

AIMBE's FDA Scholars Program

Advancing innovation and discovery from the lab to the marketplace.

Spotlight on the 2015-2016 AIMBE Scholars



Dr. Allen Chen

Upon receiving my PhD in bioengineering, I was very interested in the intersection of translational medicine, public health, policy, and organizational development. The AIMBE Scholars Program appealed to me because of the opportunity to contribute to strengthening FDA processes and policies while gaining an in-depth understanding of medical device review and federal policy development. After having gone through the Scholars Program, I am amazed at not only how much my experience has been true to the premise of the Program but also how much I have simultaneously grown in perspective and professionally beyond what I could have imagined a year ago.

As the nature of being situated in the Office of the Center Director at FDA's Center for Devices and Radiological Health (CDRH), my everyday work has been very interactive and has allowed me to meet and collaborate with people from various Offices across the Center. In this dynamic environment working on large-scale projects that impact a wide audience of internal and external stakeholders, I have been able to learn about how all the Offices and Divisions at CDRH work together. Moreover, since conversations and planning always consider a variety of stakeholders, I have found that my perspective on the clinical translation of medical devices has broadened from a simplistic understanding to one that is significantly more vivid and to scale.

My primary work has been on CDRH's patient-centered and pediatrics initiatives. In line with healthcare's increasing move toward greater patient-centeredness and CDRH's core patient-centered mission, CDRH has embarked on a strategic priority titled "Partner with Patients." This priority seeks to develop mechanisms that facilitate patient engagement throughout the medical device development and evaluation lifecycle, as well as to advance the science and mechanisms for patient input (for example, leveraging patient preferences for benefit-risk tradeoffs and collecting patient-reported outcomes) to be used as evidence in regulatory decision-making.

In addition to serving on cross-Center teams engaged in the discussion, planning, and implementation of activities related to these general patient-centered efforts, I have focused much of my work on building a foundation for CDRH's efforts in the area of patient-reported outcome measures (PROMs). These scientifically rigorous and validated questionnaires or rating scales provide an important avenue for measuring concepts that are best reported directly from a patient—such as pain, function, and quality of life—after medical intervention. Capturing these measures, in addition to other traditional objective measures, enables consideration of a more complete picture of a patient's experience in medical device development and evaluation. As a result, PROMs are being increasingly incorporated in clinical care, clinical trials, and reimbursement decision-making. I have been coordinating efforts to understand the state of PROM use across CDRH and the current gaps that exist. This is a first step towards ultimately improving the use and evaluation of PROMs in premarket device submissions and their review and ensuring efficiency in the review process. Among various aspects, my work has involved analyzing historical pre- and postmarket submissions to identify trends in PROM use as well as meeting with clinical reviewers in various review divisions to identify common themes.

As a member of the Pediatrics and Special Populations team, I assisted in developing a process for reviewing premarket applications that seek a pediatric extrapolation. The overarching goal in this effort was to make the process as standardized, consistent, and transparent as possible, as CDRH works to support innovation and development of pediatric medical devices. I additionally analyzed demographic data in premarket submissions to inform CDRH's efforts to develop a clear, meaningful way of presenting demographic information from clinical trials to the public as requested by Congress in FDASIA Section 907. Working in these areas helped me to realize how quickly the healthcare and policy landscapes change. As a result, there are wide-ranging emerging topical areas in which FDA must continually invest to ensure that processes in the medical device development and evaluation lifecycle run smoothly and optimally.

I have found my work at CDRH to be extremely meaningful and rewarding. Moreover, it has expanded and deepened my understanding of regulatory processes and policies, and enabled me to connect the dots between numerous concepts in healthcare, regulatory review, and policy-making. I am appreciative that my location in OCD has allowed me to see the larger picture of how CDRH and stakeholders work together to advance processes, policies, and science in the evolving healthcare ecosystem. Overall, I am extremely grateful for the opportunity to have served as an AIMBE Scholar at FDA. The more comprehensive perspective I now have on our healthcare system as a result of my AIMBE Scholars experiences will equip me, in my career, to more effectively collaborate with all stakeholders toward the common goal of translating promising, safe, and effective medical technologies to the clinic to improve patient health.

