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European Microbiology Conference

Workshop Validation of Microbiological Methods

Speakers:



Dr. Claudio Aguilar
rqmicro AG, Switzerland



Walid El Azab
Steris, Belgium



Dr Thomas Brinz
Bosch, Germany



**Dr Marja Claasen-
Willemse**
MSD, The Netherlands



**Dr Sven M.
Deutschmann**
*Roche Diagnostics,
Germany*



Carolin Fromm
Labor L+S AG, Germany



Barbara Gerten
Merck, Germany



**Prof. Edwin van den
Heuvel**
The Netherlands



**Dr Pieta IJzerman-
Boon**
MSD, The Netherlands



Jens Jesse
Biotest, Germany



Dr Roman Mathaes
Lonza, Switzerland



Dr Bryan Riley
FDA, USA



Dr Petra Rösch
*University Jena,
Germany*



Jim Polarine
Steris, USA



Kevin Williams
bioMerieux, USA



European Microbiology Conference
9-10 May 2017, Prague, Czech Republic

Workshop Validation of Microbiological Methods
11-12 May 2017, Prague, Czech Republic

Highlights:

- Laboratory Automation
- Method Validation
- Regulatory Developments



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

Invitation to the European Microbiology Conference 2017 with post-conference workshop on “Validation of Microbiological Methods”

Dear Colleague,



I would like to invite you to the European Microbiology Conference (EMC) and the Workshop on Validation of Microbiological Methods, organised by the ECA Academy in Prague, Czech Republic.

Since 9 years, the ECA organizes the European Microbiology Conference in spring. The very good responses from attendants, speakers and exhibitors turned it to an annual event with presentations and workshops on current topics in pharmaceutical microbiology. In 2017, the EMC will be combined with a Post-Conference Workshop on “Validation of Microbiological Methods” with special focus on using statistical methods. The combination of these two events gives you an outstanding possibility to keep you up-to-date with the current developments and state of the art handling in microbiological quality control. Pharmacopoeial experts, representatives from pharmaceutical quality control and from testing laboratories will show you their experiences and what are the challenges and how they implemented an 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 Prague



Dr Sven M Deutschmann
Chairman of ECA's Pharmaceutical Microbiology Working Group

European Microbiology Conference

9-10 May 2017, Prague, Czech Republic

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 Key Note 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. It is also increasingly in the focus of regulators during product submission and inspections. Current challenges are Low Endotoxin Recovery, implementation of alternative microbiological methods and the ongoing issues with contamination control – there were an increasing number of findings in the authority reports. The challenge is therefore to satisfy regulatory requirements alongside management's financial expectations.

European Microbiology Conference

9-10 May 2017, Prague, Czech Republic

- Target Audience** This conference is of interest to professionals in microbiology from
- Pharmaceuticals and Biopharmaceutical Companies
 - Academic Research Institutions
 - Government Agencies
 - Contract Service Laboratories
- who are involved in
- Contamination Control
 - Monitoring
 - Validation
 - Quality Affairs
 - Regulatory Affairs
 - Research and Development
- Moderator** [Sven M. Deutschmann, Chairman, ECA Pharmaceutical Microbiology Working Group](#)
- Programme**
- Biologics Are Different - A New Paradigm for Microbiological Contamination Control**
- Microbiological control
 - The new science of immunological control
- [Kevin Williams, GE Analytical Instruments](#)
- Revised ISO Methods for Validation and Detection of Pathogens**
- Revised ISO 16140: Validation of alternative methods
 - Other revised ISO methods: Enterobacteriaceae, Cronobacter, Salmonellae
- [Barbara Gerten, Merck](#)
- FDA perspectives on Burkholderia cepacia and risk-based microbiology review**
- CDER perspective on Burkholderia multivorans contamination case study
 - Regulatory expectations for Burkholderia control
 - Risk-based microbiology quality assessment by CDER
- [Bryan Riley, FDA](#)
- Industry case study: A microbial investigation of contamination by Burkholderia multivorans**
- The role of microbiological analysis
 - The role of subject matter experts
 - Coordination with FDA
- [Marja Claassen-Willemsse, MSD](#)
- PDA's Technical Report No. 70: Fundamentals of Cleaning and Disinfection Programs for Aseptic Manufacturing Facilities**
- Key Areas of TR No. 70
 - definitions and inspections
 - validation
 - frequencies and rotations
 - shut downs
 - How this new technical report compares and relates to Europe, Asia, and Latin America
- [Jim Polarine, Steris](#)
- Validation of a Rapid Sterility Test – Realisation from the Perspective of a Contract Laboratory**
- Implementation and validation of an ATP Bioluminescence method for rapid sterility testing
 - Comparison of the requirements of Ph. Eur. 5.1.6, USP <1223> and PDA TR 33 for the validation of a RMM
 - Results of the method validation and equivalence testing of a selected spectrum of various products
- [Carolin Fromm, Labor L+S AG](#)
- Container Closure Integrity for Frozen Drug Products**
- Container Closure Integrity Introduction
 - Latest Regulatory Changes – USP <1207> Revision
 - Container Closure Integrity for Frozen Drug Products
 - Container Closure Integrity Strategy: Holistic Approach
- [Roman Mathaes, Lonza](#)

