European Microbiology Conference

Workshop Validation of Microbiological Methods

Highlights:

- Laboratory Automation
- Method Validation
- Regulatory Developments

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

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

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

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

Sven M. Deutschmann, Chairman, ECA Pharmaceutical Microbiology Working Group

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-Willemse, 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
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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 automatisation 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 prefilled 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.
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.

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.

Important:

This is a binding registration and above fees without deductions within 10 days after receipt of invoice. Payable terms of payment: Incurred due to a cancellation.

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:
   - until 1 week prior to the conference: 50%
   - until 2 weeks prior to the conference: 10%
   - entirely: no refund of fees paid. CONCEPT HEIDELBERG will not be entitled to participate in the conference (receipt of invoice and includes conference documentation, dinner on 9 May, lunch on both days and all refreshments during the conferences. VAT is reclaimable.

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

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Registration

Via the attached registration 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.

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

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