FDA Medical Device Industry Coalition
www.FMDIC.org

Speaker Bios

Beckie Ellis

Vice President, RA/QA

Argon Medical Devices, Inc.

Beckie is an internationally experienced RA/QA professional with more than 30 years of diversified experience in the medical device and pharmaceutical industries. She holds a B.S. in Microbiology, an MBA in Operations Management and a Master's Certificate in Organizational Leadership. She has her RAC from RAPS and is certified as a CQA, CBA, CSSGB, CQE, CQIA and CQM/OE from the American Society of Quality. Beckie has served 2 years as a site examiner with Quality Texas. She has held leadership positions for the Dallas Section of ASQ as well as the ASQ Biomedical Division, and currently serves as Industry Representative to the FDA/Medical Device Industry Coalition in Dallas, TX.

During her career she has worked with a wide range of disposable and implantable products from Class I to Class III. She has worked for such companies as NeoRx, Fuller Laboratories, Parke-Davis, International Isotopes, Medical Incorporated, St. Jude Medical, and OsteoMed before joining the Argon team. These organizations cross a variety of product platforms including kidney dialysis, brachytherapy products, radiopharmaceuticals, heart valves, vascular grafts, arterial and cardiotomy blood filters, and dental, IVC filter, breast and orthopedic implants.

During her career Ms. Ellis has worked overseas where she oversaw the relocation of a mini-assembly plant in Rio de Janeiro, Brazil and served as Operations Manager for a heart valve manufacturing facility in Perth, Australia.

She has specialized experience in Global Quality Systems, process improvement, new product development, and sterilization science. In her current role with Argon, Beckie has global responsibility for plant Quality Assurance, global Quality Systems' development, Regulatory Compliance, Certifications, Submissions and Approvals. Her current focus is integration of changing global regulatory requirements including the EU Medical Device Regulation while harmonizing to requirements of other Regulatory Bodies, including US FDA.

Dr. John C. Criscione

Professor, Biomedical Engineering

Texas A&M University

Dr. Criscione is a professor in the Department of Biomedical Engineering at Texas A&M University. Dr. Criscione's research focuses on how mechanics – the study of force and motion in matter – applies to the biology of the heart and how to utilize such knowledge to obtain better clinical outcomes. Toward this end, state-of-the-art modeling tools are essential for representing the mechanical behavior of biological tissues, and Dr. Criscione has made fundamental contributions to the non-linear field theories of mechanics.

In order to translate research discoveries into therapies for heart failure, Dr. Criscione is an active inventor and entrepreneur. As a founder of CorInnova, an early stage medical device company, he has firsthand knowledge of the medical device industry – experiences that he uses to guide his research and teaching in the research, development, design and regulation of medical technologies.

Educational Background

- Ph.D., Biomedical Engineering, Johns Hopkins University
- M.D., Medicine, Johns Hopkins University
- B.S., Applied Physics, Purdue University

William Shackelford

Supervisory Consumer Safety Officer, Division 3/West, Office of Medical Device and Radiological Health Operations

U.S. Food and Drug Administration

William is a Supervisory Consumer Safety Officer with the U.S. Food and Drug Administration located in the Austin Resident Post in Austin, Texas. He supervises a medical device investigative team for device inspections within Division 3 of the Office of Medical Devices and Radiological Health Operations West to determine a firm's compliance with the Quality System Regulation and other medical device regulations. He has been with the FDA since 2009 performing original medical device submissions review, device compliance monitoring, and recalls review with the Center for Devices and Radiological Health (CDRH), and recently performing medical device investigative work in field operations for the Office of Regulatory Affairs (ORA). Prior to joining FDA, he worked in the medical

device diagnostics industry developing in-vitro diagnostic devices for the marketplace. He holds a Master of Science in Biotechnology, and a Bachelor of Science in Biology.