ECA Academy
Your GMP/GDP Information Source

European Microbiology Conference

25-26 April 2018, Vienna

+ Workshop

Data Integrity in Microbiology | 24 April 2018

Highlights

- Data Integrity – focused on Microbiology Laboratory Challenges
- ECA Guidance for Microbiological Environmental Deviations in Non-Sterile Manufacturing
- Next Generation Sequencing
- Case Studies: Validation of different Microbiological Methods

Speakers

Walid El Azab
Steris Corporation, Belgium

Dr Isabelle Bekeredjian-Ding
Paul-Ehrlich Institut, Germany

Dr Elena Bolchakova
Thermo Fisher Scientific , USA

Dr Björn Breth
bioMérieux, Germany

Dr Sven M. Deutschmann
Roche, Germany

Carolin Fromm
Labor L+S, Germany

Dr Marcel Goverde
MGP, Switzerland

Prof. Edwin van den Heuvel
University Eindhoven, The Netherlands

Dr Gerald Kindermann
F. Hoffmann-La Roche, Switzerland

Audrey Meade
MSD Arzneimittel, Ireland

Di Morris
GSK, United Kingdom

Dr Antje Motzek
Labor L+S, Germany

Dr Youwen Pan
Genentech, USA

Dr Petra Parizek
Lavus Arzneimittel, Switzerland

Mousumi Paul
MSD, USA

Robert Porzio
Lonza, USA

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

Introduction

Invitation to the European Microbiology Conference 2018 with pre-conference workshop

Dear Colleague,

I would like to invite you to the European Microbiology Conference (EMC) and the Workshop on Data Integrity in Microbiological Laboratories, organised by the ECA Academy in Vienna, Austria.

The ECA has been organizing the European Microbiology Conference every spring for ten years. The very good responses from attendants, speakers and exhibitors alike turned it to **an annual event with presentations and workshops on current topics in pharmaceutical microbiology**. In 2018, the EMC will be combined with a Pre-Conference Workshop on Data Integrity, a topic which challenges all parts of pharmaceutical quality management. The workshop will focus on the requirements and approaches to handle it in the field of microbiology.

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, what their challenges are 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 Vienna.

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

European Microbiology Conference | 25-26 April

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. 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 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

- Pharmaceuticals and Biopharmaceutical Companies
- Academic Research Institutions
- Government Agencies
- Contract Service Laboratories

who are involved in

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

Moderator

Dr Marcel Goverde, MGP
Vice Chair of ECAs Pharmaceutical Microbiology Working Group

QA Oversight - environmental improvement program including aspects of the aseptic observer initiative

Audrey Meade, US – Merck/MSD

ECA Guidance for Microbiological Environmental Deviations in Non-Sterile Manufacturing

Marcel Goverde, MGP
David Roesti, Novartis

- Differentiation between critical and non-critical deviations
- Clear definition of actions to be taken
- Needs for final approval by QA
- Propositions for control levels

Q&A on Microbiological Media Challenges

Björn Breth, bioMérieux

Validation of an Alternative Microbial Enumeration Assay

Sven Deutschmann, Roche

- Introduction
- Requirements
- Method Validation

Validation of Microbiological IPC Methods

Petra Parizek, Laves

- IPC of biofermentation samples
- Practical examples of validation approaches

Automation in Clinical Microbiology and/or Bacteria Reference Standards

Isabelle Bekeredjian-Ding, Paul-Ehrlich Institut

How to handle Spreader Bacteria

Marcel Goverde, MGP

- What is the spreading phenomenon?
- How many CFUs are needed to spread?
- How can spreaders be inhibited?

