ECA ACADEMY

European Microbiology Conference

With Pre-Conference Workshop "Bioburden" on 6 May 2014

7-8 May 2014, Prague, Czech Republic

HIGHLIGHTS

Workshop Bioburden

- USP <1115>
- Non-Sterile Products
- Sterile Products
- Combination Products

European Microbiology Conference

- Advanced Monitoring
- Human Contamination
- Biological Indicators

SPEAKERS

DR MARJA CLAASSEN
MSD, The Netherlands

GILBERTO DALMASO
Particle Measuring Systems, Italy

DR JÖRG DEGEN
Bioservice Scientific Laboratories, Germany

DR SVEN M. DEUTSCHMANN
Roche Diagnostics, Germany

JÖRG DRESSLER
PMT, Germany

ANJA FRIEDRICH
Bioservice Scientific Laboratories, Germany

BARBARA GERTEN
Merck Millipore, Germany

DR OLIVER GORDON
Novartis Pharma, Switzerland

DR MARCEL GOVERDE
MGP, Switzerland

RAJESH K. GUPTA
Biologics Quality & Regulatory Consultants, USA

DR TIMO KREBSBACH
Labor L+S AG, Germany

DR JELENA NOVAKOVIĆ JOVANOVIĆ
Galenika AD, Serbia

DR DIETMAR MAYER
IDT, Germany

DR JOSEPH PIERQUIN
Advenics, France

JIM POLARINE
Steris Corporation, USA

DR TIM SANDLE
BPL, United Kingdom

ALEXANDRA STÄRK
Novartis Pharma, Switzerland

DR RADHAKRISHNA TIRUMALAI
USP, USA

MARY-ANN WEATHERHEAD
Pfizer, United Kingdom

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

Invitation
to the European Microbiology Conference 2014 with pre-conference workshop "Bioburden"

Dear Colleague,

I would like to invite you to the European Microbiology Conference and the Bioburden Workshop 2014 organised by the European Compliance Academy (ECA).

In 2008, ECA organised the first Microbiology Conference and the first Mycoplasma Testing Conference in Berlin, Germany. Referring to the very good response of Attendants, Speakers and Exhibitors it became an annual event with presentations and workshops on current topics in pharmaceutical microbiology.

In the July/August edition of their Pharmacopeial Forum 39(4), the USP published the draft of chapter <1115> "*Bioburden Control of Nonsterile Drug Substances and Products*". The document outlines a risk-based approach to the control of potential contamination in non-sterile product manufacturing.

But "bioburden" is not only a topic of Non-Sterile Products. Annex 1 of the European GMP Guideline requires *"The bioburden should be monitored before sterilisation. There should be working limits on contamination immediately before sterilisation, which are related to the efficiency of the method to be used. Bioburden assay should be performed on each batch for both aseptically filled product and terminally sterilised products."*

And last but not least, bioburden testing for medical devices made or used in the USA is governed by Title 21 of the Code of Federal Regulations and worldwide by ISO 11737.
The current developments determines us to address this topic in a special workshop session to look at this from various angles and provide you with information about the regulatory background and practical examples and strategies for bioburden control. Pharmacopoeial experts, representatives of pharmaceutical quality control and from testing laboratory will show you what are the challenges of the bioburden control strategy and how they implemented an adequate 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 and it is the aim of this conference and workshop to equip the pharmaceutical microbiologist with practical knowledge and "know how" which can be applied within the daily business. In addition it will provide a forum for interesting and open discussion between presenters, regulators and your colleagues from the industry.

It would be great pleasure for me if you could join us in Prague.

Dr Sven M Deutschmann
Chairman of ECA's RMM Working Group

Objectives

These two events offer a unique possibility to become acquainted with ongoing regulatory requirements, the development of microbiological methods for quality and process control, as well as 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 and the participants will have ample opportunity to discuss with speakers and other participants about specific issues.

Background

The role of pharmaceutical microbiology gets more and more important in the last years. It is more focused by the regulators during product submission and inspections. With the harmonisation of the different pharmacopoeias the harmonised methods must be implemented and the challenge is therefore to satisfy regulatory requirements alongside financial expectations of the management. Furthermore the field of Rapid Microbiological Methods developed very fast in the last years, and promises possibilities, to optimise the factors time and money in microbiological in-process-control and release.

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 Quality Affairs, Research and Development, Validation, Regulatory Affairs, Hygienic Aspects, Mycoplasma Testing

Pre-Conference Workshop "Bioburden"

6 May 2014, Prague, Czech Republic

During this workshop, the following contents and questions should be addressed by presentations and panel discussions. Considering that, panelists from the fields Non-Sterile Products, Sterile Products, Combination Products as well as biopharmaceutical APIs will on hand for the workshop.

