. The product 3 team, working on Class I equipment, first used an internet search to acquire information and had difficulty finding the resources they needed on the internet. They used what little resources they could find. Their precedence for FDA approval can help design new products; however, the student must understand the purpose. Other resources at RIT were also unhelpful. Finally, they turned to another university they had a connection with. It took one team member three different attempts to find the information needed to understand the product's requirements.

A team member working on Product 3 recalled, “I talked to a professor that said RIT lacks at helping students with documentation, research, and knowing what to do. So I scheduled a meeting with our customer, who is a medical director at another college, and she got me into contact with the regulatory director at another university, and he gave guidance on the clearances we needed.” A team member for Product 4, a Class I equipment, did their own research. He concluded that due to the nature of their product, no testing or FDA concerns were necessary. The team member drew the conclusion from online research but did not consult any expert or contact the FDA to corroborate this conclusion. Their lack of assurance from expert sources may be a risk when furthering the device for commercialization.

Product 5, a Class I device, used a single team member to do the FDA compliance research for the project. The search resulted in vague results. Their information was based mainly on design standards and predicate devices, which are used as a point of comparison for new medical devices seeking approval (“Predicate Device: Greenlight Guru,” n.d.). The team guide, a faculty member appointed to assist in any issues, was unsure how to help with the search. The team relied solely on the internet and still does not believe their results were thorough enough to be confident in receiving FDA approval.

Product 7, a Class I or II device, relied heavily on internet research and predicate device standards. The standards for many predicate devices did not help the team, as their product design was to be completely different from previous products; their internet research resulted in generic results that needed interpretation. The team decided to follow some International Organization for Standardization (ISO) standards for the materials used in the product and then rely on mechanical testing for safety standards.

All of the students relied on the internet for information. As mentioned earlier, internet information, such as information on device class, can be interpreted in many ways and may set a project up with incorrect information. Students also looked to international design standards for their product because they needed indisputable and unquestionable sources. The incentive to commercialize may be lower for these products because uncertainty in the path to compliance makes it a riskier endeavor. Without expert consultation, no one could be sure the information the students gathered was 100% correct. Lastly, the personal knowledge the students used was more often intuition-based than experience-based. This is not promising for compliance standards and moving forward with FDA approval. The only student with an expert consultation used her personal connections for the information, which all students do not have access to.

Primary Barriers Encountered

Lack of Knowledge

For this group of products, there were several barriers mentioned by project owners. Some of these issues were caused by a lack of knowledge. It was usually a student's first time navigating the FDA compliance information; therefore, the students were unsure how to proceed with much of the investigation. The students also must interpret all findings on the internet, and without previous knowledge, they may consider inaccurate or incomplete information to be true. For example, one of the students stated, “For regulatory information, I did most of the research. There were ISO standards I found, however, nobody told me whether I needed that. It was hard to find, so I put a lot of time into it. There were ASTM, ISO, and IEEE standards, and I found the device class and used it as a guideline knowing in the future it would be able to pass FDA approvals.” The student used information recognized for engineering practices; however, it is not

explicitly for medical devices. There is much that goes into the safety and efficacy of a project besides the mechanical properties. Based on the lack of information for the student, they used the best compliance suggestions available.

As another example, until the final product design is near completion, it may be unknown whether the device can use an existing predicate and therefore be exempt from a pre-market approval process and qualified for a 501(k). This happened for Project 7. One student stated that, "We believed we could use a 501(k) device pathway so we put in much time learning about the process and understanding predicate devices. By the end of our design process, we found out that the device would need to go through a different process." Without a knowledgeable consultant, the team's assumption caused extra work and wasted time. This mistake could have been avoided with more understanding of the process. It is unclear whether the student prematurely chose a pathway and needed to change the product after initial designs or if the student misunderstood the FDA requirements. Either way, the student was confused about the process, and prematurely chose a pathway that caused unnecessary rework time and cost.

With many companies having departments committed explicitly to stay up to date with FDA regulations, it is no surprise that students would have trouble navigating the changes in regulatory standards that frequently occur. With so much information and change, it is challenging for an inexperienced FDA regulation interpreter to stay up to date with everchanging FDA policies.

