Biomedical Engineering Education (2024) 4:225–234
https://doi.org/10.1007/s43683-024-00134-w

BMES BIOMEDICAL ENGINEERING SOCIETY

INNOVATION ARTICLE

Just-In-Time Education of FDA Regulation and Protection of Intellectual Property for Medical Products: A Course Review After Our First 10 Years

Joan E. Adamo[1] · Erin L. Keegan[2] · John W. Boger[3] · Amy L. Lerner[4]

Received: 5 September 2023 / Accepted: 4 January 2024 / Published online: 12 February 2024

Abstract

Successful translation of medical devices requires a clear pathway through the business environment, including regulatory obligations and the protection of intellectual property. Introducing these topics can be challenging for biomedical engineering programs, as students prefer hands-on activities and retain concepts best when directly applied to projects or research. To address this challenge, 10 years ago, we created a two-semester course sequence covering these topics, primarily intended for MS students focused on medical device design. Course content is delivered with a "just-in-time" approach to align with ongoing year-long design projects. In the fall semester, our course covers IP and regulatory topics relevant to the selection of an unmet clinical need for further development. The spring course covers topics related to implementation of a business model for a new product, such as licensing, clinical trials, quality systems, and submission of material to the FDA. Over 10 years, we have added numerous special features, including a regulatory science competition, a mock Pre-Submission Project reviewed by regulatory experts, and an IP presentation modeled after industry practices. In this manuscript, we review course content, structure, and outcomes. A survey was used to obtain feedback from graduates now in widely varying positions in the medical innovation space. In addition, we obtained feedback from a sample of external reviewers. With a response rate of ~50%, the survey identified strong support for the courses and identified chosen career paths. The mock Pre-Submission Project was highly valued by students and their employers, as were other assignments that aligned with ongoing design or research activities. Several opportunities for improvement and possible expansion of the course were identified to further enhance this valuable part of our curriculum.

Keywords Regulations · Intellectual property · Patents · Medical devices · FDA · Innovation

✉ Amy L. Lerner
Amy.Lerner@rochester.edu

Joan E. Adamo
Joan_Adamo@urmc.rochester.edu

Erin L. Keegan
Erin.Keegan@fda.hhs.gov

John W. Boger
John.Boger@hrfmlaw.com

[1] School of Medicine and Dentistry, Clinical and Translational Science Institute, University of Rochester, 601 Elmwood Ave, Box 708, Rochester, NY 14642, USA

[2] Center for Devices and Radiological Health, Food and Drug Administration, White Oak, Bldg. 66, Rm. 1649, 10903 New Hampshire Avenue, Silver Spring, MD 20993, USA

[3] Heslin Rothenberg Farley & Mesiti P.C., 5 Columbia Circle, Albany, NY 12203, USA

[4] Department of Biomedical Engineering, University of Rochester, 307 Goergen Hall, Rochester, NY 14627-0168, USA

Introduction

The development of skills outside of traditional engineering concepts is critical for students who are completing a biomedical engineering MS degree. Two areas in particular, the regulatory process and the protection and analysis of intellectual property (IP), often receive minimal attention when planning an engineering curriculum, even though regulatory procedures was ranked as a highly important skill for biomedical engineering students in a recent survey of biomedical engineering faculty [1]. In many cases, this material is delivered in a lecture and quiz format, not allowing students to directly engage with examples of how these topics create challenges and opportunities within medical innovation. To accomplish the broad goals that we believe are necessary for educating students on the commercialization of medical products, we created a pair of courses within the University of Rochester's Center for Medical Technology and Innovation (CMTI) program in the Biomedical Engineering (BME) Department, in conjunction with the Clinical and Translational Science Institute (CTSI) of the University of Rochester.

The close proximity and frequent partnerships with the University of Rochester Medical Center have resulted in vibrant, clinically-based collaborations with many opportunities for experiential learning for our engineering students. In addition, the CTSI has been supporting translational research since 2006, when the first Clinical and Translational Science Award was granted by NIH. A key component of the first award was the establishment of an Office of Regulatory Support to provied regulatory affairs services for Sponsor-Investigator researchers across the university who are conducting studies with FDA-regulated products. One of the main missions of this office was education of faculty, staff, and students.

In 2011, the MS program within the CMTI was designed as a unique educational program where students experience clinical observation along with bioengineering design to prepare them for careers in medical technology design, development, and innovation. Inclusion of a clinical practicum with hands-on experience in the product development process was central to the training. During this practicum, students work in teams to identify unmet clinical needs and are then expected to select one clinical need for further development with a prototype and business model. Understanding the potential regulatory obligations and the process of protecting created intellectual property are critical to the final clinical need selection, as well as to the concept development and business planning, as these can strongly influence the feasibility of implementation.

