

AIMBE's FDA Scholars Program

Advancing innovation and discovery from the lab to the marketplace.

Spotlight on the 2014-2015 AIMBE Scholars



Dr. Sonja Fulmer

“As a scientist, I have continuously enjoyed sharing my interest in biomedical research with non-scientists in order to help more people in the general public understand the significance of biomedical research. During graduate school, this grew into a career goal: to use my scientific training to influence public policy decisions. In order to explore this goal, I learned how to advocate for research funding; I considered how academic and industry scientists speak to legislators at the state and federal level; and I studied Supreme Court cases on scientific questions. However, I never gained an understanding of how the decisions made by scientists and policy makers at the U.S. Food and Drug Administration (FDA) affect the public health and biomedical industry until I became an AIMBE Scholar.

This immersive experience at FDA's Center for Devices and Radiological Health (CDRH) has been not only enlightening, but also very rewarding. Throughout my experience as an AIMBE Scholar, I have gained a greater understanding of the impact the FDA has on our lives. I am grateful to be a part of the process that brings high-quality, safe and effective devices to patients. Through this program, Scholars are placed in the Office of the Center Director, which provides scientific, policy and managerial leadership and direction to the seven offices comprising CDRH. Therefore, I have been able to interact with many program offices and gain an understanding of the Center's activities and functions as a whole.

Specifically, I was assigned to the Regulations Staff and Quality Management within the Office of the Center Director. Regulations Staff manages the Center's regulations development process, including communication, rulemaking and policy development, and citizen petition responses. In my role on this staff, I worked with CDRH teams to assist in rulemaking by drafting proposed rules and managing the clearance of the rules. I also managed the document clearance for

other Federal Register publications, including notices of availability for draft and final guidance documents and notices of workshops and public meetings. For each of these projects, I must understand the policy and rationale and be able to communicate this to Center leadership. As a member of Regulations Staff, I ensured that CDRH regulatory information is consistent with Federal statutes and regulations. In addition, I ensure that the Federal Register publications and other documents that I review promote FDA's public health mission. These documents provide the public with accurate, science-based information that communicate the regulatory decisions and policies of CDRH in order to assure the safety and efficacy of medical devices. When reviewing these documents, I strive to ensure that the information is conveyed in a clear and organized manner, so that the information is communicated effectively. Furthermore, by efficiently managing the review and clearance of rules and other Federal Register publications, I impact public health by ensuring the timely publication of these documents.

With the Quality Management team, I have implemented the recommendations and findings of the Booz Allen Hamilton Assessment of the Premarket Review Process. I have lead and supported the implementation of Quality Management recommendations, the recommendation to improve consistency of the review process, and to provide clarity to the eCopy process. In addition, I have worked to move forward two quality management priority areas, management review and document control. Many of my QM projects focus on CDRH's 2014-2015 Strategic Priorities, which were developed to help medical device developers choose the U.S. as the country of first choice for their technologies, as the country of first choice is a key contributor to early patient access to high-quality, safe and effective devices. My work on customer service aims to improve CDRH's interactions with stakeholders and colleagues, both internal and external, support better regulatory outcomes, and ultimately, improve patient health.

As I have gained regulatory policy experience during my tenure as an AIMBE Scholar, my commitment to use my scientific training to analyze and influence science policy has been reaffirmed. I will directly apply the skills I have acquired in regulatory policy, such as rulemaking, policy decision-making, and project management, to my role as a permanent FDA employee. The AIMBE Scholars Program is an immersive experience in regulatory policy that I cannot imagine having anywhere except at the FDA. Since there are so many scientists at the FDA, this policy fellowship is unlike many others. Instead of being the only scientist in a room, I am surrounded by scientists who are applying their scientific backgrounds to regulatory decisions. I am looking forward to continuing on this career path and grateful for the opportunity provided by the AIMBE Scholars Program.”