Lack of Guidance

At RIT, students typically research FDA pathways in classroom settings before creating any product prototypes to help with design requirements. Without experience and a full

understanding of the regulatory field, students can make incorrect choices for their product design. It is easy to decide an approval pathway before the product is finished; however, this ultimately may not be the best pathway. As seen previously in product 1, experts suggested changing the product slightly to avoid a more stringent pathway. However, the experience and knowledge used to make that decision are not available for all students. Even with specific faculty and guides, the lack of experts trained on FDA matters has an effect. A student explained, "Our guide was trying to understand the process with us and at times interpreted the information wrong."

Some students used personal resources to further their product because they could not find the necessary help at RIT. The student could not locate staff knowledgeable enough on their needs and had trouble finding the internet information. When asked if the campus resource was helpful, the student replied, "No, they were not helpful." When asked if they could use the established design standards as a means for knowing if they would pass FDA approval, the student replied, "I don't know if we would. I don't think this would need to go through the FDA, maybe a predicate device. It could also be a Class I. I think further iterations would be." The design of this product did not change much throughout the development process. It can be assumed that the uncertainty stems from a lack of knowledge rather than any design changes. This answer shows a large amount of uncertainty in their work. Handing a product with that much uncertainty off to be commercialized can cause a bad reputation for the university.

Impact

Most impacts of the resources and barriers were negative for Sponsored Projects. As noted previously, the students' resources were not sufficient, and they often did not understand

compliance standards. Many students turned to international design standards for guidance, which had a small impact on their designs. Product 4 and 8 chose their product material based on design standards. The design standards helped guide the students but did not impact their design significantly.

The Sponsored Projects all waited considerably longer in the design process than the Research Projects to consider compliance, but not many students would know that. It is concluded that a sooner consideration with expert experience and knowledge can help save time and money. With proper guidance and resources from the university, the product's impact can be improved rather than minimized. The lack of resources kept the students uninformed on how specific product characteristics can alter the FDA pathways that they choose.

Individual Project

As stated earlier, Individual Projects are recognized by RIT, not funded directly by RIT, and RIT is not a stakeholder of the project.

Information Resources

As shown in Table 5, the Individual Project did not rely on RIT help and used the internet, the FDA hotline, and international design standards. The outreach to the FDA proved to be subjective due to multiple responses with conflicting information. As mentioned earlier, one FDA worker said the device would be Class I, while the other said it would be Class II because it related to a deadly disease.

Table 5: Resources used by the Individual Project for compliance and design requirements.

Product	Design Standards	Expert Consult	Personal Knowledge	Customer	Internet
10	X	X			X

Product 10, an individual product founded at RIT, could fall under a Class I or II category. This product began during the beginning of the COVID-19 pandemic with a vision of improving an existing product rather than creating a new device. Navigating the approval process during the pandemic proved to be difficult for the team. They found that new exemptions and changes to speed approvals caused even more confusion. The interviewee explained how they "spent countless hours on the phone with them [the FDA] trying to figure out what classification our device is and received a different answer every time. They weren't able to give us the answers we needed. So, in general, it has been a pretty difficult process, maneuvering the FDA." The fast-paced nature of commercializing during a pandemic was not something the team could find resources on and at times felt lost in a sea of contradicting information.

Primary Barriers Encountered

Only one of the products within this case study is considered an individual product. While an RIT student is conducting it, it is not being funded or located on campus. The student has encountered many difficulties with finding the necessary information and funding. The student is self-employed, thus responsible for obtaining both. Their experience with finding approval information has not been comfortable, and they have gone as far as contacting the FDA directly. However, the information received from each consultant has slight irregularities and is subjective. To tackle funding, the student had to improvise and use the resources they already had for manufacturing. The student stated, "Basically, where we left off is that we did not have the necessary funds for a huge down payment for mass manufacturing, so we kind of made our own on the side, we printed them, we would rather have them injection molded, but we printed them cause that is what we can do." The student knew that the cheaper way was not the best, but due to the lack of support and using personal resources, they did the best they could.