European Microbiology Conference

9-10 May 2017, Prague, Czech Republic

Programme,
cont'd

Paperless Laboratory

- System architecture
- Paperless laboratory
- LIMS modules

Sven Deutschmann, Roche

Automated Quality Control of highly purified Water to Water for Injection

- Modular approach of lab automation solutions
- Development of new modules for water analysis
- System performance
- Data handling of results

Thomas Brinz, Bosch and Jens Jesse, Biotest

Microbial Contamination Control and Implications on non-sterile Batch/ Equipment Release

- Objectionable microorganism's definition
- Design-effective cleaning and sanitization procedures (process equipment, clean room & water system)
- Categorize the objectionability and propose a risk-based decision making to assess product quality impact prior to product release
- Case studies of common cause for microbial contamination

Walid El Azab, Steris

Rapid detection of pathogens by IMS and flow cytometry

- The Cellstream and IMS technology for Legionella
- Benefits of IMS for plating
- Viability as a marker for detection
- Does 1 cfu really spread?
- Test of different growth media and inactivators
- Test of different incubations conditions on spreading

Dr. Claudio Aguilar, rqmicro AG, Switzerland

The optimal experiment for validation of qualitative RMMs

- How to create samples: independent or from one stock?
- How to quantify the performance of the method?
- How many test samples needed, with which spike level?

Pieta IJzerman-Boon, MSD and Edwin van den Heuvel, Univ. Eindhoven

Cultivation-free Raman spectroscopic Identification of Bacteria

- Technical background
- Pros and Cons
- Possibilities, pitfalls and limitations

Petra Rösch, University of Jena



Social Event

On 9 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.

Workshop “Validation of Microbiological Methods”

11-12 May 2017, Prague, Czech Republic

Moderators

Pieta IJzerman-Boon, Principal Statistician MSD
Prof. Edwin van den Heuvel, University of Technology, Eindhoven, The Netherlands

Abstract

For the validation of microbiological test methods, several experiments must be performed to demonstrate that the new method is capable of detecting and counting organisms in test samples and at least as good as the compendial method. To quantify the performance, statistical methods form an indispensable tool. This workshop will provide information on the types of experiments and the statistical analyses that may be performed to estimate the validation parameters of the new rapid methods. The methods will be illustrated with real cases on the validation of rapid microbiological test methods.

Programme

General Part

- Guidelines
- Equivalence
- Statistical detection
- Proposed Strategies

Quantitative Methods

- Statistical detection
- Accuracy
- LOD & LOQ
- Linearity
- Precision

Qualitative Methods

- Most Probable Number
- Specificity
- Accuracy
- LOD

Robustness

- Two-factor experiment
- Multi-factor experiments
- Approaches qualitative & quantitative methods

Closing remarks

Important



Please note that a laptop is needed for the practical exercises. Also, the “Minitab” software must be installed on this computer. You can download a 30 days trial version of this software here: <https://www.minitab.com/en-us/products/minitab/>

Workshop Dinner



On 11 May, you are cordially invited to a conference dinner. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

Speakers



Dr. Claudio Aguilar, rqmicro AG, Switzerland

Claudio obtained his PhD in Molecular Microbiology from the International Centre for Genetic Engineering and Biotechnology (ICGEB) and the Open University UK. With postdoc experience obtained at Cornell, Harvard and Zurich Universities, his expertise includes bacterial physiology, biofilm development and quorum sensing. Currently he is Senior Microbiologist and Head of the Assay Development division at rqmicro.



Walid El Azab, Steris Corporation, Belgium

Walid is a Technical Services Manager for the Life Sciences Division of STERIS Corporation. He currently provides technical support related to cleaning chemistries, disinfectants and sterility assurance products and their application and validation. His areas of expertise include both upstream and downstream biopharmaceutical operation and validation. Walid has held various positions including Project Manager, Inspection Readiness Manager, Quality and Regulatory Manager, and Qualified Person (QP). Walid earned a Master's degree in Industrial Pharmaceutical Sciences from the University of Liege, Belgium and is green belt certified.