Allowing students to proceed too far down the design pathway without a solid foundation in the parameters which will influence their design choices is problematic. To ensure that students were well-prepared for decision-making related to need selection and potential for commercialization, we developed a two-part course with a "just-in-time" approach to deliver instruction on the U.S. FDA regulatory processes (primarily for medical devices) and IP analysis and protection. This course development was supported in part by a grant from the National Collegiate Inventors and Innovators Alliance (now Venturewell). With our desire to cover two topics over the course of two semesters, we were presented with the question of which topics to offer in the fall, and which to offer in the spring. We felt it was imperative that students begin to learn some aspects of each topic early in their 12-month program, prior to concept development. Therefore, we chose to develop a two-course series, meeting once per week, that spanned two semesters. The two courses, each two credits, took a novel approach by alternating the FDA regulatory and IP analysis topics weekly. The goal was to ensure that students were introduced to relevant resources and issues through course topics and key assignments (Fig. 1A) prior to clinical needs selection in the fall, and then cover issues critical to the commercialization of the created medical inventions in the spring semester. This delivery closely paralleled the design efforts within the CMTI MS program (Fig. 1B), allowing students to apply their knowledge to ongoing projects. As the courses have evolved, we have incorporated several special experiential assignments, including a mock pre-submission review (mock Pre-Submission Project), in collaboration with volunteers from the FDA and the medical innovation community. In addition, a patentability evaluation was designed to mimic industry practice related to intellectual property. Thus, we incorporated real-world simulations of practices in the medical innovation field to foster self-efficacy and confidence [2].

After 10 years of offering these courses, we have elected to conduct a thorough review of the participants, including their perspectives on the value of the course content and several key educational experiences that are completed as part of the courses. We wanted to evaluate the overall perceived value of the course content, transfer of knowledge and skills to the workplace and ensure sustainability of the program. To accomplish this, we conducted a review of the student participants and their career paths and disseminated an online survey. We also sent an email survey to the professional volunteers who participated in reviews that supported the mock Pre-Submission Project. Specifically, we hoped to answer the following questions:

