European Microbiology Conference
8/9 May 2019 | Barcelona, Spain

+ Workshop “Bioindicators”
7 May 2019

Speakers

Peter Annel
Novo Nordisk

Walid El Azab
Steris

Berthold Düthorn
Robert Bosch Packaging Technology

Barbara Gerten
Merck

Nadja Gilles
Miltenyi Biotec

Phillip Godden
Protak Scientific

Marcel Goverde
MGP Consulting

Peter Huonker
Früh Verpackungstechnik

Patrick Koch
CSL Behring

Kathrin Koeck
Greiner Bio-One

Erika Pfeiler
US Food and Drug Administration

Frank Pavan
Eurocom

Ruth Röder
Microcoat Biotechnologie

Blandine de Saint-Vis
Boehringer Animal Health

Jean-Baptiste Sauvet
Skan

Matthias Schaar
Novartis Pharma Stein

Robert Schwarz
FH Campus Vienna

Sebastian Thölken
Novartis Pharma Stein

Radhakrishna Tirumalai
United States Pharmacopeia Convention

Ulrich Zuber
F. Hoffmann-La Roche

Highlights

Conference:
Regulatory Developments – FDA, USP and more
Environmental Monitoring Methods – Verification and Recovery Rates
Hold Time Studies – Overview and Case Studies
Sterilisation and Sanitizing – Method Qualification and Process Validation
Detection of P. acnes in Biotech Processes
Purified Water – Rapid Bioburden
Filter Validation

Workshop:
Regulatory Requirements in Europe and USA
Process Validation – Challenges and Peculiarities
BI in Sterilisation Validation – Old Hat or State of the Art?
Enzyme Indicators

This conference is recognised for the ECA GMP Certification Programme „Certified Microbiological Laboratory Manager“. Please find more details at www.gmp-certification.eu
Dear Colleague,

I would like to invite you to the European Microbiology Conference (EMC) and the Biological Indicator Workshop 2019 of the ECA Academy in Barcelona, Spain.

The ECA has been organizing the European Microbiology Conference for 11 years. The positive feedback from participants and speakers made EMC an annual event that provides information on current developments and trends in pharmaceutical microbiology with lectures and workshops. In 2019, EMC will be combined with a pre-conference workshop on requirements, suitability and validation of biological indicators (BI).

The combination of these two events offers you an excellent opportunity to stay abreast of the latest developments and state-of-the-art in science and technology in microbiological quality control. Pharmacopoeia experts, representatives of pharmaceutical quality control and contract laboratories will share their experiences, what the current challenges are and how they have implemented adequate microbiological quality control in their companies.

The pharmaceutical microbiologist plays a key role in all aspects of development, manufacture and control of medicinal products and their components. It is thus the aim of this conference and workshop to equip the pharmaceutical microbiologist with practical and applicable knowledge and “know-how”. In addition, it will provide a forum for interesting and open discussions between presenters, regulators and your colleagues from the industry.

It would be a great pleasure for me if you joined us in Barcelona.

Dr Sven M. Deutschmann
Chairman of ECA’s Pharmaceutical Microbiology Working Group
Current and recent activities of the USP Microbiology Expert Committee
Radhakrishna Tirumalai, USP
- Recent approvals of new chapters and revisions (<1211>, <1222>)
- Recent major proposals in PF (<1085, <1071>, <60>)
- Future plans

What the Neighbours have learned – Validation of Methods – The Guidance for Food Microbiology
Barbara Gerten, Merck
- Introduction to ISO 16140 Method Validation
- Validation of reference and alternative methods
- Verification during implementation in the laboratory

Monitoring Systems – Requirements and Experiences
Monitoring Systems – Experiences with Valimon and Labwatch
Peter Huonker, Früh Verpackungstechnik
- Why and when do you need a monitoring system?
- Experiences with two different systems
- Pro’s and Con’s

Development of a highly sensitive PCR/DNA chip method to detect mycoplasmas in a modified live vaccine
Blandine de Saint-Vis, Boehringer Animal Health
- CytoInspect as a test system for the rapid detection and identification of mycoplasmas
- Methodology and preparation of spiked samples
- Use of 5 Eur. pharmacopoeial reference strains of mycoplasmas
- Validation criteria of limit of detection
- Sensitivity and specificity of the method in a modified live vaccine

