**AIMBE FDA Scholars Program**  
*Advancing innovation and discovery from the lab to the marketplace.*

**Spotlight on the 2018-2019 AIMBE Scholar**

**Jason Ryans, Ph.D.**

Prior to becoming an AIMBE Scholar, I developed a passion for advancing biomedical research through entrepreneurship to turn that research into practical application. My graduate research focused on creating computational tools to better understand the mechanics of the lung during physiological distress and evaluating the potential effectiveness of mechanical ventilator treatment strategies. Outside of the laboratory, I pursued various entrepreneurial endeavors including co-founding a medical diagnostic startup company. These experiences provided a better understanding of the intricate technological, financial, and business-related processes necessary to commercialize biotechnology. However, I soon realized there was a key component that I knew little about, which was the regulatory process. I knew that further insight into the regulatory environment and its application could better prepare me for a career in bio-innovation. This led me to pursue the AIMBE Scholars Program where I trained in regulatory policy at the Center for Devices and Radiological Health (CDRH), U.S. Food and Drug Administration (FDA). As an AIMBE Scholar, I worked in the Office of Product Evaluation and Quality and assisted in the development and implementation of a new medical device clearance pathway known as the Safety and Performance Based Pathway.

The regulations, policy, and guidance staff that I worked with are responsible for developing various device-specific and cross-cutting regulatory policies to ensure that the regulatory requirements set in place for manufacturers best promote the safe and effective use of medical devices by the public. My primary responsibility was to assist in the development and implementation of a new medical device clearance pathway, known as the Safety and Performance Based Pathway. This new pathway would provide increased transparency to manufacturers and the public on the evaluation of medical device performance prior to entering the market. The development of the pathway included collaborating with divisions across the Center to develop device-specific policy guidance documents that would outline the devices eligible for the pathway, as well as the performance criteria to be assessed for a regulatory submission to the pathway. This required an understanding of the current device-specific recommendations, applicable consensus standards, relationship to other FDA policies, and the vision to
see how this pathway could be utilized. Implementation included identifying associated IT and processes updates within the Center necessary to allow for regulatory submissions to the pathway. Additionally, I was part of a working group to develop internal and external communications to message key points of the Safety and Performance Based pathway to a variety of stakeholders.

During my time as an AIMBE Scholar, I had the invaluable opportunity to significantly contribute to a project that is a regulatory priority for the FDA and a chance to hone new skills in regulatory science. I was exposed to a variety of policy related aspects of the regulatory process including premarket submissions, post market compliance, standards development, and advertising/promotion. My biggest takeaway from my time as an AIMBE Scholar was learning how to develop and properly interpret regulatory policy documents. This will be beneficial in my career as whether I stay in regulatory policy or move to private industry, these documents are the primary mechanism for FDA-established suggestions and requirements for the medical product industry. Additionally, through training courses, industry workshops and exposure to the work of colleagues around me, I have established a holistic understanding of how medical devices are brought to market and how they are regulated once they are marketed. Ultimately, the ability to collaborate and network with professionals ranging from device reviewers to the Center director has provided a pivotal foundation from which I wish to build my future career in the regulatory field.