1. What is the nature of the students who have taken our courses and where have they gone in their careers?

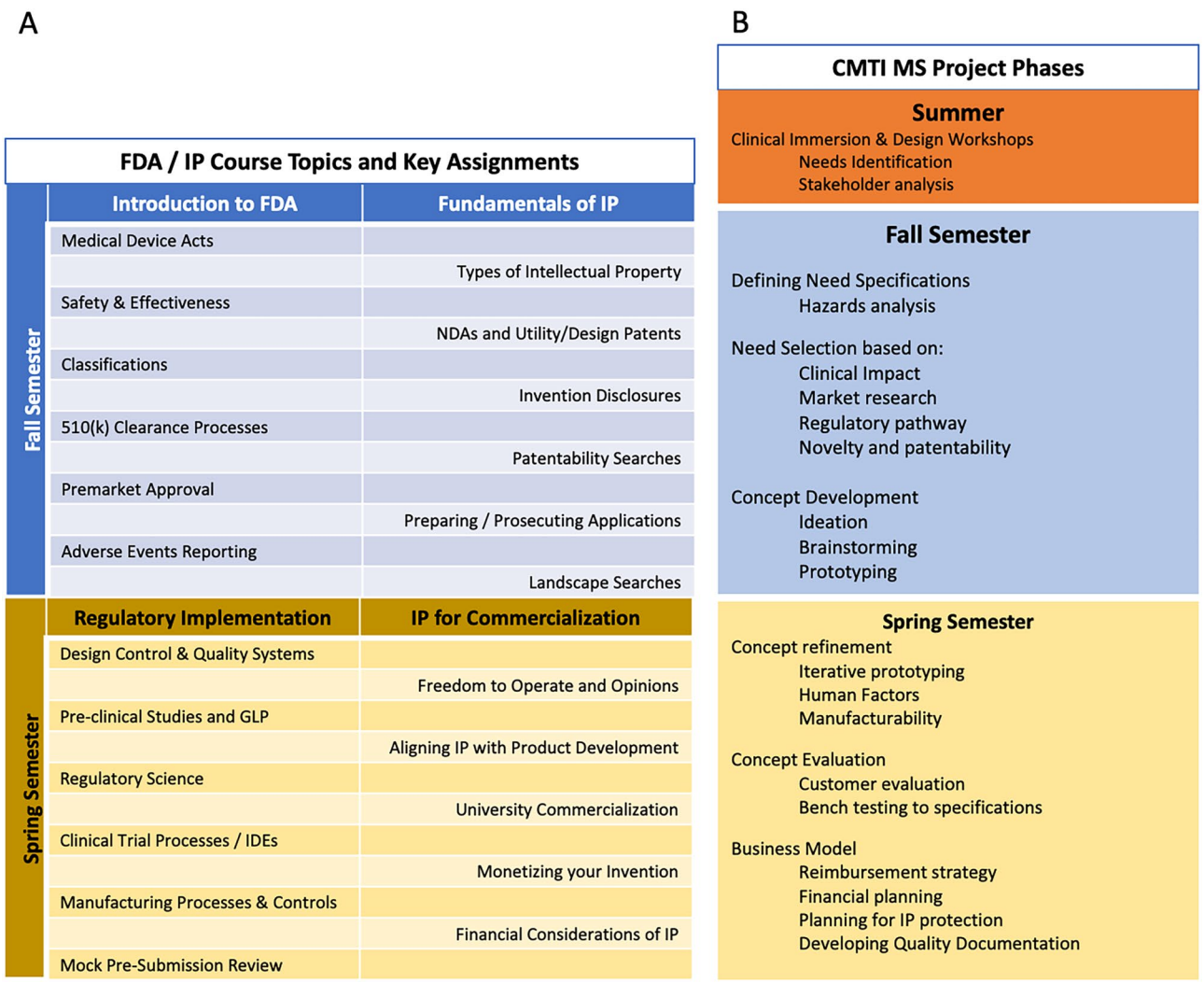

Fig. 1 **A** The two semesters of BME431 and BME432 alternate topics and assignments between the FDA regulatory concepts and fundamentals of intellectual property. **B** Highlights the sequential phases that the projects for the CMTI MS student teams will undergo as they move through their 12-month program

2. What aspects of the courses do participants (both students and volunteer reviewers) find most valuable and why?
3. Do external participants in course projects find their experience worthwhile?

Course Overview and Key Features

The specialized expertise required for this course prompted us to involve two instructors working in partnership over the course of the year. To meet didactic needs on the intellectual property focused side of the course, those lectures were taught by an experienced technology transfer professional or a licensed attorney who is registered to practice in front of the United States Patent and Trademark Office. A regulatory affairs professional was responsible for the balance of the course, including course management, TA coordination, organization, and logistics. To augment our in-house knowledge and to expose the students to a variety of career options, outside guest speakers were selected to give occasional lectures that covered a specific topic in the syllabus and also offered a view of potential career options. These also provide valuable opportunities for networking. Guest lecturers were selected not only based on their experience in the relevant regulatory, quality, IP, early-stage financing or product commercialization fields, but also on their desire to work with students and continually network even after their lecture session and student meetings had concluded.

The original goals of the courses were to offer practical, real-world instruction to students interested in supporting the translation of medical technologies. Learning

outcomes include developing abilities to describe the impact of IP and regulatory milestones on commercialization of new technology, ability to conduct patent searches, to describe patentability, device classification and appropriate use of terminology. Students were also expected to be able to outline steps for marketing applications, clinical trials and specifically to develop a pre-Submission application package for review by the FDA. While some of these learning outcomes have been successfully evaluated in final examinations and projects over the years, we were also interested in the transfer of these skills and knowledge to the workplace. Thus, for the purposes of this 10 year "look-back" review, we asked the students for feedback about several aspects of the course as part of our survey, including how they might be applying that learning to their current roles. Based on the survey results, we have chosen to highlight the following unique aspects of the courses.

Within the topic of intellectual property, students were introduced to prior art searching techniques and patentability evaluation. A critical concept is that obtaining a patent can be a costly and time-consuming endeavor and may not always be the best path forward, so we review in depth the elements that would contribute to the decision of whether to file. To educate students on this process, students perform a prior art search focused on the structural elements of the invention of their choosing using various commercially available on-line databases. They are then asked to review the found prior art and determine whether their invention is patentable or not. In this way, they develop an understanding of the steps to incorporate novel and /or non-obvious elements, if their research showed their invention to be not patentable and what novel "design arounds" are possible to include in their invention to make it patentable. Finally, each student composes an Executive Summary that is modeled after industry style reporting methods, which briefly disseminates the elements and functionality of their invention, their prior art search methodology and results and their patentability conclusion. The student then orally presents their findings to the class and fields queries related to their invention design and Executive Summary conclusions. In addition to this project, students were introduced to other "real world" IP concepts that engineers are now tasked with in industry. These topics included learning the key aspects and timing for drafting industry-specific new invention disclosure forms, understanding the different elements of a patent application and the critical contributions of the designing engineer, the process of performing third party infringement analysis of medical devices, performing IP due diligence evaluations, reviewing key provisions of various industry styled contracts, including product development agreements, royalty agreements, and license agreements. In addition, the students were introduced to the technology transfer field and the challenges of early and later stage financing in the medical device space.