Common failure observed during autoclave and sterilization validation and routine monitoring – case studies

Walid El Azab, Steris Corporation

- Discuss the top microbiological considerations when validating, requalifying and routine use of steam sterilization.
- Impact of the different regulatory updates (EMA and future Annex 1 guidance) from an end-user perspective.
- Common mistakes and lessons learned regarding steam sterilization autoclaves including Steam in Place (SIP) systems using case studies

New Data for MuScan Validation

Speaker, MSD

Next generation sequencing (NGS) and microbiological quality control

Elena Bolchakova, Thermo Fisher Scientific

- Viral detection with massive parallel sequencing of the amplified viral genomic tags
- Benefits of MPS or NGS
- Possible Challenges like host cell background
- Current conclusions

Rapid Micro Methods Development and Global Deployment approach at Merck

Mousumi Paul, MSD

- Vision and Strategy for Global Deployment of RMMs at Merck
- Business Case development to facilitate adoption
- Phases from development of Technology to implementation of RMMs in routine
- Overcoming challenges associated with the Implementation of Rapid Micro Methods
- Case studies/examples

Unique global collaboration through BPOG and Microbial control Vision

Mousumi Paul, MSD

- Mission, Benefits of membership with BPOG
- 6 Phorums covering all aspects of biopharma operations
- Microbial control Workstream efforts
- Vision and Five Year Plan for implementation

Modern Micro Methods and their LOD

Edwin van den Heuvel, University of Eindhoven

- Probabillity of Detecting Contaminations
- The USP Approach – Risk Based or not
- Relationship of LOD and Sampling Plan
- How to handle it in Practice

Different matrices require different solutions

Carolin Fromm, Labor L + S

- Selection of the best fit rapid method for sterility test
- Pros and cons

Social Event | 25 April

On 25 April, 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: Data Integrity in Microbiology | 24 April

Objectives

This workshop will cover the regulatory requirements and present approaches and practical experiences on the implementation of data integrity strategies in microbiological laboratories. It will provide you the possibility to discuss the challenges of the ongoing automation of methods and processes in relation to the increasing requirements of data integrity.

Background

Even Data Integrity is one of the basic GMP principles. Multiple Data Integrity issues were reported by FDA und European inspectors during the last 3 years. Many US Warning Letters and EU Non-Compliance Reports deal with serious Data Integrity violations. Data Integrity questions have been and will continue to be the focus of many GMP inspections.

As a consequence, international authorities – FDA, EMA, PIC/S, WHO, MHRA - published draft documents to describe the regulatory expectations of Data Integrity.

Even though the guidelines are not intended to impose additional regulatory burden upon the regulated companies, a lot of uncertainty predominates the pharmaceutical industry about how to implement these requirements into the daily business.

Microbiological laboratories are influenced by these developments, as well.

Target Audience

All persons which will be involved in collecting, analysing and trending data in microbiological laboratories and will be challenged by the lab data integrity requirements. Additionally, all persons from QC and QA who have to judge these data for risk evaluation or release questions.

Moderator

Dr. Sven M. Deutschmann, Roche Diagnostics GmbH
Chairman of ECAs Pharmaceutical Microbiology Working Group

Presentations

Requirements on Data Integrity in Laboratory
Gerald Kindermann, F. Hoffmann-La Roche, Switzerland

Life cycle approach for qualification of computerized systems in microbiological testing
Dr. Antje Motzek, Labor L+S AG, Germany

Data Integrity – Challenges in Microbiology
Di Morris, GSK, United Kingdom

Importance of Data Integrity when Testing for Endotoxin
Robert Porzio, Lonza, USA

Risk Assessment Strategies
Youwen Pan, Genentech, USA

Speakers Conference & Workshop

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 Isabelle Bekeredjian-Ding, Paul-Ehrlich Institut, German federal agency for Vaccines and Biomedicines
Dr Bekeredjian-Ding is the head of microbiology at the Paul-Ehrlich institute (PEI). She studied medicine in Heidelberg, Germany, Padova, Italy and New York, NY, USA. She received a PhD equivalent in immunology and is a board-licensed medical microbiologist who received scientific and clinical training in Munich, Dallas, TX and Heidelberg, Germany. Before being appointed to the PEI in 2015 she worked as laboratory head and senior consultant at the Medical Microbiology unit of the University Hospital Bonn.

