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

20 YEARS ECA Academy
Your GMP/GDP Information Source

Introduction

Invitation to the European Microbiology Conference 2019 with pre-conference workshop

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

European Microbiology Conference | 8-9 May

Objectives

This event offers you a unique possibility to become acquainted with ongoing regulatory requirements, the development of microbiological methods for quality and process control as well as with the recent experiences in microbial contamination control.

Speakers from different scopes of pharmaceutical microbiology will give you the chance to get to know the different views on versatile microbiological topics. Also, as a participant you will have ample opportunity to discuss your specific issues with speakers and other participants.

Interdisciplinary lectures will give you an additional benefit for understanding the current developments in pharmaceutical QC.

Background

The role of pharmaceutical microbiology is getting more and more important. The microbial control concept is also increasingly in the focus of regulators during product submission and inspections. Current challenges are Low Endotoxin Recovery or other Endotoxin-masking effects, implementation of alternative microbiological methods, control of cell-based products and the ongoing issues with contamination control – there was an increasing number of findings in the authority reports.

The challenge is therefore to satisfy regulatory requirements alongside management's financial expectations.

Target Audience

This conference is of interest to professionals in microbiology from

- Pharmaceutical and Biopharmaceutical Companies
- Academic Research Institutions
- Government Agencies
- Contract Laboratories

who are involved in

- Contamination Control
- Monitoring
- Product Testing
- Validation
- Quality Affairs
- Regulatory Affairs
- Research and Development

Moderator

Dr Sven M. Deutschmann,
Chairman ECA 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

Kathrin Koeck, Greiner Bio-One

- CytoInspect as a test sytem 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
- Implemention 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

- ContaminationWhat 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 H_2O_2 Biodecontamination - Requirements, BI Production, Quality Control

Ruth Röder, Microcoat Biotechnologie
Dr Berthold Düthorn, Robert Bosch Packaging Technology

- User requirements for H_2O_2 process validation
- Challenges of BI development and results
- Case study: Application of new BIs

Bioindicators – Expectations and Reality from Manufacturers' and Users' Point of View

Jean-Baptiste Sauvet, Skan

- Expectations from regulatory requirements, customers and manufacturers
- H_2O_2 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

Blandine de Saint-Vis, Boehringer Animal Health
Analytical support Director in R&D ASSAY

Jean-Baptiste Sauvet, Skan
Head of BI production

Matthias Schaar, Novartis Pharma Stein AG
Technical Steward Microbiology

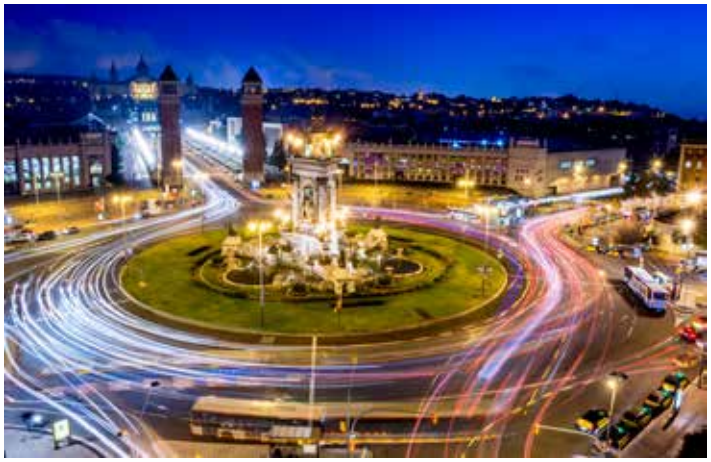
Robert Schwarz, FH Campus Vienna
Lecturer Validation and Process Analysis

Sebastian Thölken, Novartis Pharma Stein AG
Process Expert Microbiology / Microbiology in the Manufacturing Science and Technology Organisation

Radhakrishna Tirumalai, United States Pharmacopoeia Convention
Staff Liaison, Microbiology and Sterilty Assurance

Ulrich Zuber, F. Hoffmann-La Roche
Head of mEMT Parenteral Manufacturing Kaiseraugst

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
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sants@barcelo.com

Fees (per delegate plus VAT)
European Microbiology Conference
ECA Members € 1,590
APIC Members € 1,690
Non-ECA Members € 1,790
EU GMP Inspectorates € 895

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.

European Microbiology Conference combined with Workshop Bioindicators
ECA Members € 2,080
APIC Members € 2,180
Non-ECA Members € 2,280
EU GMP Inspectorates € 1,140
The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on three days and all refreshments. VAT is reclaimable.

Workshop Bioindicators
ECA Members € 790
APIC Members € 840
Non-ECA Members € 890
EU GMP Inspectorates € 445
The conference fee is payable in advance after receipt of invoice and includes conference documentation, lunch on 7 May and all refreshments during the conference. VAT is reclaimable.

Accommodation

CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form when you have registered for the event. Reservation should be made directly with the hotel. Early reservation is recommended.

Registration

Via the attached reservation form, by e-mail or by fax message. Or you register online at www.microbiology-conference.org.

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
P.O. Box 10 17 64
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For questions regarding content:
Mr Axel Schroeder (Operations Director) at +49 (0) 62 21/84 44 10 or via email at schroeder@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc.:
Mr Niklaus Thiel (Organisation Manager) at +49 (0) 62 21/84 44 43 or via email at thiel@concept-heidelberg.de.

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CONCEPT HEIDELBERG
P.O. Box 10 17 64
Fax +49 (0) 6221/84 44 34

69007 Heidelberg
Germany

Reservation Form (Please complete in full)

☐ **European Microbiology Conference**
8-9 May 2019, Barcelona, Spain
☐ **Workshop Bioindicators**
7 May 2019, Barcelona, Spain
☐ **European Microbiology Conference AND Workshop**
7-9 May 2019, Barcelona, Spain

☐ Mr ☐ Ms

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General terms and conditions
If you cannot attend the conference you have two options:
1. We are happy to welcome a substitute colleague at any time.
2. If you have to cancel entirely we must charge the following processing fees: Cancellation
- until 2 weeks prior to the conference 10 %,
- until 1 weeks prior to the conference 50 %
- within 1 week prior to the conference 100 %.

CONCEPT HEIDELBERG reserves the right to change the materials, instructors, or speakers without notice or to cancel an event. If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. CONCEPT HEIDELBERGwill not be responsible for discount airfare penalties or other costs incurred due to a cancellation. **Terms of payment:** Payable without deductions within 10 days after receipt of invoice. **Important:** This is a binding registration and above fees are due in case of cancellation or non-appearance.

If you cannot take part, you have to inform us in writing. The cancellation fee will then be calculated according to the point of time at which we receive your message. In case you do not appear at the event without having informed us, you will have to pay the full registration fee, even if you have not made the payment yet. Only after we have received your payment, you are entitled to participate in the conference (receipt of payment will not be confirmed)! (As of January 2012).

Privacy Policy: By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at http://www.gmp-compliance.org/eca_privacy.html). I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.

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