Dr. Thomas Brinz, Bosch Engineering and Application of Custom Solution

Thomas studied Chemistry at the University of Ulm and got his PhD on Liquid crystals 1994. He was employed in Corporate Research of Bosch from 1995 to 2003. After that he was involved in funding of Bosch Lab System in the Transfer Centre of Bosch. In 2006, this was integrated in Packaging Technology, and in 2011 in the Business Unit Pharma. Currently, he is Head of Lab Automation and Custom Solutions.



Dr. Marja Claassen-Willemse, MSD Oss, Senior Specialist, Global Center of Expertise Microbiology, The Netherlands

Maria Claassen studied Biology at the Radboud university of Nijmegen and got her PhD on Virology at the Utrecht University. After a post doc position in the field of Immunology at the Erasmus MC in Rotterdam, she joined MSD where she had varying positions in development, QC and manufacturing. Currently she is Senior Specialist of the Global Center of Expertise Microbiology, The Netherlands, involved in rapid microbiological method deployment in the QC laboratories of MSD.



Dr. Sven M. Deutschmann, Roche Diagnostics GmbH, Penzberg, Germany

In 1995 Sven Deutschmann joined Roche Diagnostics GmbH. Currently, Sven Deutschmann is responsible for the Biological Quality Control including microbiological, molecular and cell biological analytics of QC and In-Process-Control samples in the production of biotechnological derived commercial and clinical active pharmaceutical ingredients and for the Environmental Monitoring and Cleaning Validation activities for the API facilities. Beginning of 2012 he was appointed as Global Head of a Corporate Function called "Method Management and Technology" within the Biologics Operational Unit of Roche with special focus on PCR-based technologies and Rapid Microbiological Methods.



Carolin Fromm, Labor L+S AG, Bad Bocklet, Germany

Carolin Fromm studied Bioanalytics (Master) at the University of Applied Science Coburg. Since 2015 she is head of department research and development at Labor L+S AG. Her responsibility includes the project "Implementation and validation of a rapid sterility test" as well as the implementation of new customized microbiological methods.



Barbara Gerten, Merck, Darmstadt, Germany

After her studies in microbiology and biochemistry at the Universities of Düsseldorf and Münster, Barbara Gerten was employed in different companies responsible for Quality Control and Research and Development. Since 2008, she is working at Merck KGaA, Darmstadt, Germany, in different positions in R+D and Technical Marketing, currently as Senior Scientist Traditional Microbiology. She is a member in several national and international bodies of microbiological food and water topics in ISO and CEN and a member of ECA Microbiology Advisory Board.



Prof. Edwin van den Heuvel, University of Technology, Eindhoven, The Netherlands

Edwin van den Heuvel started his professional career in Statistics after obtaining his PhD in 1996. He started as a consultant in industrial statistics with the Institute of Business and Industrial Statistics and afterwards became head of the statistics department at the pharmaceutical company MSD. Since 2010 he is full time professor Medical Statistics at the UMCG (University Medical Center Groningen). Since October 2014 he is Professor at the TU/e department of Mathematics and Computer Science will be closely involved with the development of the Data Science Center Eindhoven (DSC/e).

Speakers



Dr Pieta IJzerman-Boon, MSD, The Netherlands, Associate Director Quantitative Sciences/Center for Mathematical Sciences - Europe

Pieta C. IJzerman-Boon received her education at the University of Twente, the Netherlands. In 1995 she obtained her M.Sc. degree in Applied Mathematics, followed by a Ph.D. in Statistics in 1999. She joined MSD after her PhD. In 2011 she moved to the non-clinical statistics group in the company, where she currently works as a senior statistician at the Center for Mathematical Sciences.



Jens Jesse, Head QC, Biotest AG, Germany

Jens Jesse studied Engineering Technology of Chemistry in Berlin. From 1994 to 2008 he worked for Abbott Diagnostics, CSL Behring and Gerresheimer. Currently, he is Head of Quality Control at Biotest AG, Germany. Besides others his current strong focus is the implementation of a lab automation for water tests as e.g. WFI, constructed and made by Bosch.



Dr Roman Mathaes, Lonza, Switzerland

Roman Mathaes is a group leader within the Lonza Drug Product Service organization. He is leading the Lonza particle lab and the container closure integrity testing. In this role, Roman is responsible for particle analytics in drug products and container closure integrity testing of vials and pre-filled syringes and process development of capping/crimping. Prior to this assignment, Roman was working within Roche/Genentech network supporting process development of the commercial manufacturing. Roman is an active member of the European CCI industry focus group and part of the BPOG CCI workstream. Roman is a pharmacist by training and conducted his studies at the University of Marburg and King's College London. He holds a PhD in pharmaceutical technology from the University of Munich for work on subvisible particle characterization.