Topic: General Information

- **Bioburden control strategy dependent of the lifecycle phase of the product (so-called "Phase-appropriate control strategy")**
  - Early clinical phase
  - Late clinical phase
  - Commercial phase
- **Test for "specified microorganisms" and / or "objectionable microorganisms"?**
  - Raw materials,
  - In-process-control samples,
  - Drug substance,
  - Drug Product,
  - Final Product

Topic: Testing

- **Where is bioburden tested in processes?**
- **Predefinition of bioburden and / or endotoxins levels for raw materials**
- **Assessment of the presence / absence of "objectionable microorganisms" in your raw materials ?**
- **What are the method in use ?**
  - TAMC
  - TYMC
  - MPN
  - Any other bioburden testing method
  - Rapid micro methods
- **Is it necessary to have a limited shelf life for bioburden samples?**
- **How to treat so called "missing bioburden" results ?**

Topic: Limits

- **Predefined bioburden and / or endotoxins levels for your upstream / fermentation processes (if applicable) and downstream processes or for the whole process**
- **What will be preferred? A two-tiered-control system (warning and alert level) or a three-tiered control system (warning and alert level AND rejection level) ?**
- **Methodologies in use to define the limits, e.g**
  - Methodology
  - How many data points are required to define the limits
  - Philosophy for new processes / new manufacturing processes without having experience of process capabilities

Topic: Deviation Management

- **Do you perform ID?**
- **If YES, when:**
  - Each colony
  - Only in case of an excursion of limits / level
- **What's the preferred ID technique**
  - Measures in case of an excursion of a limit ?

Topic: USP <1115>

- "**Bioburden Control of Nonsterile Drug Substances and Products**"

Panelists:

DR MARJA CLAASSEN, MSD
DR JÖRG DEGEN, BSL
DR SVEN DEUTSCHMANN, ROCHE DIAGNOSTICS,
DR MARCEL GOVERDE, MGP
ALEXANDRA STÄRK, NOVARTIS
DR RADHAKRISHNA TIRUMALAI, USP

Validation of Microbiological Methods – Expectations for Regulatory Compliance
- Verification, Qualification or Validation
- Relevance of ICH Q2(R1)
- Expectations and Common Practices
- Equivalency or Superiority Alternate Rapid Methods to Compendial Methods

DR RAJESH K. GUPTA, BIOLOGICS QUALITY & REGULATORY CONSULTANTS, USA

Revised ISO methods for Gram-negative bacteria
- Detection of Enterobacteriaceae
- Detection of Salmonellae
- Detection of Cronobacter sakazakii
- Improvement of pre-enrichment

BARBARA GERTEN, MERCK MILLIPORE

'The Human Microbiome and its implications for cleanroom microbiology'
- The human microbiome and current research
- The microbiology of human skin
- Implications for cleanroom control
- Implications for personnel and cleanroom practices
- Implications for disinfectants and culture media

DR TIM SANDLE, BPL

Case Study of Human Flora and Spore Contamination
- Pathways to use the data obtained from environmental monitoring
- Case studies on human flora and spore contamination in cleanroom operations
- Solutions to proactively present future contamination issues

JIM POLARINE, STERIS

High-Magnification Automated System for Rapid Detection of Microbiological Contaminants in Water Samples
- Technical background high resolution images and imaging software
- Reliability and Robustness
- Accuracy and Linearity

DR JOSEPH PIERQUIN, ADVENICS, FRANCE

Biolaz©: Real-Time Air Microbial Monitoring in an Environmental Monitoring Program
- Cleanrooms design for aseptic processes
- Environmental monitoring methods and plans
- New technologies in microbiological environmental monitoring
- Application and validation of real time microbiological air monitoring
- Benefit and saving in new microbiological technologies in microbiological cleanrooms monitoring

GILBERTO DALMASO, PMS

Real time detection of bioburden in PW and WFI water
- Technical concept of auto fluorescence concept
- Adaption for water applications
- Typical points of use in PW and WFI systems
- Applications
- Presentation of field data

JÖRG DRESSLER, PMT

Transfer of microbiological methods
- Steps of Transfer
- Know-how Transfer
- Transfer Plan
- Transfer without/with Examination
- Special Features of Microbiology
- Suitability Testing of Microbiological Methods
- SOP vs. Transfer Plan
- Transfer Report
- Objectives Transfer

DR TIMO KREBSBACH, LABOR L+S AG

Talking about Bacteria and QPs – The cooperation between Microbiologists and QPs
- What useful information can the Microbiologist supply to the QP
- How to make a QP interested in your data
- What data to leave out
- Why should Microbiologists become QPs

MARY-ANNE WEATHERHEAD, PFIZER

Container Closure Integrity
- Guidelines
- Physical vs. microbial test
- Microbial ingress testing
- Test design
- Choice of microorganisms
- Detection limits