Our content related to regulations currently focuses on the US FDA, emphasizing medical devices. We cover classification of devices, risk assessments, market clearance and approval options, quality systems, recalls, reporting, investigational device exemptions, clinical trials, and more. Given the limited timeframe of a 12-month MS program, nascent student designs would not be truly ready to bring to market within the timeframe available. To structure an individualized, "just-in-time" approach to the FDA regulation of the student's projects, we incorporated an experiential learning opportunity in the form of a mock Pre-Submission (Pre-Sub) to the FDA's Center for Devices and Radiological Health (CDRH) [3]. This project was structured under the FDA/CDRH Q-Submission program in partnership with a CMTI alumna, where each student team would follow the FDA/CDRH Q-Submission guidance document [3] to create a Pre-Sub for review. Under the Q-Submission Program, a Pre-Sub is a written request from a sponsor for feedback from FDA that is provided in the form of a formal written response or, if the sponsor chooses, formal written feedback followed by a meeting. A Pre-Sub provides an opportunity for interaction between FDA and the sponsor to guide the sponsor's next step in the device development process. A Pre-Sub with CDRH is voluntary and free of charge. For the mock Pre-Submission Project, students worked in teams of three to four to prepare and submit their Pre-Sub document for a mock review by either FDA volunteers or external volunteers in the broader medical device community. Each year, a series of FDA reviewers and external regulatory experts are selected based on their expertise in the area of interest and their availability to take on pro-bono work. The volunteer reviewers conduct their review and provide written feedback accordingly. Following receipt of the written feedback, consistent with the Q-Submission guidance, students prepare a presentation for a student-led mock review meeting with their volunteer reviewers and a volunteer regulatory project manager guiding the meeting. At the conclusion of the mock Pre-Submission Project, the students have a greater understanding of how a real Pre-Sub interaction with the FDA/CDRH would occur. All FDA feedback was clearly labeled as "mock" with caveats including that the feedback does not constitute formal FDA feedback, it was prepared as part of an educational exercise, the responses were assembled by volunteers and must not be used to guide regulatory decision-making, and finally, that the information must not be shared with any third parties (e.g., industry partners).

We planned for, and experienced, interest in the course from students well beyond the CMTI program including doctoral students from the University of Rochester Medical Center, the Translational Biomedical Sciences Program and the Hajim School of Engineering and Applied Sciences,

along with a number of undergraduates. For a small subset of students in the course whose interests focused on technologies that were unlikely to be under the purview of FDA/CDRH (e.g., projects that included drugs or biologics), we used a corollary to the Pre-Submission Program, a mock pre-Investigational New Drug (pIND) Project; thereby, allowing those students to ask regulatory experts questions about their preclinical or clinical needs.

As the course matured, we desired to bring in Regulatory Science elements that would serve in addition to the Regulatory Affairs foundation of the course [4]. A fitting conclusion to the discussion of these concepts was to have the students take part in the *America's Got Regulatory Science Talent* Student Competition (AGRST) [5]. Created in partnership with the University of Maryland and working closely with the FDA's Office of Regulatory Science Innovation (ORSI) [6], this AGRST student competition provides any student matriculated at the University of Rochester the opportunity to present their creative solution to challenge highlighted in the Regulatory Science focus areas as outlined by the FDA [7, 8]. The FDA first released their Regulatory Science Priority Areas in 2011, with subsequent updates in 2012, 2021, and 2022. Each year, teams of up to four students review what the FDA has updated and prioritized as their most pressing needs and then create a unique solution to present to judges in a 5-min competition setting.

Methods

To conduct the review of our courses, we used three approaches—a career path review through professional social networking tools, an online survey to all course participants over the last 10 years, and an informal emailed survey to professionals engaged as reviewers for the mock Pre-Submission Project. First, using the course rosters from each offering of the course, we identified 202 total students and noted what type of educational program they were in at the time of taking the course, i.e., undergraduate or graduate degrees and type of discipline. We then searched for each student on the professional networking site LinkedIn. This enabled us to find contact information and also current employment titles for the majority of the students who participated. For those students not identified on LinkedIn, we used departmental records for alumni to identify similar information. For participants from the first 5 years of the courses, we also identified the number of promotions over the time since graduation.

To obtain perspective from course participants, we designed an anonymous online survey to be delivered on the Qualtrics platform (Qualtrics, Provo UT). The survey and our planned protocol were submitted to our Institutional Review Board and was received a Not Human Research determination. After initial invitation in July 2023, non-respondents were given two additional reminders before the survey closed. The survey results were exported to Microsoft Excel (Microsoft, Redmond WA) for analysis of quantitative responses with descriptive statistics. Open ended responses were reviewed to identify general themes and opportunities for improvement. Survey questions focused on the impact of the course content and experiences on interviews, learning curves, sense of preparation as well as frequency of application of the material. The survey also allowed us to assess the transfer of learning and skills to the workplace [9]. In addition to general questions about the course, specific questions targeted special projects such as the mock Pre-Submission Project, AGRST competition, and patentability reviews. The survey was estimated to take less than 10 min, and included branching logic to tailor questions relevant to the year that each participant completed the course.