Jim Polarine Jr., MA. Formulated Chemistries Technical Service Manager, STERIS Corporation

Jim Polarine graduated from the University of Illinois with a Master of Arts in Biology. He has been with Steris Corporation for over 163 years and is today senior technical service manager. He is also currently active on the PDA task force on microbial excursions cleaning and disinfection and has co-authored the PDA technical report No. 70 Fundamentals of Cleaning and Disinfection Programs for Aseptic Manufacturing Facilities on cleaning and disinfection. He is part of the faculty at the University of Tennessee Parenteral Medication course.



Bryan S. Riley, Ph.D., Branch Chief (acting), U.S.FDA, CDER, Office of Pharmaceutical Quality, Office of Process and Facility, Division of Microbiology Assessment

Bryan Riley is an acting Branch Chief in the Division of Microbiology Assessment in the Office of Pharmaceutical Quality, Center for Drug Evaluation and Research at the Food and Drug Administration. He is a member of the CDER/OPQ Emerging Technology Team which is delegated with facilitating the adoption of innovative technologies for pharmaceutical manufacturing. Dr. Riley has also been involved in the efforts to adopt a risk-based review process as a member of the OPQ Continuous Improvement Team. Prior to coming to FDA in 1998, he directed a clinical microbiology laboratory specializing in molecular diagnostic methods. He holds B.S. and M.S. degrees in Microbiology from Texas Tech University and a Ph.D. in Microbiology from the University of North Texas. He completed his formal scientific training as a post-doctoral fellow at the University of Texas Southwestern Medical Center at Dallas.



Dr Petra Rösch, Institute for Physical Chemistry, Friedrich-Schiller-University Jena

Petra Rösch received her Ph.D. in chemistry from the University of Würzburg in 2002. In her current position at the University Jena, she is working on the investigation of all kind of biological, medical, and pharmaceutical relevant problems with various vibrational spectroscopic methods. Her main focus lays on the cultivation-free characterization and identification of microorganisms with Raman.



Kevin Williams, bioMerieux, USA

Kevin is a recognized expert in the endotoxin detection field with over 30 years of experience in Pharma (Eli Lilly, Hospira, Lonza). He authored and edited the 2nd and 3rd editions of "Endotoxins" book from Informa Healthcare as well as authoring many journal articles in PDA, BioPharm, Pharmaceutical Technology, and American Pharmaceutical Review. He is often a speaker at PDA and other microbiological focused conferences.

Easy Registration

 **Reservation Form:**
CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg
Germany

 **Reservation Form:**
+ 49 6221 84 44 34

 **e-mail:**
info@concept-heidelberg.de

 **Internet:**
www.microbiology-conference.org
www.gmp-compliance.org

Dates

European Microbiology Conference

Tuesday, 09 May 2017, 09.00 – 17.30 h
(Registration and coffee 08.30 - 09.00 h)
Wednesday, 10 May 2017, 08.30 – 17.00 h

Workshop Validation of Microbiological Methods

Thursday, 11 May 2017, 09.00 – 17.30 h
(Registration and coffee 08.30 – 09.00 h)
Friday, 12 May 2017, 09.00 – 13.00 h

Venue

Corinthia Hotel Prague
Kongresova 1
14069 Prague 4, Czech Republic
Phone +420 (261) 191 111
Fax +420 (261) 225 011

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 9 May, lunch on both days and all refreshments during the conferences. VAT is reclaimable

European Microbiology Conference combined with Workshop Validation of Microbiological Methods

ECA Members € 2,780

APIC Members € 2,880

Non-ECA Members € 2,980

EU GMP Inspectorates € 1,490

The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on 9 and 11 May, lunch on three days and all refreshments during the conferences. VAT is reclaimable.

Save up to
€ 500

Workshop Validation of Microbiological Methods

ECA Members € 1,490

APIC Members € 1,590

Non-ECA Members € 1,690

EU GMP Inspectorates € 845

The conference fee is payable in advance after receipt of invoice and includes conference documentation, lunch and dinner on 11 May, and all refreshments during the conferences. 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.gmp-compliance.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

D-69007 Heidelberg, Germany

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For questions regarding content:

Mr Axel Schroeder (Operations Director) at +49-62 21/84 44 10 or per e-mail at schroeder@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc.:

Ms Katja Kramer (Organisation Manager) at +49-62 21/84 44 16 or per e-mail at kramer@concept-heidelberg.de.

If the bill-to-address deviates from the specification to the right, please fill out here:

Reservation Form (Please complete in full)

+49 6221 84 44 34

European Microbiology Conference
9-10 May 2017, Prague, Czech Republic

Workshop Validation of Microbiological Methods
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European Microbiology Conference AND Workshop
9-12 May 2017, Prague, Czech Republic

Yes, I will take part in the social event on 9 May

Mr Ms

Title, first name, surname

Company

Department

Important: Please indicate your company's VAT ID Number

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69007 Heidelberg
Germany

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 week 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 HEIDELBERG will 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).

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