Impact

The resources and barriers of this project did not have a physical impact on the equipment. However, it did impact the timeline of the project. The uncertainty about resources and difficulties communicating with the FDA caused a slower timeline for the project. In this case, time wasted meant money wasted, and it eventually slowed the project to a halt, missing a window of opportunity for commercialization.

Chapter VI: Discussion and Conclusion

Analysis of Findings

This study highlighted the difficulties faced by innovators at multiple levels at the Rochester Institute of Technology. The analysis shows the current resources and supports the projects have is insufficient in overcoming the barriers and issues they face. Lastly, compliance is daunting and may push researchers away from considering their device for the market. With proper help, the success rate could increase and limit the struggles faced by students and researchers. Luckily, some researchers could collaborate with companies, experts, and other helpful resources. On the other hand, students participating in innovation at RIT lacked knowledge and resources to acquire this knowledge advance, e missing out on potential success for their project and the Institute. These limitations slowed project progress, led to incorrect information, and hampered project success. A consistent theme in the interviews was how information about regulatory requirements for a specific product was difficult to come by.

Project type	Project Owner	Primary Information Source	Information Quality	Confidence in Compliance
Sponsored & Individual	→ Students	→ Internet	→ Low	→ Low
Research	→ Staff	→ Company	→ High	→ High

Figure 2: A comparison of project types and a pathway to their confidence in compliance.

The first research question to be answered is, "What sources of information did the project have to learn about compliance standards for FDA regulations?" Across the ten devices, most researchers obtained their knowledge through entirely different sources, and not all of these sources were easy to use or reliable. As shown in Figure 2, the primary information source for

Sponsored and Individual Projects was the internet, while Research Projects have access to company experts. Based on the information pulled from the interviews, it can be concluded that the quality of information depended on the source. The research showed that no projects could complete innovation to market processes using only RIT resources. Similarly, the lack of resources and funding for compliance and approval efforts was a central theme across the projects. The access to company collaboration and resources gave owners high confidence in compliance. Thus, there seems to be a strong correlation between the origin of the project and the strength of their resources. The Research Projects had external resources and experts while Sponsored, and Individual Projects used more internet and personal knowledge. This may be because support for Sponsored Projects tends to come from customers with small fixed budgets.

Although it is clear that using external resources, such as those found in an established company, has advantages, these resources are not always easy to attain. The external connections used for the Research Projects are gained throughout the researcher's experience, and typically not through RIT. The experts used by the researchers are not advertised to the entire university body. It is important to keep in mind, as stated in the literature review, there is a need for continued research and collaboration, even following the commercialization of technology. This type of continued support is a burden that universities cannot bear (Pober et al., 2001).

As expected, all of the projects faced barriers related to regulatory compliance; however, the issues were different based on the type of project. The Individual and Sponsored Projects had issues that related to lack of knowledge and a lack of resources to attain this knowledge, which led to confusion, frustration and misinformation. On the other hand, while Research Projects had problems related to knowledge, such as FDA documentation requirements, and lack of university resources to acquire this knowledge, some projects were able to overcome this barrier through

external collaboration. It was clear from interviews that different resources available to the projects affected the type of issues they experienced.

Lastly, perceptions of regulatory requirements did impact the product design choices. Multiple projects in the research and sponsored category changed their designs based on the resources and barriers. The Sponsored Projects had smaller tweaks based on design standards, while one Research Project changed a main function to avoid a more stringent FDA pathway.

The cases highlight the importance of when a project starts considering FDA compliance. On one hand, the earlier you start considering this, the less rework you might require based on regulation and the fewer unexpected speedbumps. This is particularly important for regulatory requirements on product development documentation. I found, however, that some researchers are not interested in commercializing the product on their own and therefore do not consider FDA approval or the necessary documentation. For these products, it was only thought of after the product showed commercial promise. Thus, much of the testing and documentation needed rework. These researchers aim to prove that the product is helpful and useful in the medical field and it will be the partner company's job to carry it to market.

On the other hand, this points to a paradox when it comes to timing consideration. As seen with students, there can be issues with early consideration of regulation if the information is incorrect or is interpreted incorrectly. This has the potential to lead the project down a specific design path that might prove to be the wrong one. This points to the importance of access to expert consultation early in the innovation process.