Dr Elena Bolchakova, Sr.Staff Scientist, Themo Fisher Scientific
Dr Elena Bolchakova graduated from the Biology department of Moscow State University in Russia and received her PhD degree from the Institute of Molecular Genetics in Moscow. After moving to the United States, she joined Applied Biosystems as a postdoctoral fellow and then became a research scientist. During her tenure with Applied Biosystems/Life Technologies/Thermo Fisher Scientific Dr Bolchakova led development of several new commercial products in the area of Sanger sequencing, qPCR detection of microbial pathogens and biological contaminants in pharmaceutical products, MicroSEQ® ID microbial identification system and 16S Metagenomic analysis of microbial communities using massively parallel sequencing. Dr Bolchakova is currently working on a new rapid detection method of viral contamination in cell cultures based on NGS of PCR-amplified viral genomic signatures.

Dr Björn Breth, Industry Cluster Head Central Europe, bioMérieux
Björn studied Biology at the University of Kaiserslautern. After his Ph.D. he worked until 2011 for Greiner Bio-One as Product Scientist Manger. In 2011 he started his career at bioMérieux as Product Manager Industry DACH Food/Veterinary. Since April 2017 he is Industry Cluster Head Central Europe.

Speakers

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

In 1995 Sven Deutschmann joined Roche Diagnostics GmbH. Dr Sven M. Deutschmann studied at the University of Brunswick. He holds a PhD (1994) and a MSc/Diplom (1991) in Biology. In 1995 he joined Roche Diagnostics GmbH. In the past two decades he took over increasing responsibilities within the local and global Roche QC Network. He has been extensively involved in various fields of Quality Control - Microbiology, Bioassay, Adventitious Agents Testing, Environmental Monitoring, Cleaning Analytics/Validation, and many more. Currently, Sven is Head of a Corporate Function within the Global QC Network of Roche called "Analytical Science and Technology – Adventitious Agents Testing & Alternative 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.

Dr Marcel Goverde, MGP Consulting, Switzerland

Marcel Goverde earned his PhD in ecology at the University of Basel where he subsequently was employed as an academic tutor. 2002 to 2010 he was leading the quality control lab for non-sterile products as well as the lab for research & development of microbiological methods at F. Hoffmann-La Roche Ltd in Basel. After one year at Novartis ChemOps Ltd. running the microbial QC lab for API and drug development, he started his own company for consulting and training. Furthermore he is the Swiss delegate for group 1 (microbiological and statistical methods) and vice-chair of the ECA Pharmaceutical Microbiology Working Group.

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

Edwin obtained his Ph.D. in 1996. He started as a consultant in industrial statistics and afterwards he became head of the statistics department at MSD. Since 2010 he is fulltime professor Medical Statistics at the UMCG and 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).

Dr Gerald Kindermann, F. Hoffmann – La Roche, Basel, Switzerland

Dr Gerald Kindermann is "QA and GMP Compliance Lead for global QC" working in the Global Quality Group at Roche. Before that he held several positions within Roche, amongst others Group Leader Quality Control and Quality Manager for the Supply Center.

Audrey Meade, Associate Director Sterile IPT Process Microbiologist, MSD, Ireland

Audrey studied Cell and Molecular Biology and Applied Bioscience at Cork Institute of Technology. After a postgraduate training in pharmaceutical validation technology, she joined DePuy Synthes as microbiologist, later as Senior Sterilisation Scientist until 2014. Since 2014, she is employed at MSD as Associate Director Sterile IPT Process Microbiologist

Di Morris, Audit Manager CAG, GSK, United Kingdom

Di Morris worked more than 6 years as Midicines Inspector for the UK Department of Health. After 4 years of consultancy in Quality Assurance and as QP, she joined GSK in 2015. She has a broad experience in regulatory requirements, microbiology and quality topics.

