

# AIMBE's FDA Scholars Program

*Advancing innovation and discovery from the lab to the marketplace.*

## Spotlight on the 2017-2018 AIMBE Scholars



### **Matthew M. Jacobsen, Ph.D.**

Prior to my time as an AIMBE scholar in the Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA), I had only ever been exposed to negative opinions of the regulatory agency. These interactions served to inspire me to get involved in the space between science and regulation, to become part of the solution, and to try to ameliorate these sort of wounded relationships between industry and FDA. Thanks to the AIMBE Scholars Program, I have had a wonderful opportunity to gain firsthand experience with the agency and I can say confidently that my time in CDRH has given me a great deal of encouragement for the future of the regulatory landscape in the United States. This is because a more progressive culture has been taking root in recent years throughout the Center, shifting towards proactive problem solving rather than reactionary gatekeeping of America's medical devices.

In this vein, many new Center policies and programs have been spearheaded in order to advance regulation to both address persistent regulatory issues and get ahead of cutting edge medical developments. As an AIMBE Scholar, I have been privileged to work with two new programs that are driving towards a faster, more efficient review process with the goal of getting new medical technology to patients as quickly as possible. The two programs are the Medical Device Development Tools (MDDT) Program and the Software Precertification (Pre-cert) Pilot Program.

My work with the MDDT Program has been focused on its programmatic expansion, both internally and externally. Because it is a relatively new program, there was not much familiarity with its goals and purposes among the medical device reviewers within the Center. Given this obstacle, part of my efforts drove towards engaging reviewers with two goals in mind: first, to educate them on the program; and second, to begin fostering a collaborative relationship to cater the program benefits towards the specific work of each review division. In particular, we needed their feedback to know which tools we should pursue to bolster FDA's repertoire of qualified tools. In order to be comprehensive in this approach, I leveraged existing FDA programs with Center-wide agendas, such as the Critical Path and Regulatory Science Needs programs, to better understand what are CDRH's current regulatory gaps and needs. Specifically, I filtered this large quantity of information in order to find

where new potential MDDTs could be used to address these needs. After this initial filter, I then developed an objective scoring system to rank all of the relevant feedback in such a way as to produce a rank order of potential MDDT targets that would address the highest priority areas possible in the most reasonable timelines. This scored list has been filtered again based on currently available Center resources. From this, a robust and targeted external outreach strategy is now being developed from these priority areas. In combination with FDA external resources, such as the Network of Experts, the next steps will be to establish new collaborations with the express intent of developing tools that will accelerate the review of medical device submissions through the use of qualified MDDTs.

The second program to which I have been able to contribute is the newly forming Software Precertification (Pre-Cert) Pilot Program. This program intends to reconfigure the regulatory review paradigm for software by appraising companies for their excellence and reducing or forgoing entirely product-specific review. A major challenge in accomplishing this is answering the question of how a new regulatory review pathway can be developed that is both in line with these ambitious goals while also maintaining legality within the framework of current regulatory legislation. I have helped in answering this question by providing insight based on the framework built around the MDDT program, which provides a review structure that is not based on the traditional medical device review pathways due to its unique place in evaluating tools. Thanks to the lessons learned from my experience in managing the MDDT process—including streamlining the program’s standard operating procedure, external templates, and program communications—we have been able to avoid duplication of effort by applying the same foundational elements to develop the Pre-Cert program’s working model. In particular, the current working model incorporates the use of the informational meeting structure to engage in a review process with customized timelines and processes without being beholden to the stringent guidelines mandated by the MDUFA IV legislation as seen with traditional pathways such as the 510(k). This flexible system allows FDA to have as interactive a review as desired with submitters and has helped flesh out the working model for both the excellence appraisal and streamlined review workstreams of the current Pre-Cert working model.

Taken together, these roles have given me the opportunity to take part in a great endeavor to put FDA at the forefront of medical science innovation. I am very pleased to have witnessed firsthand real effort to build a better future with industry and FDA working as partners rather than adversaries with a shared interest of ensuring delivery of safe and effective medical science to the United States. Having gained this experience, I hope to build upon it as a foundation of my professional depth within the regulatory field. My career aspirations remain the same: I intend to continue improving the interface of the medical science enterprise, i.e. between government, academia, and industry. I will do this by continuing to gain additional hands-on experience that will enable me to transition organically into roles more vested in policymaking and advocacy. I believe that continuing in this vein will put me in a position to help accelerate improvement in public health while making the process more efficient and cost-effective. I know that I am more capable than ever to engage in this work thanks to the knowledge and experience I gained serving as an AIMBE scholar.