We also reached out by email to 45 professionals who had served as reviewers for the mock Pre-Submission Project. This included individuals from the FDA, external consulting firms, and medical device companies. Our inquiries included approximately five questions that were primarily open-ended. These responses were reviewed for qualitative findings related to reasons for participation, satisfaction with students' effort, and time commitments required.

Results

Our career-related demographic review of the course participants identified 202 students who were formally registered for one or both of the courses in our sequence. The majority of the students (140 or 69%) were enrolled, or intending to enroll, in our CMTI program and thus, the course sequence was a mandatory part of their curriculum. In addition, there were two undergraduate students, 35 PhD students, and 19 students from other MS programs. Our course enrollment started at 11 students during our first year, growing, with some fluctuation to 24 students in year ten, and an average class size of twenty students. Detailed information about the distribution of course participants is shown in Fig. 2.

After excluding any students still enrolled in programs over which the authors could have future supervisory roles, we identified contact information for 184 students, with approximately 90% found on LinkedIn, and the remainder identified through departmental contacts across the university. The survey had a response rate of 53%, three of whom actively chose not to participate after opening the survey, and a completion rate of 95%, leaving us with 87 responses with representative respondents from each of the 10 years of the courses offering. The response rate from students in the CMTI program was slightly higher, but there were still

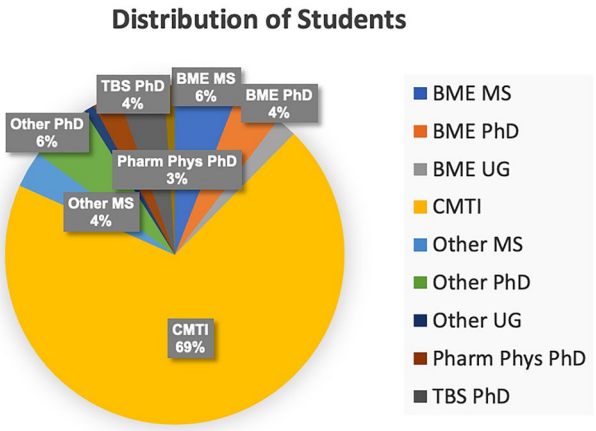

Fig. 2 Detailed information about participants in the BME431 and BME432 course series. *BME* Biomedical Engineering, *UG* undergraduate students, *TBS* Translational Biomedical Science Program within the CTSI, *Pharm Phys* Pharmacology and Physiology. Students in the "Other" category included departments such as Microbiology, Immunology, Toxicology, Neuroscience, and Biophysics

several representative responses from all other types of students (MS, PhD, undergraduate) from various disciplines.

Our initial review of career paths identified a wide range of job types, with the majority in design engineering, research and development, and quality engineering, as shown in Fig. 3. This distribution was confirmed by questions in our online survey, which also indicated that many participants had diverse job responsibilities. While activities related to regulatory and intellectual property may be inherent to many of the career paths identified, only 9% had identified roles directly related to these specialty areas, with an additional 21% in quality engineering, which is often related to support for regulatory pathways. Review of course participants' career paths also indicated successful trajectories with several notable promotions over the time since completion of the course. Numerous participants listed titles such as principal engineer, senior scientist or manager. An averge of 2.6 promotions were identified for those who participated in the first 5 years of the course.

Survey results indicate that our courses were well-received, with all but three respondents indicating that they would recommend the course to others. Respondents indicated that the courses had a positive influence on experiences in job interviews (32% very positive, 43% slightly positive) and their learning curves at initial positions (28% very positive, 32% slightly positive). In addition, when asked how prepared they felt with respect to course topics compared to other engineers, scientists or clinicians starting at the same time, our respondents stated that they felt much better prepared (45%) or slightly more prepared (41%). This positive effect is notable given that frequency of use of course content was highly varied among respondents, with 36% stating that they used the content at least once per week, but 14% using it only once per year and another 25% giving no estimate. In their open remarks, respondents mentioned that the course gave them more concrete examples to describe their knowledge of regulatory or IP topics. In some cases, the terminology was most useful, and for others the ability to apply concepts to a project experience was noted as helpful. Numerous responses gave specific examples of ways that the skills and knowledge gained in the courses were applied to work activities or responsibilities.

