

AIMBE FDA SCHOLARS PROGRAM

Advancing Policy. Ushering Innovation.

The American Institute for Medical and Biological Engineering (AIMBE) partners with FDA to strengthen the connections between industry, the scientific enterprise, and the regulations governing the medical device sector.

This ground-breaking partnership enables the most promising post docs to work first-hand on hot button regulatory science and policy issues within the Centers for Devices and Radiological Health.

AIMBE SCHOLARS WORK SIDE-BY-SIDE WITH KEY DECISION MAKERS AT FDA.



2015-2016 Scholar
Dr. Douglas Dumont

“I assist in efforts to develop a National Medical Device Evaluation System that leverages real-world evidence to support regulatory decision-making and device innovation.”

“The AIMBE Scholars program has been very successful. It’s been very positive to get new, smart engineering talent interested in policy issues come in and hit the ground running and making a difference.”

- Senior Regulatory Staff at FDA



2014-2015 Scholar
Dr. Chris Medberry
Senior Regulatory Affairs Specialist, DePuy Synthes Johnson and Johnson

“I learned from engineering experts and witnessed medical device manufacturers, FDA, and clinicians coming together to discuss critical problems and develop collaborative solutions.”

“My efforts focused on taking critical feedback provided in response to a draft guidance document, evaluating the comments, and working with CDRH to develop consensus. In this process, we evaluated how standards are currently used in FDA pre-market submissions and devised systems aimed at making it easier and more efficient for submitters to use standards.”

Advancing regulatory science and policy at FDA

Training rising leaders about regulatory processes

THE ONLY PROGRAM PROVIDING FIRST-HAND IMMERSION EXPERIENCES IN REGULATORY POLICY AT FDA UNDER LEADERSHIP OF CDRH DIRECTOR JEFF SHUREN.

TRANSFORMING REGULATORY SCIENCE & POLICY THROUGH GROUND-BREAKING COLLABORATION

AIMBE Scholars learn how to apply their experiences from the lab bench to inform regulatory policy decisions at FDA.

Scholars work alongside both scientific and public policy experts and build relationships with key stakeholders.



2014-2015 Scholar
Dr. Sonja Fulmer
Regulatory Policy Analyst
Centers for Devices and
Radiological Health, FDA

'I led the use of recommendations to improve consistency of the review process, provided clarity to the eCopy process, and drafted proposed rules. As such, I gained invaluable skills in regulatory policy, such as rulemaking, policy decision-making, and project management.'



2015-2016 Scholar
Dr. Robert Allen

"I contribute to streamlining the reclassification of medical devices from class III to class II to improve patient access to safe and effective medical devices."

EXTENDING THE CAPACITY OF FDA

Scholars work on streamlining regulatory processes at the FDA. They are involved in standards development and other critical initiatives that enable the FDA to provide better guidance to industry and clinical partners.



2014-2015 Scholar
Dr. Maria Murray
Senior Consultant
Life Science Technology
Practice, Deloitte

'I collected data on CDRH initiatives to reveal how effective they are by developing metrics to determine the impact of regulatory science research at FDA.'



2015-2016 Scholar
Dr. Allen Chen

"I analyze the use of Patient-Reported Outcome Measures (PROMs) in pre-market device submissions to improve the medical device review process."

"...an incredible opportunity to new and young talent and helps develop valuable awareness of the regulatory aspects of science, often not addressed in the graduate school environment. I strongly encourage AIMBE to continue with this program."

- Senior Regulatory Staff at FDA

ADVANCING REGULATORY SCIENCE & POLICY FOR THE BENEFIT OF THE FIELD

Beyond the contributions to FDA, the AIMBE Scholars are working to improve policies that govern the medical device and drug industries.

AIMBE Scholars are rising leaders in the field and will serve as tomorrow's innovators. **The marketplace will benefit from bioengineers who know the ins-and-outs of regulatory policy.**

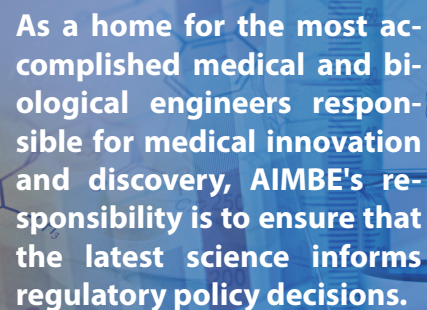
SPOTLIGHT ON INDUSTRY PARTNERS

Industry partners engage with AIMBE Scholars—who will go on to careers in industry, government (such as FDA) or research—throughout the program year. They may organize seminars and host Scholars at their industry labs or headquarters for an educational experience. Sponsors have included **Medtronic, Becton Dickinson, Stryker, St. Jude Medical, and C.R. Bard.**

“...creating a cadre of well-trained engineers with first hand experiences at the FDA to help the U.S. sustain its innovation edge.”

- AIMBE Past President Ravi Bellamkonda

WHY DOES AIMBE PARTNER WITH FDA?



As a home for the most accomplished medical and biological engineers responsible for medical innovation and discovery, AIMBE's responsibility is to ensure that the latest science informs regulatory policy decisions.

- ✓ Increasing the use of science in public policy decisions
- ✓ Addressing timely public policy issues concerning industry and consumers
- ✓ Building knowledge to maximize the efficiency of regulatory processes

STRENGTHENING A WORKFORCE OF BIOENGINEERS FOR A REGULATORY ENVIRONMENT SPURRING INNOVATION.

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