AIMBE's FDA Scholars Program

Advancing innovation and discovery from the lab to the marketplace.

Spotlight on the 2015-2016 AIMBE Scholars

Dr. Robert Allen

Before joining the AIMBE Scholars program, I directed a professional development program for life science PhD students at the University of Pittsburgh. So when it came time for my job search, I took my own advice and sought opportunities with strong career-building value. I applied to the AIMBE Scholars Program because it seemed like an excellent opportunity to gain experience in the in-demand field of regulatory affairs, practice my soft skills in a professional setting, and grow my professional network - all while doing work that advances public health.

My AIMBE Scholars experience delivered on these expectations. I worked with the Regulatory Advisor team in the Office of Device Evaluation (ODE), Center for Devices and Radiological Health (CDRH), to appropriately reduce regulatory requirements for certain devices. This work benefits patients by creating a more economically favorable environment for current and new medical device innovation. My project focused on reducing unnecessary regulatory requirements using a process called device downclassification, which re-categorizes certain devices from a classification with more regulatory requirements and controls to one with less (e.g., from Class III to II or I). Devices are only downclassified when they can be regulated appropriately with reduced regulatory requirements, which translates into benefitting the whole medical device ecosystem by reducing the resources needed by both industry and FDA to ensure that new devices are high-quality, safe, and effective. Furthermore, downclassifications promote a least burdensome approach to medical device regulation, which is required by law. I found it exciting and rewarding to work on a project with the potential for large, positive impact on human health.

My responsibilities included project and data management, communication, and strategy development. My first task was to manage efforts to identify devices that could be considered eligible for downclassification without compromising patient safety.

My assistance significantly contributed to the on-time completion of a scientific review of over 160 device types regulated by ODE. Once the candidates for downclassification were selected, my responsibilities shifted toward moving these downclassification efforts forward. I developed a dashboard for managing workflow for these downclassifications, and I wrote work-instructions to improve the consistency and efficiency of the process. I also analyzed the regulatory histories of multiple device types across ODE to help the Regulatory Advisor team develop strategies that are consistent with FDA's past decisions. Concurrently, I developed written and oral communications to promote transparency and communicate strategy to both internal and external stakeholders.

This experience delivered substantial professional development value for me. I can complement my technical expertise with firsthand experience in device regulation, project management, and strategy development. Importantly, I now have new and stronger examples for describing my soft skills. Teamwork, resolving differences of opinion, and working under pressure were particularly useful experiences.

Perhaps the most unique benefit of the program was professional networking. At FDA I regularly met with regulators across a wide range of medical device areas. By working alongside these experts, I formed strong professional connections and learned their views on device regulation, technology trends, and career pathways. I met industry professionals as well. Through the AIMBE Scholars Site Visits, I met over 40 high-level decision makers at 5 large medical device companies. By having in-depth discussions with these industry professionals about my projects at FDA, I formed meaningful connections that would be difficult to achieve through online networking or cold-calling. I also met a variety of other medical device stakeholders: policymakers and lobbyists at the AIMBE Policy Institute, biomedical engineering faculty at the AIMBE Annual Meeting, and countless more professionals at industry-focused conferences for which AIMBE paid my attendance and travel.

Career value aside, I enjoyed my time with the AIMBE Scholars Program. It was particularly rewarding to work on projects whose primary objective was to improve public health. Like many people, I enjoy doing work that I believe in. My interest in improving public health was the reason I studied biomedical engineering, and it has been fulfilling to do work so directly aligned with that interest. I highly recommend the AIMBE Scholars Program to all life science PhDs who are interested in advancing public health while simultaneously growing their own career prospects.