DR TIMO KREBSBACH, LABOR L+S AG

Suitability test- theoretical and practical point of view
- Why is suitability test needed?
- EPs recommendations for testing of non-sterile products (2.6.12. and 2.6.13.)
- Most common procedure modifications caused by inhibitory effect of drug product
- Adjustment of pH value, less common but efficient way to avoid inhibitory drug effect
- Demands, rational thinking and scientific base- solution for every problem

DR JELENA NOVAKOVIC, GALENIKA

Biological indicators – Helpful tools for process validation
- Different types of bioindicators and their features
- Choice and application within process validation
- Resistance, D-value, z-value and Sterility Assurance Level
- Actual Guidelines
- Recommended practices and specific requirements
- Challenges and case studies

ANJA FRIEDRICH, BIOSERVICE SCIENTIFIC LABORATORIES

Opportunities and limitations in extraneous agents testing with molecular biological methods
- Challenges and case studies
- Case study microbial contamination control
- Adventitious virus testing on the example PCV
- Requirements on the lab and reagents

DR DIETMAR MEYER, IDT GMBH

Role of Environmental Monitoring and Microbiological Testing during Manufacture of Sterile Drugs
- Sterility Assurance – Role of Testing, Manufacturing Process and Monitoring
- EM for a Sterile (sterility test) and Non-sterile (bioburden) Manufacturing Process
- Limitations of Bioburden or Microbial Limit Test
- Impact of Recent Changes in Regulations and Guidelines on Sterility Assurance

DR RAJESH K. GUPTA, BIOLOGICS QUALITY & REGULATORY CONSULTANTS, USA

Comparison of different incubation conditions for microbiological environmental monitoring
- Short overview of applicable guidelines
- In-vitro versus in-situ study
- Strain selection bias in in-vitro studies

OLIVER GORDON, NOVARTIS

DR MARJA CLAASSEN-WILLEMSE, MSD, THE NETHERLANDS, SENIOR SPECIALIST, GLOBAL CENTER OF EXPERTISE MICROBIOLOGY, THE NETHERLANDS

Maria Claassen studied biology at the universities of NiJmegen and Utrecht. After a post doc position at Erasmus MC, she joined MSD (former Organon). Today she is as pharmaceutical specialist responsible for quality of sterile products, pharmaceutical and aseptic production, compliance to guidelines and procedures. Performing risk assessments upon quality issues, followed by root cause analysis and the definition of preventive actions. Strong focus on continuous improvement and right-first-time.

GILBERTO DALMASO, GLOBAL ASEPTIC PROCESSES DEVELOPMENT MANAGER, LIFE SCIENCES DIVISION PARTICLE MEASURING SYSTEMS, ITALY

Gilberto Dalmaso has over 25 years' experience in pharmaceutical microbiology and sterility assurance, primarily with GlaxoSmithKline (GSK) where he started in 1984 with Glaxo Verona. Over his last five years with GSK, Gilberto led a series of initiatives implementing Process Analytical Technologies (PAT) and Rapid Microbial Methods (RMM) that improve quality and process understanding while yielding significant cost savings. Today Gilberto is the Global Aseptic Processes Development Manager for Particle Measuring Systems. In this role he collaborates and consults with pharmaceutical companies to develop and implement science-based strategies and processes that utilize Quality by Design (QbD) principles to monitor, control, and improve the chemical, physical, and microbiological state of various production processes.

DR JÖRG DEGEN, HEAD OF MICROBIOLOGY, BSL BIOSERVICE SCIENTIFIC LABORATORIES GMBH, GERMANY

Jörg Degen studied Biology at the University of Würzburg. 2006 he joined BSL Bioservice and in his current position, he is the head of BSL's Microbiology Laboratory.

DR SVEN M. DEUTSCHMANN, ROCHE DIAGNOSTICS GMBH, GERMANY

Sven Deutschmann studied biology (major: microbiology, biochemistry and biotechnology) at the University of Braunschweig where he obtained his PhD in cell culture technology. In 1995 he joined Boehringer Mannheim GmbH, now Roche Diagnostics GmbH, as Manager QC. Since 2001 he is Director of the Microbiology QC Department. Sven Deutschmann is member of the Microbiology Commission and the Working Party "Pyrogentests" and member of the German Pharmacopoeia Commissions and specialist resp. member in the Working Parties "Monocyte Activation Test" and "Bacterial Endotoxins" of the European Pharmacopoeia Commissions.

JÖRG DRESSLER, PMT GMBH, GERMANY

Joerg Dressler studied physics at the University Düsseldorf. 1999 he joined PMT – Particle Measuring Technique where he became head of sales and marketing. Since 2003, he is a member oft he company management and responsible for all activities in sales, marketing and service.

