Six key Microbiology presentations from FDA, STERIS, Boehringer Ingelheim Microbiological Consulting, Parexel

SMi Reports: Six microbiology presentations by FDA, STERIS, Boehringer Ingelheim Microbiological Consulting, Parexel discussed at Pharma Microbiology East Coast

P-345 Pharma Microbiology EC

Pharma Microbiology EC Brochure Cover

BOSTON, MA, UNITED STATES, January 22, 2021 /EINPresswire.com/ -- Six key presentations will be covered at the 2021 East Coast Pharmaceutical Microbiology Conference by Boehringer Ingelheim, FDA/CDER, Microbiological Consulting, LLC, STERIS Corporation, FDA and Parexel sessions, the presentations will cover sterility regulation and guidance, microbial risk based detection, monitoring water systems and contamination control.

The conference brochure has been updated, download online to see the full agenda and speaker line-up http://www.microbiologyeastcoast.com/PR2

1. Manufacturing facility assessments during COVID Pandemic, covering:
Introducing the changes to the manufacturing facility assessment to support application required in light of the COVID Pandemic
Insight into how the FDA CDER Office of Pharmaceutical Quality has evolved its approaches to continue manufacturing facility

assessments
Recommendations to manufacturers for a successful remote manufacturing facility assessment

Commander Qiao Bobo, Division Director, Office of Pharmaceutical Quality, FDA/CDER

2. Emergency Use Authorization: Understanding a Regulatory Strategy Weapon Used to Battle a Pandemic, covering:
Describing EUA approaches developed by global regulatory health authorities
Understanding how EUA authority could be applied
Case studies: Application of EUA authority to combat COVID-19
Lynne Ensor, Vice President, RCS Head of Global Compliance, Parexel

3. Live, Stressed, and Dead Microorganisms – Their Role in Microbial Test Method Validation, covering:
The effects of different stress factors, i.e., heat, starvation, growth phase, extreme pH, osmotic stress, antimicrobial agents, etc. on representative microorganisms
These stress factors will be related to manufacturing processes and drug product attributes; simulating these stresses with candidate study protocols
Emphasising the continuum from repairable cell damage, loss of cell viability to cellular death
Reviewing the role of repair mechanisms to damage to cell membrane function, enzymatic activity, protein synthesis and nucleic acids in terms of the recovery and enumeration of microorganisms using growth and non-growth methods
A case will be made that use of stressed microorganisms as challenge organisms in method validation, suitability testing and growth production testing is not necessary
Dr. Tony Cundell, Principal Consultant, Microbiological Consulting, LLC

4. A Risk Based Cleaning and Disinfection Program, covering:
Addressing Cleaning and Disinfection as a critical component of a contamination control program during a pandemic
Discussing current regulations, disinfectant and sterilant technologies, and operator safety in-depth
Insight into global regulatory expectations: FDA, MHRA, ANVISA, ANMAT, HPRA, EMA, and ANSM

Assessing critical industry guidance documents: Annex I, USP 43 <1072>, PDA Technical Report #70
Best practices in designing an effective risk-based program and understanding current industry trends regarding cleaning and disinfection
Current industry FDA Warning Letters and FDA 483s
Jim Polarine, Senior Technical Service Manager, STERIS Corporation

5. Common Issues in The Sterility Assurance Assessment, covering:
Introduction to FDA small molecule microbiology/ manufacturing
Common deficiencies seen in applications

Recommendations for applications to expedite approval
John Arigo, Director, Division of Microbiology Assessment, FDA

6. ENDOTOXIN TESTING SPOTLIGHT SESSION - Automating Endotoxin water monitoring at Boehringer Ingelheim with Endosafe® Nexus™ – A business and validation perspective, covering:
Build your business case to show the impact of automation in your lab
- Why is an economic assessment necessary?
- Definition of financial parameters for your business case
- Case study: business case of water monitoring with Endosafe® Nexus™ at BI
Define your validation strategy
- Match the technology to the right application: water monitoring
- Validation approach for automated compendial methods
- Case study: validation of water monitoring with Endosafe® Nexus™ at BI
The Endosafe® Nexus™ in routine
- The importance of monitoring your automated rapid microbiological method
- A look at the operating performance of Endosafe® Nexus™ units installed at BI
- Benefits and opportunities of Endosafe® Nexus™ from BI perspective
Johannes Oberdörfer, Scientist, Rapid Microbiology Methods, Boehringer Ingelheim

This event is ideal for those who are interested and work as Senior Microbiologist, Lead Scientist, Laboratory Manager, QA Specialist Drug Substance External Manufacturer, Business Development Manager – Testing, Pharmaceutical Microbiology Consultant, Higher Pharmacopoeia Scientist, Analytical Standards Specialist.

For more information on the conference visit http://www.microbiologyeastcoast.com/PR2

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SMi's 4th Annual Pharmaceutical Microbiology East Coast Conference
Conference: April 28th – 29th, 2021
Workshops: April 27th, 2021
Virtual Conference: Online Access Only
http://www.microbiologyeastcoast.com/PR2

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