In conclusion, the investigative nature of the study found many instances of innovation at the Rochester Institute of Technology. However, none of the projects analyzed in this study could complete the commercialization process using RIT resources alone, and some faced

significant barriers. The origin of the project directly relates to the strength of the resources that are available for that project. Those products with little access to external expert's struggle. The study concluded there was a significant gap in a university setting between FDA compliance, the commercialization process, and the resources and expertise needed to achieve it.

Limitations

There are a number of limitations of this study. The limited amount of medical device innovation at RIT narrowed the sample size of the research. Only one person from each project team was interviewed, which may have restricted the experiences and information about each project. The lack of access to project details and only relying on interviews for project information may cause discrepancies in the data.

The snowball sampling technique caused a nonrandom selection of each project (Johnson, 2014). Only ten projects were chosen, and they may have related experiences based on the sampling technique. I also did not talk to administrators at RIT that might know of available projects that were not taken advantage of.

Implications

Implications for Research

As noted in the literature review, there is a need to address regulatory concerns more specifically on the research that looks at commercialization of university research. This study shows that this is, indeed, a barrier to commercialization. Future research can address the limitations of this study with large and less exploratory research on the topic. Increasing the sample size, the number of individuals interviewed, and the number and type of universities investigated are a number of ways future research can build on this study. For example, other universities, such as the University of Michigan (UM), have a different culture around medical

innovation. UM has an entire program to help innovators, which contributes to their supportive culture and big success. Conducting a comparative study would be very interesting.

Implications for University Policy

If RIT (and other universities) are genuinely interested in commercializing medical devices, they need to provide better support for the regulatory compliance aspect of medical device innovation. This support can take multiple forms. With some students forced to find experts at another university, an open channel with other universities would allow innovators to gain access to information not available at RIT.

RIT currently runs a Personalized Healthcare Technology program that aims to "integrate interdisciplinary research" to solve medical problems (Personalized Healthcare Technology, n.d.). However, this program does not solve or mention the issues associated with regulation or compliance efforts, as analyzed in this thesis.

Education and training for those involved in innovation could go a long way for the university. There is currently a lack of knowledge or where to look elsewhere for it. There are some researchers on campus with experience in compliance that could help students relying on personal knowledge and the internet. However, there are not enough people with the amount of knowledge needed. Specifically, for students that do not have access to external resources or companies, a full-time regulatory expert would be useful. The expert could also aid faculty and, thus, would significantly decrease rework times and facilitate innovation efforts.

Alternatively, the university could help facilitate external networks with regulatory experts. Teaming up with a company or expert as soon as the product shows promise would relieve some barriers and extra rework. This type of network could also help medical device innovators at the university to share their experience with each other on topics such as

documentation, testing, and other difficulties. With stronger documentation of observations regarding the regulatory and compliance process, a network can educate other innovators in the same scenario. Previously, I mentioned how the Wallace H. Coulter Foundation at the University of Michigan was created to give students and staff the help needed to commercialize. This could be a model for other universities, including RIT, could use to build structures and change the culture to support collaboration between the university faculty and professionals in the medical field (Pienta, 2010). This would require extra support at the university level.

Implications for FDA Policy

FDA policy can do more to explicitly address the barriers for university innovators, such as lack of knowledge, lack of guidance, and lack of motivation. FDA policy has proven to be difficult to navigate for many I interviewed. From the novice's perspective, the FDA does not have clear-cut instructions on how to achieve compliance works. To decrease the knowledge barrier, more accessible resources need to be available for researchers and students. The current information can be seen as confusing, non-specific, and difficult to find. The FDA could easily understand quick fact sheets or a more comprehensive requirement list for innovators to reference. The information for innovation is not placed together on the website. The interviewees explained how information was hard to find or confusing to understand; hence, why multiple project owners began companies with paid experts.

To address the lack of information and guidance, more grants could be created by the FDA to have specialists visit universities. Another idea is to offer guest lectures to universities by compliance specialists. Often, students and researchers are wary of reaching out to the FDA first. To address this problem, the FDA could develop a program to reach out about compliance efforts first or creating an inquiry box on their website.

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