PDA Filtration Interest Group Meeting
April 17, 2012
Meeting Summary

The PDA Filtration Interest Group met on April 17, 2012, in conjunction with the 2012 PDA Annual Meeting in Phoenix, Arizona. Approximately 55 people attended.

There were three formal presentations, all dealing with pre-filtration post-sterilization integrity testing.

Maik Jornitz, Senior Vice President, Marketing & Product Management Bioprocess, Sartorius Stedim Biotech, discussed "Pre-use/Post-sterilization Integrity Testing - Update on Initiatives."

Ranjeet Patil, Biomanufacturing Engineer, EMD Millipore, spoke on the subject of "Considerations for post-sterilization pre-use integrity testing in single use redundant sterile filtration systems."

Michael Moussourakis, Biopharmaceutical Marketing Manager, Pall Life Sciences, presented "Pre-Use, Post Sterilization, Integrity Testing (PUPSIT)."

Following the formal presentations, the attendees participated in an informal discussion about the presentations and other topics of interest.

Hemisha Ly, leader of PDA's Pre-Use Post-Sterilization Integrity Test (PUPSIT) Task Force, updated the audience on the status of PDA's position paper on the topic. The paper is essentially complete and will be submitted for approval to the appropriate PDA Boards. It is hoped that the paper will provide a stimulus for regulatory change, particularly regarding the interpretation of Annex 1.

ASTM F 838-05 "Standard Test Method for Determining Bacterial Retention of Membrane Filters Utilized for Liquid Filtration," is being sent to Subcommittee D19.24 for re-approval in mid-May. If re-approved, the standard will likely be transferred to ASTM E55.03, General Pharmaceutical Standards, for review and revision as appropriate.