AIMBE's FDA Scholars Program

Advancing innovation and discovery from the lab to the marketplace.

Spotlight on the 2014-2015 AIMBE Scholars

Dr. Christopher J. Medberry

As a trained Biomedical Engineer with a Ph.D., I have come to understand that systems beyond the purely technical aspects of medical device design and development play an equal role in translating innovative research and ideas into useable products. My time as an AIMBE Scholar has reinforced the importance of these systems through the perspective of regulatory policy. As I have learned, good policy can stimulate innovation and create an environment that fosters medical device development. From the introductory Public Policy Institute to the projects I worked on, the Scholars Program furthered my knowledgebase far beyond the traditional technical training into an in-depth understanding of the policies, processes, and perspectives associated with medical device development.

Beginning the AIMBE Scholars Program with a Public Policy Institute opened my eyes to the current political environment and the role that environment plays with how the FDA achieves its mission. I had been unaware of the extent to which different groups place their influence on how the FDA seeks to protect public health. Ranging from directives from Congress to issues raised by industry and advocacy groups, the FDA must maintain a balance across the unique perspectives. And through this all, the FDA regulates close to a quarter of American GDP with a budget that is consistently underfunded. These and other insights set the foundation for my understanding of many of the major policy decisions within CDRH and were crucial for my work in both the Standards Management Staff and with the Executives in Residence Labeling Initiative.

The development of standards for medical devices is an opportunity for FDA and industry to talk, work, and learn together. In my work with the Standards Management Staff, I have had the opportunity to learn from engineering experts

and watch medical device manufacturers, FDA, and clinicians come together to discuss critical problems and develop collaborative solutions that will help their overall field. My efforts focused on taking the critical feedback provided in response to a draft guidance document, evaluating the comments, and working with the Standards Management Staff to develop consensus on the revised document. In this process, we evaluated how standards are currently used in FDA pre-market submissions and devised systems aimed at making it easier and more efficient for submitters to use standards. Ultimately, our group attempted to balance the varying perspectives of the commenters to create policy that would benefit the center.

My work in the Executive in Residence Labeling Initiative evaluated different, yet important aspects of the medical device industry: the lack of a standardized content and format for medical device labeling. The efforts stemmed from anecdotal evidence of adverse events deriving from poorly constructed labeling materials. Our goal, then, was to develop a standardized content and format that could be used across the range of medical devices (yes, tongue depressors to MRIs) containing information that would be easily accessed. In essence, we wanted to develop a system that would enable a user of medical devices to quickly identify key pieces information regardless of which company manufactured that device. This experiential learning process has taken me through reading and evaluating labeling for several different devices, creating clinical scenarios, and performing human factors testing that quantitatively evaluated current versions of manufacturers labeling to a standardized content and format version of that same labeling. By immersing myself in this process, I have come to understand the importance of usability testing for all aspects of a medical device.

Overall, I could not be more grateful for my opportunity as an AIMBE Scholar. I've gained an immense amount of knowledge into the regulatory process that will be immediately applicable in my next role as a Senior Regulatory Affairs Specialist. Further, the insights I've gained into the FDA's perspective, culture, and people will be instrumental in guiding medical devices through the regulatory pathway. In the end, I believe FDA and medical device manufacturers are two sides of the same coin and by working together we can create systems that truly have a positive impact in the lives of patients around the world.