Regulatory Science at FDA’s Center for Devices and Radiological Health and Its Application to Medical Device Biofilms

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ABSTRACT This seminar will introduce medical device regulation in CDRH, and the importance of regulatory science. The structure and roles of FDA organization will be explained, and the types of products regulated will be introduced. The submission process as described by FDA will also be summarized, and databases that students can use to research products will be highlighted. The importance of the total product lifecycle (TPLC) will be emphasized. As an example of regulatory science in CDRH, we will introduce the public health challenges of biofilms and the regulatory science challenges associated with infections. We will also briefly summarize some current research in our group to address this public health challenge. Time will be provided for a question and answer session and discussion of what a career at FDA is like.

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BIO CDR K. Scott Phillips, USPHS, is a Commissioned Officer and Senior Group Leader in the Laboratory of Microbiology and Infection Control, in the Division of Biology, Chemistry and Materials Science in FDA’s Center for Devices and Radiological Health. He received his PhD at UC Riverside Chemistry Dept. where he developed the first biomimetic microfluidic immunoassay, and did postdoctoral work at UNC Chapel Hill where he developed the first microfluidic single cell analysis platform based on laser cell lysis with electrophoretic separation and laser-induced fluorescence. At FDA he has become a recognized expert in the field of medical device biofilms and antimicrobial device technologies. His research career at FDA is focused on bacteria-medical device material interactions, biological interaction analysis and biosensors. He pioneered the concept of Medical Devices on Chips (Guan et al. Nature Biomedical Engineering 2017, 1, 0045). He is the PI of a project developing an instrument to measure cleanliness of endoscopes at the point of reprocessing, and Co-PI on several projects studying biofilm-associated infections. He has led projects involving collaboration with industry and academia, including negotiation and development of multi-party collaborative agreements needed to do groundbreaking research. He has mentored 5 postdoctoral fellows, 6 graduate students, and 14 undergraduates at FDA. Dr. Phillips has over 35 publications, several book chapters and one patent and frequently gives invited talks at several Biofilm Conferences. In 2014, he co-organized a workshop at FDA on Medical Device Biofilms which was attended by over 430 people with representatives from most of the large medical device companies in attendance. He has numerous recent peer-reviewed papers on bacteria-material interactions and biofouling, and has provided over 300 consults in the past 6 years on antimicrobial medical device technology, chemistry and mechanism of action to CDRH reviewers.