Dr Antje Motzek, Quality Assurance, Labor L+S AG, Bad Bocklett, Germany

Antje Motzek studied Molecular and Cell Biology in Mainz and Erlangen-Nürnberg. She worked then as scientist at the Institute for Human Genetics in Mainz and later at Alfatraining. After further trainings in QM and Projectmanagement she is employed in the Quality Assurance of Labor L+S AG since 2016.

Dr Youwen Pan, QC Scientist/Microbiologist at Genentech

Youwen studied at the Lanzhou University and the North Carolina State University Biology and Microbiology. After his Ph.D. he worked as research scientist at Baxter. Since 2013 he is employed at Genentech, where he is involved in Rapid Microbiological Methods Development; Global Change Control and Global CAPA.

Dr Petra Parizek, Laves Arzneimittel, Switzerland

Petra Parizek studied Biology at the University of Zurich and got her PhD in Biochemistry. Since 2013, she is working at Laves Arzneimittel GmbH, Schoetz, Switzerland, a company with focus on biotechnological production of pharmaceuticals and food supplements. As Head of QC, Petra Parizek is responsible for the Quality Control of starting materials, In-Process-Control samples and products including microbiological, chemical and molecular biological analytics of QC as well as Environmental Monitoring.

Mousumi Paul, Director Manufacturing and Quality Center of Expertise Microbiology, Merck, Sharp and Dohme

Mousumi is the Global deployment lead for Rapid Micro Methods at MSD. She is also responsible for managing the Quality and Compliance initiatives within Center Of Expertise Microbiology. Prior to this role Mousumi worked in Biologics Quality Operations where she was the Quality lead for new product launches. Mousumi has over eighteen years of diverse experience from development through technology transfer, manufacturing and quality support for vaccines and biologics. Mousumi has directed transformation efforts and operational excellence projects focused on enhancements to sterility assurance. She holds a Master's Degree in Microbiology and in Pharmacology and a Master of Business Administration degree in Management.

Robert Porzio, Global Product Manager at Lonza, Walkersville, USA

Robert is a graduate from the College of Charleston and holds a degree in Biology and Psychology. He has specialized in Endotoxin Testing Matters for the last 20 years holding different positions in production, marketing and sales at market leading providers of Endotoxin Testing Solutions. In this current Product Management Position at Lonza, Walkersville Robert is focusing in instrumentation, automation and software solutions.

Dates
Workshop Data Integity in Microbiology
Tuesday, 24 April 2018, 09.30 - 17.00 h
(Registration and coffee 09.00 – 09.30 h)

European Microbiology Conference
Wednesday 25 April 2018, 09.00 – 17.30 h
(Registration and coffee 08.30 – 09.00 h)
Thursday, 26 April 2018, 08.30 – 16.15 h

Venue
Austria Trend Parkhotel Schönbrunn
Hietzinger Hauptstr. 10-14
1130 Vienna
Austria
Phone +43 (1) 878 04 0
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parkhotel.schoenbrunn@austria-trend.at

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 25 April, lunch on both days and all refreshments during the conferences. VAT is reclaimable.

European Microbiology Conference combined with Workshop Data Integrity in Microbiology
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 25 April, lunch on three days and all refreshments during the conferences. VAT is reclaimable.

Workshop Data Integrity in Microbiology
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 24 April 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
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For questions regarding content:
Mr Axel Schroeder (Operations Director) at +49 (0) 62 21/84 44 10 or via e-mail 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 e-mail at thiel@concept-heidelberg.de.

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Reservation Form (Please complete in full)

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25-26 April 2018, Vienna, Austria
☐ **Workshop Data Integrity in Microbiology**
24 April 2018, Vienna, Austria
☐ **European Microbiology Conference AND Workshop**
24-26 April 2018, Vienna, Austria

☐ Yes, I will take part in the social event on 25 April

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