To assess the course elements with the greatest impact, we asked participants to review several key course activities with respect to their contributions toward understanding the commercial pathways or knowledge of career options (Fig. 4). The mock Pre-Submission Project, which was

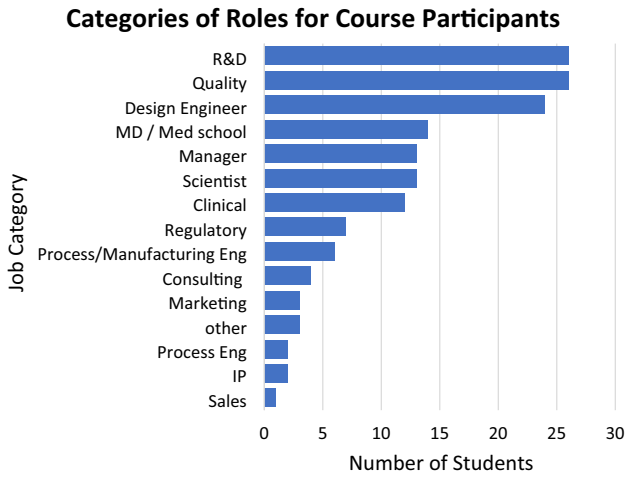

Fig. 3 Roles identified from career path review of former students who had participated in one or both of the courses reviewed. In this chart, the closest category was selected for each student, though the subsequent survey shows that many roles are quite multi-disciplinary

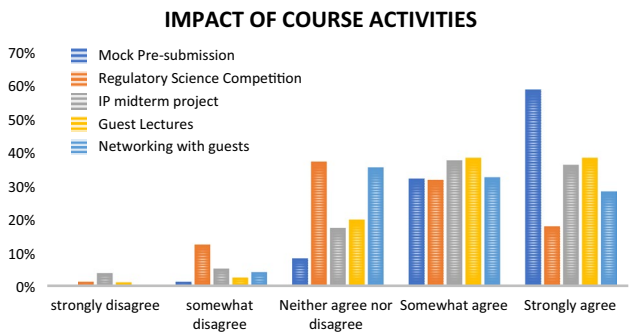

Fig. 4 Impact of various course activities identified by survey responses. Students were asked: "Consider the following course activities in terms of how much you agree or disagree that they contributed to your understanding of commercialization pathways or knowledge of career opportunities"

started in 2018, was one of the most impactful aspects of the course. Nearly 60% of respondents strongly agreed that it contributed to their understanding of commercialization pathways or knowledge of career opportunities. For those who participated, nearly all agreed that it clarified their understanding of the FDA processes. This understanding was gained whether or not the review had an impact on their ongoing projects, and 75% agreed that their experience with the project was beneficial in their job interviewing process. For those who have been involved in FDA submission activities in their current roles, nearly 50% found the experience very valuable in helping them to prepare or anticipate challenges.

Course content related to intellectual property was also well-received by those who responded to our survey, with 32% describing it as having considerable benefit in their careers and 41% having slight benefit. When asked about what aspects of the content was valuable in careers or design/research projects, most respondents listed several topics, with the most frequently selected topic to be "learning how to perform searches" (selected by 82%). This was followed by patentability opinions (60%), freedom to operate opinions (51%), licensing due diligence (37%), opinions (30%), and drafting patent claims (28%).

Our courses are designed not only to introduce content related to regulatory and intellectual property topics, but also to introduce career paths and occupational activities. Only 20% strongly agreed that they had taken the courses because they knew that they were interested in careers involving regulatory or intellectual property activities. In contrast, 31% strongly agreed and 46% somewhat agreed that the course had helped them consider several options for careers related to medical product innovation. Ultimately, 75% of respondents agreed strongly (36%) or somewhat (39%) that the course content was relevant to the career path that they had chosen.

Our courses use a novel approach of combining topics related to FDA and IP into a pair of courses in order to provide a closer "just-in-time" match between classroom experiences and ongoing design or research projects, while also demonstrating how companies must consider potential implications arising from these two topic areas when pursuing commercialization of a medical product. Respondents generally agreed (33% strongly and 42% somewhat) that the course content was presented at approximately the right time to be useful. When asked if they would prefer if the content were split into two separate courses, most were neutral—35% neither agree nor disagree. However, 12% strongly agreed that such a split would have been preferred, with no apparent distinction by the type of degree program being pursued. The overwhelming majority of students agreed that having assignments that were directly applicable to their research or design projects was helpful in developing and retaining understanding of course topics. Of note, the only respondents who strongly disagreed with this were students in PhD programs outside of Biomedical Engineering.

We received feedback from thirteen professionals who served as reviewers for the mock Pre-Submission Project, for a response rate of approximately 25%. All respondents found the effort rewarding and a reasonable time commitment. Estimated time commitments varied based on experience and effort needed, with most ranging from 1 to 2 h, though one reviewer described spending approximately 20 h. Many enjoyed working with students and recognized the importance of educating the next generation of reviewers and innovators. Several reviewers mentioned the goal of education as part of the mission of the FDA and found this "real-world" experience a powerful tool to disseminate information and possibly recruit new reviewers.

Discussion

Providing course content on the FDA regulation of medical devices and intellectual property for biomedical engineering students can be quite a challenge, especially in a manner that is both engaging and easily retained for future industry application. While seminars and lectures can provide the terminology and basic concepts, a better understanding can be developed when students are required to directly apply material to design and/or research projects. Based on feedback from former students and professional reviewers, our novel course sequence has provided an approach for training that is highly valued and offers a realistic and relevant exposure to commercialization pathways for medical product innovation.

