

# AIMBE's FDA Scholars Program

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

## Spotlight on the 2016-2017 AIMBE Scholars



### **Chelsea Gregg, Ph.D.**

Upon completing my PhD, I wanted to understand how emerging medical technology translated into clinically impactful products. The AIMBE Scholars Program was an ideal postdoctoral opportunity for me to learn about the medical device industry from the perspective of the regulators. Furthermore, I was excited to gain in-depth knowledge of the review process, regulation and policy development while contributing to the initiatives of the agency. My time as an AIMBE Scholar was incredibly rewarding and far surpassed my expectations. I am amazed at the scope and importance of the projects I had the privilege to work on. The AIMBE Scholars Program has contributed significantly to my own professional development and larger understanding of the medical device industry.

As a Scholar, I worked in the Office of Device Evaluation (ODE) in the FDA's Center for Devices and Radiological Health (CDRH). During my time as a Scholar, I worked on four different projects focused on the initiatives outlined within the Strategic Priorities of the Center. My projects included device reclassification for better premarket-postmarket data balance, establishing the regulatory framework for preamendment unclassified devices, regulatory questions for emerging digital health technology in combination products, and support of the establishment of a quality management unit. Overall, my projects were focused on the premarket aspects of the total product life cycle.

The device reclassification project was concerned with appropriate premarket-postmarket data balance with a particular emphasis on downclassification of Class III PMA devices to Class II with special controls. This project has been an ongoing effort of CDRH and prior to my participation on the project, all PMA device candidates for downclassification had been identified after a thorough retrospective review. My contributions to this project came in the form of project management. While working closely with the Regulatory Advisor of each Division within ODE, I spearheaded communication with the staff on the status of each proposed order including prioritization and timelines for each in addition to monitoring progress and assisting in order drafting when needed. The device reclassification project is a continuing effort at CDRH but the overall end goals for this initiative is to accelerate U.S. patient access to high quality safe and effective medical devices by removing unnecessary regulatory burdens.

Similar to the device reclassification efforts, a second project I led involved establishing the regulatory framework for pre-amendment unclassified devices. After the Food, Drug, and Cosmetic Act was amended to include medical devices as a regulated product, all medical products that were already marketed were called unclassified devices. While many of these devices have been classified, some remain unclassified. Outside of administrative action that can be taken, a formal process is required to regulate these unclassified devices including a panel. In April 2015, an Ear, Nose, and Throat (ENT) Devices panel evaluated 8 different product codes and a consensus between the panel experts and agency was achieved on the necessary classification and general/special controls for each device type. Based on the panel material, I drafted a proposed rule that encompassed information such as the regulatory history of the device, its intended use, the special controls for the device if necessary, and the regulatory authority of the agency to enforce this rule. When I left the agency, I finished a draft proposed rule which will eventually be open to the public for comment. It was exciting for me to take ownership of this project and it helped me gain an appreciation for the challenges navigating regulation development, balancing the technology with the law.

Outside of my work in the device reclassification and classification, I served in support roles for two emerging areas of interest at CDRH. The first was digital health considerations for emerging medical technology. CDRH is establishing a centralized digital health unit and digital health program that incorporates many aspects of this type of technology including wireless devices, mobile medical applications, telemedicine, interoperability, standalone software, and cybersecurity. Digital health technology is becoming an important part in new medical devices and presents unique and difficult regulatory challenges that require a lot of consideration. I largely participated in evaluation of mobile medical applications in the context of combination products. This project is in early phases where the regulatory framework and necessary considerations are being evaluated to ensure that new combination products with a mobile medical application component are safe and effective. Being a member of the efforts in digital health has been really interesting from an engineering perspective but I also had the opportunity to work with the Center for Drug Evaluation and Research on these efforts which enhanced my learning and perspective of the agency.

My other support role was in the establishment of a quality management unit within CDRH. The impetus for these efforts is stipulated in the MDUFA IV commitments with the goal to support better review consistency, particularly on cross cutting issues (e.g. biocompatibility) within the CDRH to ensure that all device submissions are being held to the same accountability standards ensuring a reliable, efficient review process.

My experience as an AIMBE Scholar has been hugely positive and rewarding. The opportunity to spend time working at the FDA is invaluable and has given me perspective and understanding of the medical device industry that I would not have gained at this point in my career otherwise. The mentorship that I had at the agency was phenomenal and I appreciate the trust the staff at the FDA put in me when working on my projects. Due to this opportunity, it has shaped the idea of what I want my career to look like and I am excited to begin working in the medical device industry.

