# Rapid Microbial Methods, Contamination Control, Sterility Assurance and EM to be covered at Microbiology East Coast Conf

*SMi Reports: Questions on rapid microbial methods, contamination control, sterility assurance and environmental monitoring addressed at Microbiology East Coast*


BOSTON, MA , UNITED STATES , March 8, 2022 /EINPresswire.com/ -- Microbiology remains an essential tool in reducing microbial growth in the manufacture of pharmaceuticals, to detect and eliminate microorganisms that would pose a risk to patients and jeopardise product batches.

SMi's 5th Annual Pharmaceutical Microbiology East Coast Conference will review implementation guidance and validation for efficient disinfectant efficacy programs and uncover principles in best-practice and the benefits of a robust contamination control strategy. The conference is taking place on 27th to 28th April 202 in Boston, MA, USA.

Interested parties can interested parties can secure their attendance via: http://www.microbiologyeastcoast.com/PR3

SMi Group has released key conference sessions and questions that will be answered by key influential and inspiring experts in the pharmaceutical microbiology field over the two-day conference, the sessions include:

Day One - OPENING ADDRESS on Designing an Efficient Disinfectant Efficacy Program covering:
•Review disinfectant efficacy validation and implementation guidance
•How to leverage multi-site data to reduce redundancies in validation or verification and to efficiently qualify disinfectants without impacting the quality of the study
•Case studies will be presented from two companies discussing global disinfectant efficacy studies that support and supplement site disinfectant efficacy programs
Hilary Chan, Principal QC Scientist, Takeda

Stephen Yang, Director – Global Sterile & Validation COE, Merck & Co.

Day One - COVID SPOTLIGHT on Impacts of the SARS-CoV-2 pandemic on the biopharmaceutical industry, covering:
• The impact of the COVID-19 pandemic on the following areas will be discussed during the presentation:
•Regulatory Emergency Use Authorizations and Final Approval Process
•Regulatory Manufacturing Facility Assessment and Inspections
•Manufacturing Facility Design
•Supply Chain Integrity Considerations
Lynne Ensor, Vice President, Regulatory Consulting Services Head of Global Compliance, Parexel International, Inc.

Day One - FDA SPOTLIGHT SESSION on Common Issues in The Sterility Assurance Assessment, covering:
•Introduction to FDA small molecule microbiology/manufacturing, covering:
•Common deficiencies seen in applications
•Recommendations for applications to expedite approval
John Arigo, Director, Division of Microbiology Assessment, Office of Pharmaceutical Manufacturing Assessment, FDA

Day Two OPENING ADDRESS on a Case Study: Expediting Mold Contamination Investigations with the Use of Biofluorescent Particle Counting Technology, covering:
•This presentation will provide an overview of the rapid microbiological technology used, specifically BFPC
•It will provide a case study for the application of BFPC technology to support mold remediation in an aseptic processing facility
•The presentation will review the benefits and outcomes yielded with use of the BFPC technology to support resolution of an investigation
•The presentation will provide opportunities for additional use of the BFPC technology to ensure successful return to operation following major shutdowns, facility modifications or breaches
Dawn Watson, Director – Microbial Control, Sterile & Validation Center of Excellence, MSD

Day Two - KEYNOTE SESSION on Microbial control: Risk assessment of traditional culture-based microbiological tests requiring contemporaneous verification, covering:
•The FDA is particularly focused on the data integrity of microbial tests as these often use manual methods that could be open to error or fraud
•A BioPhorum survey into this area found that more than 50% of members were doing second-person verification of tests to satisfy FDA scrutiny, but did not think the risk was being properly managed
•The presentation looks at the fundamentals of ensuring microbiological test data integrity and proposes that a qualitative risk assessment is performed for the traditional, culture-based

quality control tests that currently require verification by a second person. In addition, lab controls are recommended to ensure that testing is robust
•One member company applied the risk assessment approach outlined in the paper and was able to remove 12 million second person verification samples from its global testing program. A case study also demonstrated that it is possible to save one to two full time equivalents if the risk-based approach is applied
•The workstream members are now implementing this approach and sharing both operational experience and feedback at audit. The recommendations outlined are currently being considered for incorporation into an update of USP 1117
Lena Hoch, Microbiologist Specialist, Quality Control Microbiology - Projects, GSK

Day Two - MICROBIOTA SPOTLIGHT SESSION on Contamination Control as it relates to Microbiome Drug Product manufacture - Misconceptions and grey areas in non-sterile product manufacturing, covering:
•Defining the human microbiome as a symbiotic ecological community and its role in human health
•Ascertaining that an ecological community is implicitly a densely interconnected living system

•The challenges associated with eliminating extraneous bacteria from drugs to ensure patient safety without compromising the microbiome drug product
•Addressing material management as a crucial component of certified cleaning strategy
•The importance of a holistic, homogenously intricate cleaning strategy and avoiding a focus on operation protocol and procedural controls
Sean O'Brien, Director, Quality Control External Operations, Seres Therapeutics

To view the full the agenda, download the conference brochure, please visit:
http://www.microbiologyeastcoast.com/PR3

Sponsored by: Associates of Cape Cod, Bioscience International, Ecolab, Mettler Toledo and Microbiologics

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SMi's 5th Pharmaceutical Microbiology East Coast Conference
April 27-28, 2022
Boston, MA, USA
#SMiPharmaMicroEC
http://www.microbiologyeastcoast.com/PR3

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