The review of our course was based on a review of participants, an online survey for course participants and an email survey to external professionals. The response rate for our survey was approximately 50%, with an excellent distribution across the 10 years of former students. This response rate is slightly above the average found for education related surveys [10, 11], and perhaps impressive given its timing in mid-summer and the lack of incentives for participation. It is possible that there may have been a selection bias leading to slightly higher favorability findings, since satisfied students were more likely to respond. However, the feedback provided was candid and included many recommendations for improvements. Our qualitative survey approach and the lack of a control group limited our ability to assess knowledge gained from the courses. Because the course was designed specifically to support a new MS program, it would not have been feasible to exclude some students from participating, and no historical data were available for reference. Feedback from external reviewers, survey respondents who are now in hiring positions, and our review of career progression support our findings. While their career trajectory has not been

compared to a control group, the course participants appear to have found professional success in their chosen areas.

Our courses were primarily designed for MS students in a medical device design program, for whom it was required. However, our review of participants highlights the number of students who chose to take the courses as electives. Generally, these students were considering careers in industry and recognized the importance of understanding medical device regulatory paradigms and IP related topics for their future paths. The undergraduates taking the course were typically advanced students and performed well in comparison to the graduate students. Our senior design program covers introductory material in both regulatory and IP topics. However, the courses being reviewed go into much greater depth, in part by requiring more detailed assignments and activities such as the mock pre-submission project. This format would be difficult to manage for the 60–70 students typically in our undergraduate class. We did have numerous students from translational biomedical sciences or pharmacology areas, whose interests were often more related to pharmaceuticals than devices. Some of these students expressed frustration with the courses' emphasis on FDA regulation of medical devices and IP analysis and modes of protection for medical devices, rather than drugs or other biotechnology. This highlights possible opportunities for a parallel course or further modifications of assignments to better meet their needs and interests. One recent graduate mentioned that knowledge of regulatory affairs was "exceedingly rare for bench scientists" and thus they stood out in interviews. While some non-CMTI students had more difficulty finding relevant projects on which to base their assignments, it is clear that there is demand for this sort of elective course from a wide range of students at our institution.

It has been suggested [12, 13] that experiential learning increases motivation and offers the best opportunities for students to develop understanding and retain concepts. The retrospective survey approach taken did not offer proof that our approach improved learning when compared to seminars, lectures or case studies. However, our survey results highlighted the value placed on assignments directly applied to ongoing projects and those involving interactions with external professionals from the FDA and other industry partners. In particular, the mock Pre-Submission Project stood out has highly impactful, both for developing understanding of regulatory concepts, and in interviews and learning curves at new positions. Several comments clearly demonstrated the transfer of skills and knowledge to current roles. In open-ended responses, student participants offered the following comments:

> The pre-sub project was a very accurate representation of participating in an actual pre-submission process with the FDA. It was helpful with drafting questions for feedback and understanding the different needs of the various types of submissions and clearances.
>
> The pre-submission helped to understand exactly what information the FDA would want for submission, and furthermore cemented our knowledge of being able to find the guidance necessary for any future medical device submission. I don't work within Regulatory; however, having this knowledge of finding the right guidance has helped me in discussions with regulatory specialists.
>
> Helped understanding of technical writing so my communication with regulatory affairs is wonderful.
>
> In my first year on the job, I wrote and successfully submitted a 510k using the knowledge I learned in this class
>
> The course focused on medical devices and my current position is related to biologics. However, coming into the role with a non-zero understanding of the general requirements the FDA expects was beneficial.
>
> It was great to have an actual experience to speak to in interviews instead of just saying I learned about regulations

Although we did not specifically ask about oral and written communication skills, we were pleased to see this topic come up within several open-ended comments. There were several activities conducted during the class that required practice developing students' communications skills. In the fall semester the midterm assessment included an oral presentation, and the spring semester included a presentation related to regulatory science. In addition to other weekly homework assignments, the pre-Submission application document allowed them to hone their written skills, while closely following the guidance set forth by the FDA. A subsequent call with their FDA or third-party reviewers required a brief presentation followed by design and regulatory discussion regarding their pre-Sub questions and the feedback from the FDA.

