AIMBE FDA Scholars Program

Advancing innovation and discovery from the lab to the marketplace.

Spotlight on the 2017-2018 AIMBE Scholars

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During my PhD, I learned that healthcare innovation requires multi-disciplinary teamwork at the border between science, business and government. The AIMBE Scholars Program appealed to me because of the opportunity to build upon my scientific training and contribute to FDA processes that directly influence healthcare innovation and delivery. My projects throughout the Scholar's Program at FDA's Center for Devices and Radiological Health (CDRH) spanned across the total product life cycle, from efforts to foster innovation within the start-up community to analyzing best practices for maintaining marketed medical devices. These learning experiences were invaluable to my career growth and have allowed me to appreciate FDA's perspective on emerging medical technologies and policymaking.

My primary responsibility as a scholar was to analyze third party medical device servicing as part of a cross center policy working group. Medical device servicing is vital to the healthcare system since many devices, such as imaging equipment and endoscopes require maintenance or repair for their continued safe and effective use. I was tasked with contributing to a report to Congress on the quality, safety, and effectiveness of medical device servicing, as mandated by the 2017 FDA Reauthorization Act (FDARA). I collected and analyzed medical device servicing information and had the opportunity to speak with various stakeholders to shape my understanding of the issues from different perspectives. This project required me to learn about the types of post-market safety data collected within the center and the quality system regulations that medical device manufacturers must comply with. I have also been coordinating efforts across the center to develop a guidance document to clarify the important distinction between medical device servicing and remanufacturing. During this project, I learned strategies for consensus-building and effective stakeholder communication, critical skills for well-informed policymaking.

Outside my role with the medical device servicing workgroup, I served in support roles for three initiatives at CDRH. Firstly, I was involved with the Innovation Group within the Office of the Center Director to provide early regulatory assistance to NIH grantees

through the NIH Commercialization Accelerator Program. This project was especially rewarding to me since I had experience developing commercialization pathways for early stage medical technology startups at the University of Pittsburgh and knew firsthand how hard it was to find regulatory clarity. In this role, I matched medical device startups with pre-market review staff to facilitate feedback on early regulatory strategy. CDRH's collaboration with the NIH CAP program reinforced FDA's commitment to providing patients with timely access of innovative technologies and a recognition that new and innovative solutions often come from small companies. This project also highlighted the importance of cross-agency collaboration to achieve practical and impactful outcomes.

Secondly, I supported development of the Digital Health Software Precertification (Pre-Cert) Program, as outlined in the Digital Health Innovation Action Plan. Digital Health technologies are becoming more and more prevalent in healthcare delivery and pose unique challenges to existing regulatory paradigms. The Pre-Cert Program is intended to provide more streamlined and efficient regulation of software-based medical devices for timelier and safer patient access. CDRH is developing this program through persistent engagement with the public and participants in a Pre-Cert pilot program. As part of the working group, I strategized ways to implement different components of the program and worked to incorporate external feedback into the working model framework. Contributing to the development of the Pre-Cert program was very exciting because it required stepping outside the box and rethinking how to effectively regulate technologies that are rapidly changing.

My third support role was in developing materials for the Case for Quality Initiative (CfQ). CfQ is being established in collaboration with the Medical Device Innovation Consortium (MDIC) with the goal of improving quality of medical devices and patient experience. I created educational materials about CfQ geared towards early stage startups to help facilitate interactions and receive input from small medical device companies. Overall, these support roles exposed me to several mechanisms FDA uses to engage external stakeholders in the decision-making process and I was impressed by the center's highly collaborative approach to building new policies and programs.

Through my experience as a scholar, I gained a great appreciation for the forward-thinking and impactful work that is done at FDA. My mentors at CDRH provided me with endless support and opportunities to learn and have enriched my understanding of the role of regulatory processes within the larger healthcare ecosystem. I am confident that these experiences will allow me to more effectively contribute to the shared goal of enhancing public health and I am exceedingly grateful to have had the opportunity to participate in the Scholar's Program.