

# 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*

BOSTON, MA, UNITED STATES, January 22, 2021 /EINPresswire.com/ -- Six key presentations will be covered at the [2021 East Coast Pharmaceutical Microbiology Conference](http://www.microbiologyeastcoast.com) 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



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## Pharmaceutical Microbiology East Coast

Implementing Robust Sterility Assurance Strategies for Effective Contamination Control

28 - 29 April 2021  
Virtual Conference – Online Access Only

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## Pharmaceutical Microbiology East Coast

Implementing robust sterility assurance strategies for effective contamination control

Virtual Conference: Online Access Only

WORKSHOPS: 27TH CONFERENCE: 28TH – 29TH  
**APRIL 2021**

**HIGHLIGHTS FOR 2021:**

- EXPLORE the latest advancements in robust risk-based disinfection strategies for effective cleaning and microbe elimination
- INVESTIGATE the extensive and complex regulatory landscape alongside the regulator
- DELVE into recent case studies delivered by experts in microbial monitoring and contamination control programs
- ATTAIN expert fultion of the post-conference workshops in new quality risk management tools for contamination control and the latest revisions in the US Pharmacopoeia
- VIRTUAL CONFERENCE BENEFITS INCLUDE: virtual exhibition booths packed with information, networking features to discuss and share contact details with other attendees, and virtual meetings and networking socials.

**CHAIR FOR 2021:**

- Lynne Essar, Vice President, RC3 Head of Global Compliance, Parexel

**2021 KEYNOTE SPEAKERS:**

- John Argo, Director, Division of Microbiology Assessment, FDA
- Commander Gloria Babo, Division Director, Office of Pharmaceutical Quality, FDA/CDER

**FEATURED 2021 SPEAKERS INCLUDE:**

- Jennifer Vansteegen, CEO, International Serum Industry Association
- Lynne Essar, Vice President, RC3 Head of Global Compliance, Parexel
- Sean O'Brien, Quality Assurance Director, Contamination Control, Sanofi
- Maximilian Augustin, DE Process Validation Manager / MBAT, Roche

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PLUS TWO INTERACTIVE HALF DAY PRE-CONFERENCE WORKSHOPS | TUESDAY 27TH APRIL 2021

A. USP Microbiology 2021 – Keeping Up with standards  
Workshop Leader: Donald Singer, Microbiology Expert Committee Chair, IS Pharmacopoeia  
08.30 – 12.30

B. Quality Risk: Management Tools for Contamination Control  
Workshop Leader: Cheryl Essex, Head of Microbiological Control for Biologics, Sanofi and Jon Williams, Global Proactive Risk Manager, Sanofi  
13.30 – 17.00

[www.microbiologyeastcoast.com](http://www.microbiologyeastcoast.com)  
Register online or fax your registration to +44 (0) 870 9090 712 or call +44 (0) 870 9090 711

Pharma Microbiology EC Brochure Cover

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

Emphasizing 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. **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>

Sponsored by Microcoat

For sponsorship enquiries contact Alia Malick on +44 (0)20 7827 6164 or [amalick@smi-online.co.uk](mailto:amalick@smi-online.co.uk)

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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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