Validation of Hold Times for aseptic processing
Sebastian Thölken, Novartis
- Overview of relevant hold times: product hold times & equipment hold times
- Validation approaches
- Experiences from Inspections and Product-Submissions

Status Updates: Current Topics in Quality Microbiology at the FDA – An overview of the quality microbiology review process
Erika Pfeiler, FDA
- A description of quality microbiology related policy initiatives
- A discussion of current information requests frequently sent to applicants

IMD-W “In-line system for purified water systems” and other devices for rapid water bioburden analyses
Ulrich Zuber, Roche
- Feasibility studies as offline device in the lab
- Feasibility study as online device at a purified water loop
- Challenges and possible solutions for online WFI bioburden analysis

Qualification of Laboratory Heaters and Refrigerators
Patrick Koch, CSL Behring
- Differences of Temperature Mapping – the Past and Today
- Implementation of: DQ/IQ/OQ/PQ

Microbiology, Personnel and Qualification – who’s affected and what’s included
Robert Schwarz, FH Campus Vienna
- QC Lab Microbiology – the equipment, the method and the operator and how qualification and validation is handled
- Aseptic processing – qualification of operators and validation of processes from a microbiological perspective
- From Guidelines to daily business – examples from the industry

Microbiological Control of Primary Packaging
Marcel Goverde, MGP
- Guiding documents for the microbiological testing of primary packaging
- Potential methods and suitability test approaches
- Acceptance criteria

Microbiological Aspects of Filter Validation
Matthias Schaar, Novartis
- Requirements
- How to set up a microbiological filter validation
- How does the Integrity test correlate to bacterial retention

Contamination control and company culture – A Case Study of a Microbiological Contamination
Dr. Ulrich Herber, CRL
- Contamination: What happened?
- What should have happened?
- Company culture
- Putting in into perspective

Recurring Microbial Contamination in grade A (ISO 5) filling Restricted Access Barrier System (RABS)
Walid El Azab, Steris
- Initial Investigation and Root Cause Analysis
- Corrective and Preventive Actions
- Ongoing Deviation
- Cross Functional Investigation
- Short- and Long Term CAPA’s

Risk-based aseptic process step simulation for automated cell processing
Nadja Gilles, Miltenyi Biotec
- Automated processing of human cells with regulatory requirement for media fill
- Risk analysis based on clustered process steps
- Aseptic process step simulation shortened by bracketing
Objectives
This workshop will provide you with the current regulatory developments in relevant guideline documents, e.g. Ph Eur 5.1.2. USP <1229.8> or <1035>, regarding Biological Indicators (BI) and practical experiences of industrial experts and BI manufacturers on validation of processes, evaluating BI resistance and more. Furthermore, you will get the possibility to discuss the challenges in the use of BI with speakers and colleagues during the presentation and the following panel discussion.

Background
Manufacturers of sterile medicinal products as well as producers of medical devices should provide safe and microbiologically unobjectionable products. Therefore, they have to validate their processes for sterilisation, for autoclaving, and for room gassing and fogging. In addition to multidisciplinary teamwork, this also requires suitable and high-quality bioindicators. USP <1035> defines BI as a characterized preparation of a specific microorganism that provides a defined and stable resistance to a specific sterilisation process which will be used in the performance qualification of the sterilisation equipment as well as in the development and establishment of a stable, validated sterilisation processes.

Target Audience
- Microbiologists from pharmaceutical and biopharmaceutical Industry
- Manufacturer of medical devices
- Responsible QC/QA staff
- Experts from contract laboratories
- Manufacturer and suppliers of BI
- Responsible Authorities

Moderator
Dr Marcel Goverde
Deputy Chair ECA Pharmaceutical Microbiology Working Group

Presentations

USP Thinking on Bioindicators
Radhakrishna Tirumalai, USP
- Biological Indicators (BI) are only tools to measure efficacy of the sterilization process
- BI is not the target of the Sterilization process. It is the bioburden in the article that is being sterilized that should be the focus for the process.
- Complete destruction of a BI is not necessary to develop a validated sterilization process

Biological Indicators for H2O2 Biodecontamination - Requirements, BI Production, Quality Control
Ruth Röder, Microcoat Biotechnologie
Dr Berthold Düthorn, Robert Bosch Packaging Technology
- User requirements for H2O2 process validation
- Challenges of BI development and results
- Case study: Application of new BIs

