AIMBE’s FDA Scholars Program

Advancing innovation and discovery from the lab to the marketplace.

Spotlight on the 2017-2018 AIMBE Scholars

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Throughout my career, I have been drawn to support biomedical innovation. During my graduate school research, I designed and manufactured numerous biomaterials with additional functionality for regenerative medicine applications. Post-graduate school, I worked for three start-up ventures that had developed biotechnologies spanning regenerative medicine, diagnostics, agriculture, and aquaculture. It was in pursuit of venture funding for these endeavors that I learned a base of knowledge in regulatory science and policy could further my career. I would be better positioned to understand and contribute to the total product lifecycle of innovative biomedical technologies from development, as I had started in graduate school, to commercialization, where some technology may ultimately require regulatory approval from the U.S. Food and Drug Administration (FDA or Agency). It was this that led me to pursue the AIMBE Scholars Program at the FDA where I worked on multiple projects that supported innovation at the Center for Devices and Radiological Health (CDRH). Ultimately, my efforts as an AIMBE Scholar focused on three major initiatives at CDRH, including support of the CDRH Guidance Program, Patient Preferences Group, and the Digital Health Software Precertification Program.

The CDRH Guidance Program is responsible for assisting in the development of guidance documents for CDRH staff, industry, and the public. Guidance documents describe the Agency’s interpretation of or policy on a particular issue, such as the design, production, or manufacturing of regulated medical products, information on regulated product submissions, which may include content or evaluation, as well as policies regarding hot topics, such as additive manufacturing or digital health. Development and clearance, meaning writing and review, of guidance documents is a complex process. In support of the 2018-2020 CDRH Strategic Priority of ‘Simplicity,’ my role was to streamline processes within the Guidance Program while continuing to support the development of guidance that is helpful for CDRH, industry, and the public. My efforts supported Center development and collaboration on standard operating procedures, work aids, templates, and process maps for guidance development, clearance, and issuance, as well as guidance implementation and guidance training for FDA staff and industry. I was also able to contribute to the development of a number of guidances, as well as work with the Guidance Program to keep our inventory of guidances up-to-date in our yearly review. This work was extraordinarily beneficial to develop skills in quality management, understand good guidance practices, and learn about CDRH and cross-Center interactions related to guidance.
Outside my main role in the CDRH Guidance Program, I also supported the Patient Preferences Initiative. Patient preference studies help determine what benefits and risks patients are willing to trade off when comparing treatment options, which makes involving the patient decision an important factor in regulatory decision-making for new medical devices. As part of the Medical Device User Fee Amendments of 2017, the Agency will ‘identify priority areas where decisions are preference-sensitive and patient preference information data can inform regulatory decision-making, in order to advance design and conduct of patient preference studies in high impact areas.’ In this project, our team was tasked to identify preference-sensitive areas that are of importance to patients, especially for patients that may have few medical device options to choose from where regulatory decisions are particularly impactful. We also worked with CDRH review staff who would also find patient preference information related to preference studies very useful so that patient input may be considered in the context of benefit-risk trade-offs in regulatory decision-making. Until this project, I had never thought of using patient input data as something that could be considered in regulatory decision-making. It broadened my view of the many types of data used in regulatory decisions and is a creative way to leverage patient input at CDRH to support its mission and vision while ensuring reasonable safety and effectiveness of medical devices.

I also worked with the Digital Health Unit at CDRH in the ongoing development of the Software Precertification (Pre-Cert) Program. Innovation in digital health is rapidly accelerating, from the creation of mobile applications that control infusion pumps for diabetic patients to computer-aided cancer diagnostics for healthcare professionals. In order to achieve the CDRH vision that patients have timely access to high-quality, safe and effective medical technology, CDRH has stated as part of the Digital Health Innovation Action plan to reimagine the approach to regulatory oversight of digital health technologies. The Pre-Cert team has focused on developing the pilot program where CDRH may take a firm-based approach in looking at the digital health technology developer rather than conducting in-depth reviews of each digital health technology. Digital health technology developers could be ‘precertified’ if they demonstrate a culture of quality and organizational excellence (COQE). Leveraging FDA’s understanding of a company’s processes related to software development and their COQE, FDA could potentially adopt a risk-based, faster regulatory approach to review digital health technologies. In support of these efforts, my work focused on further developing the risk-based approach to software review, which was initially developed by the International Medical Device Regulator’s Forum. While this framework set initial boundaries for software risk, I worked with reviewers, other FDA staff, pilot program participants, and external organizations to refine the risk framework. It has been exciting to work with the Pre-Cert team to develop a reimagined approach to regulation of digital health technologies that have rapid development and iteration cycles in comparison to traditional medical devices. It will be amazing to see how this pilot program develops in the future and how it may reshape regulatory approaches for future innovative medical devices.

The AIMBE Scholars Program has provided me with an incredible opportunity to work at CDRH. It has afforded me the ability to work on a number of projects that support FDA innovation in regulatory decision-making, including in policy simplicity and development, building and piloting new and exciting programs for rapidly developing technology, and supporting new research efforts that could inform regulatory decisions. Ultimately, these efforts that drive innovation are of the utmost importance so that patients have timely access to high-quality, safe and effective medical technology.