While coordinating the timing of that assignment has always been challenging within an academic framework, the process was deemed realistic and our external reviewers also recognized how valuable it was for students. The FDA reviewers found it rewarding and an opportunity to train new innovators, while also offering an opportunity for recruiting. As our program has grown, and especially with the impact of the pandemic, we began to identify outside reviewers to supplement those at the FDA, finding them to be a suitable addition to allow for sustainability of the approach. Interactions directly with the FDA were still preferred by students, but external reviewers provide an interesting alternate perspective on regulatory approval processes. These external reviewers were often regulatory consultants, or others with experience in regulatory affairs familiar with

the pre-submission process. They also found working with students to be rewarding and a manageable time commitment for this voluntary contribution to our program, which is crucial for the sustainability of this approach. They offered the following comments related to their participation:

> I'm happy to be involved in these types of activities and consider education part of our official responsibilities. Education is something we do with "real" sponsors, not simply in the context of mock submissions.
> I feel passionately about providing students with real-life learning experiences that are useful and relevant.
> I believe it is incredibly beneficial for students to have interacted with FDA and understand what we do, what we review, what kind of feedback we provide, and how we can interact with the medical device industry. I also believe that including regulatory real-life learning experiences as part of an engineering curriculum is something that is missing from many BME curricula (both at the undergraduate and graduate level) and should be included in more programs.
> The University of Rochester Mock Pre-submission Program not only gives students something they can add to their resumes but is a great recruiting opportunity for FDA. The more exposure FDA and the Office of Product Evaluation and Quality (OPEQ) has with high-quality engineering students who are interested in product development and regulatory affairs/science, the better future job candidates we can get.
> It is enjoyable working with people who are interested in the topic and really invested in what they're doing. They come up with some neat projects!
> This is an awesome program and requires students to better understand the medical device space and not just the design elements. This is a great add to the course work.
> I enjoy giving back and helping others learn. Even if they don't want to become a regulator and they go into industry, having the information somewhere in the back of their mind may help both them and us somewhere. I think it's also good to let people know that there are good people working at FDA, that we're not robots, we're not just out to get people, and truly care about our work. It also makes them aware of a career path that they may not know existed (I didn't, but maybe it comes through more in BME type work).

In addition to training students in medical device design, another goal of our program is to introduce students to the wide range of opportunities available in the medical innovation landscape. Our review of the career paths of students taking these courses reinforces the many types of positions taken. While many are in design engineering or research and development, a large number pursue positions in quality engineering, clinical support or medical professions. Interestingly, while a relatively small number enter careers directly related to regulatory affairs or intellectual property, the course content was still appreciated as a valuable education experience. In addition, students welcomed the fact that the course introduced them to career paths they hadn't previously considered. The instructors for our courses have professional expertise in the areas of regulatory affairs and intellectual property, thus offering direct exposure for students to these careers. If such expertise were not available, some of the course content may be delivered by a traditional faculty member. However, engaging such professionals for direct student discussions, case studies or feedback on assignments might still enhance student understanding of course topics and career opportunities. Remote learning approaches may make this feasible.

As noted above, our content related to regulations currently focuses on the US FDA. While this existing scope lends itself to a full schedule and there may not be room for additions, we were interested to read feedback suggesting that we add content on audits, and regulations outside of the US.

Our survey suggested that the material related to intellectual property was of slightly less benefit to the respondents. By reviewing the types of careers chosen by our course participants, detailed knowledge of licensing agreements, drafting of patent claims and other opinions may be less frequently within their scope of direct responsibility. In addition, when comparing the types of assignments for the two parts of the course, we note that the FDA regulatory component has activities that involve more direct applications of content to ongoing projects or research. Therefore, it may be of benefit to create more experiential active-learning projects to the IP component of the courses, or to consider engaging more external partners to enhance understanding of the impact and potential career opportunities in intellectual property.

In summary, our 10-year review of our courses suggests that many of our goals have been met in providing our students exposure to topics related to FDA regulations and intellectual property. We have gone beyond lectures and quizzes to create meaningful assignments in a sustainable model that brings value to a variety of students.

Acknowledgements We appreciate the time and contributions from all of the former students and other course participants who responded to our survey.

Author Contributions JA and AL planned the manuscript and survey. JA managed the ethics approval and gathered input from external reviewers. EK gathered input from reviewers at the FDA. AL disseminated the Qualtrics survey. JA and AL drafted manuscript text with input from EK and JB.

Funding These courses were developed in part through a course and program grant from National Collegiate Inventors and Innovators Alliance (Lerner, #10624-13). The University of Rochester Clinical & Translational Science Institute is supported in part by grants UL1 TR002001, KL2 TR001999, and TL1 TR002000 from the National Center for Advancing Translational Sciences, a component of the National Institutes of Health. https://ncats.nih.gov/director https://www.urmc.rochester.edu/clinical-translational-scienceinstitute/funding/nih-funding-acknowledgment.aspx.

Data Availability To ensure privacy of reviewers and survey respondents, data will be available by request to authors only.

Code Availability Not applicable.

Declarations

Conflict of interest Not applicable.

Ethical Approval The survey and our planned protocol were submitted to our Institutional Review Board and was received a Not Human Research determination.

Consent to Participate Responding to the online survey was optional, and it included an option to refuse consent and not participate as the first question.

Consent for Publication All email and survey respondents were aware that we were preparing a manuscript for publication.

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