Biological Indicators – Expectations and Reality from Manufacturers’ and Users’ Point of View
Jean-Baptiste Sauvet, Skan
- Expectations from regulatory requirements, customers and manufacturers
- H2O2 Biological Indicators (BI): Model behavior of BI and design of BI components

Bioindicators in sterilization and decontamination validation – pitfalls and some maths
Robert Schwarz, FH Campus Vienna
- Differences in bioindicators for sterilization and decontamination
- Comparative D-Value Study
- Time is money – considerations for optimization
- Calculation models vs biological system

Routine control of bioindicators for steam sterilization
Matthias Schaar, Novartis
- Requirements
- Spore count determination
- D-value determination

Industrial Experiences
Peter Annel, NovoNordisc

Biological Indicators – Common challenges observed
Walid El Azab, Steris and Customer (TBC)
- Supplier qualification and validation (production to shipping)
- Common challenges/failure observed at end-users’ site
- Common challenges during QC testing
- Failure decision tree

Enzyme Bioindicators
Phillip Godden, Protak
Frank Pavan, Eurocom
- What is an Enzyme Indicator
- Key improvements compare to Biological Indicators
- Case studies
Speakers

Peter Annel, Novo Nordisk
Principal Scientist, Microbial Competence Centre

Walid El Azab, Steris Corporation, Belgium
Technical Services Manager for STERIS Life Sciences.

Dr Berthold Düthorn, Robert Bosch Packaging Technology GmbH
VP of Robert Bosch Packaging Technology GmbH and General Manager of Valicare GmbH

Barbara Gerten, Merck
Senior Scientist Traditional Microbiology and Chairwoman DIN Working Group Microbiological Food Testing incl. Rapid Methods

Nadja Gilles, Miltenyi Biotec
Compliance Manager, Quality Assurance GxP Products

Phillip Godden, Protak Scientific
Founder & Chief Executive Officer at Protak Scientific Limited

Marcel Goverde, MGP Consulting
Founder & Chief Executive Officer

Ulrich Herber
Charles River Laboratories
Director of Global Product Specialists

Peter Huonker, Früh Verpackungstechnik
Head Quality Management

Patrick Koch, CSL Behring
Sr. Scientist Microbiological QC

Kathrin Koeck, Greiner Bio-One
Product Specialist for Biopharmaceutical Applications

Erika Pfeiler, US Food and Drug Administration
Microbiologist/Branch Chief, CDER/OPQ/OPF/Division of Microbiology Assessment

Frank Pavan, Eurocom S.A.R.L.
Sterile Compliance and Troubleshooting Expert/Distributeur France Indicateurs Enzymatique Protak Scientific

Ruth Röder, Microcoat Biotechnologie GmbH
Project Manager

Social Event | 8 May

On 8 May, you are cordially invited to a social event. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.
Dates

**Workshop Bioindicators**
Tuesday, 7 May 2019, 09.30 - 17.00 h  
(Registration and coffee 09.00 – 09.30 h)

**European Microbiology Conference**
Wednesday, 08 May 2019, 09.30 – 17.30 h  
(Registration and coffee 09.00 – 09.30 h)  
Thursday, 09 May 2019, 09.00 – 16.30 h

**Venue**
Barceló Sants Hotel  
Plaça dels Països Catalans, s/n  
08014 Barcelona  
Spain

Tel. +34 (93) 503 53 00  
Fax +34 (93) 490 60 45  
sants@barcelo.com

**Fees (per delegate plus VAT)**

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The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on 8 May, lunch on both days and all refreshments during the conferences. VAT is reclaimable.

**Conference Language**
The official conference language will be English.

**Organisation and Contact**
ECA has entrusted Concept Heidelberg with the organisation of this event.

**CONCEPT HEIDELBERG**
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**For questions regarding content:**
Mr Niklaus Thiel (Organisation Manager) at +49 (0) 62 21/84 44 34 or via email at thiel@concept-heidelberg.de.

**For questions regarding reservation, hotel, organisation etc.:**
Mr Axel Schroeder (Operations Director) at +49 (0) 62 21/84 44 10 or via email at schroeder@concept-heidelberg.de.

**General terms and conditions**
If you cannot attend the conference, you have two options:
- If you have made the payment yet. Only after we have received your message, you will have to pay the full registration fee, even if you have not made the payment yet. After only have received your message, you will have to pay the full registration fee, even if you have not made the payment yet.
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