Workshop Co-Chairs: Reto Luginbuehl
Robert Mathys Foundation
Bettlach, Switzerland

Stephen Spiegelberg
Cambridge Polymer Group
Boston, MA

Terry Woods
FDA
Silver Spring, MD

TUESDAY, NOVEMBER 16, 2010

8:30 AM
Opening Remarks
Reto Luginbuehl, Robert Mathys Foundation, Bettlach, Switzerland
Stephen Spiegelberg, Cambridge Polymer Group, Boston, MA
Terry Woods, FDA, Silver Spring, MD

SESSION 1: FDA AND LEGAL IMPLICATIONS

8:45 AM
Reprocessing of Reusable Medical Devices: an FDA Perspective
Pamela Scott, Daniel McGunagle, FDA, Silver Spring, MD

9:10 AM
The Legal Implications of Medical Device Cleanliness Standards
Steve Bennett, John Schlafer, Baker & Daniels, LLP, Fort Wayne, IN

9:35 AM
Q&A for Session 1

9:45 AM BREAK
SESSION 2: CLEANING AND TESTING, PART 1

10:05 AM
Exploring Methods of Optimizing Surgical Instrument Reprocessing Operations
Jahan Azizi, Linda Lavey, CBET, University of Michigan, Dearborn, MI

10:25 AM
Validation Strategy for an Automated Endoscope Reprocessor
Bradley Catalone, Thomas Gilmore, David Barlow, Olympus America, Center Valley, PA

10:45 AM
Effects of Non-Aqueous Vapor Degreasing Solvent Cleaning on Ultra-High Molecular Weight Polyethylene (UHMWPE)
Ray Gsell, Zimmer, Warsaw, IN

11:05 AM
Breaking the Myth that Caustic Surgical Instrument Cleaners are Necessary for Safe and Effective Decontamination of Medical Devices
Marcia Frieze, Case Medical, South Hackensack, NJ

11:25 AM
Q&A for Session 2

11:35 AM LUNCH (On Your Own)

SESSION 3: CLEANING AND TESTING, PART 2

12:50 PM
Cleaning and Testing for Debris in Reusable Medical Devices
Shani Haugen, Vicki Hitchins, FDA, Silver Springs, MD

1:10 PM
Evaluation of the Cleaning Efficiency of a Aqueous Based Detergent System for Cleaning Metallic Medical Devices
Boopathy Dhanapal, Zimmer, Warsaw, IN

1:30 PM
Two-phase Flow Cleaning of Endoscope Channels
Mohamed Labib, Stanislav Dukhin, Joseph Murawski, Yacoob Tabani, Richard Lai, Michelle Alfa, Novaflux Technologies, Princeton, NJ

1:50 PM
Assessment of Organic Residues on Medical Devices
Boopathy Dhanapal, Zimmer, Warsaw, IN

2:10 AM
Q&A for Session 3
SESSION 4: ESTABLISHING CLEANING LIMITS

2:20 PM
Establishing and Justifying Limit Values for Residual Analysis
Kierstanandrascik, QVET Consulting, Layton, UT

2:40 PM
Residual Soil on Reusable Medical Devices: How to Determine Limits?
Steve Goldstein, Steve Goldstein Consultants, Albuquerque, NM

3:00-4:00 PM
Q&A For Session 4 and General Discussion