ANJA FRIEDRICH, BIOLOGIST, BSL, GERMANY

Anja Friedrich studied biology at the TU Munich with focus on microbiology and molecular biology. In that time she worked as scientist at the Institute for Pharmacology and Toxicology at the TU. In 1994 she joined BSL Bioservice where she was involved in building up the microbiological division at BSL as deputy head. She is a member of the working group Cleaning, Disinfection and Sterilization of the ZLG. Since 2011 she is Senior Manager Marketing and Sales Microbiology.

BARBARA GERTEN, MERCK KGAA, GERMANY

After her studies in microbiology and biochemistry, Barbara Gerten was employed in different companies responsible for QC and R+D. Since 2008 she is head of the laboratory RTU Media / Validation at Merck KGaA. She is a member in several national and international bodies of microbiological topics in ISO and CEN.

OLIVER GORDON, NOVARTIS PHARMA STEIN AG, SWITZERLAND

Oliver Gordon studied Molecular Biology (main focus in Microbiology and Infection Biology) at the Biocenter and the University Hospital in Basel, Switzerland. Since 2010 he is working at Novartis Pharma AG in Switzerland in the QA/QC-Microbiology department in the Launch Center for Rapid Microbiological Methods. He is also advisory board member of the ECA Working Group on Rapid Microbiological Methods.

DR MARCEL GOVERDE, MGP CONSULTING, SWITZERLAND

Marcel Goverde has attended the University of Basel, where he majored in biology. After one year of working for the agro biological department of Novartis, he led a development project on sustainability and education in Costa Rica. After returning to Switzerland he 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. Furthermore he is a member of the working party for Modern Microbiological Methods (MMM) from the European Directorate for the Quality of Medicines (EDQM).

DR RAJESH K. GUPTA, CONSULTANT, VACCINOLOGIST & MICROBIOLOGIST, FORMER FDA , USA

Dr Gupta has a Ph.D. in Microbiology and was Deputy Director and Lab Chief in the Division of Biological Standards and Quality Control, Office of Compliance and Biologics Quality, CBER, FDA. He was responsible for lot release of biological products, regulatory reviews of applications and supplements and generation of standards and reagents used in the manufacture and testing of biological products. Dr Gupta has more than 30 years experience in the development, production, testing and regulation of biological products, working both in the public and private sectors.

DR DIETMAR MAYER , HEAD OF MOLECULARBIOLOGICAL QUALITY CONTROL, IDT, DESSAU, GERMANY

He studied at Institute of Genetics, Department of Virology in Stuttgart Hohenheim. 1999 – 2001 he worked as group leader at FEP and BioTeSys GmbH. Since 2005 he is Head of Molecular Biology Quality Control at IDT Biologika GmbH. Responsible for the development of product specific methods as release tests.

DR JELENA NOVAKOVIC JOVANOVIC, GALENIKA AD, SERBIA

Jelena Novakovic holds a PhD in microbiology. She works since 2008 for Galenika AD as deputy head of microbiology in QC. She is responsible for sterility testing, testing of non-sterile products and environmental monitoring.

DR JOSEPH PIERQUIN, CEO, ADVENICS, FRANCE

Joseph studied electrical engineering at University of Lille. He worked for Pechiney, Air Liquide and for Merck KGaA in the R&D Biomonitoring, before he founded Advenics in 2011.

JIM POLARINE JR., MA. FORMULATED CHEMISTRIES TECHNICAL SERVICE MANAGER, STERIS CORPORATION

Mr Polarine graduated from the University of Illinois with a Master of Arts in Biology. He has been with Steris for over 13 years and is today technical service manager. He is also currently active on the PDA task force on cleaning and disinfection and has co-authored the PDA technical report on cleaning and disinfection. He is part of the faculty at the University of Tennessee Parenteral Medication course.

DR TIM SANDLE, BIO PRODUCTS LABORATORY, UK

Tim Sandle has over twenty years experience of working in the pharmaceutical industry. Tim has worked both as a parasitologist and microbiologist. Tim has extensive experience of cleanrooms, water testing, endotoxin analysis, microbial identifications, sterility testing, aseptic filling and risk assessment.

In addition Tim has published over seventy articles and book chapters on the subject of pharmaceutical microbiology. Tim is a committee member of the Pharmaceutical Microbiology Interest Group (Pharmig) and an associate staff member with the pharmacy department at the University of Manchester.

DR RADHAKRISHNA TIRUMALAI, PH.D., USP, USA

Dr Tirumalai has been at the USP since 2003 and is currently a Principal Scientific Liaison in General Chapters / Science and Standards. He is the Staff Liaison to the USP Expert Committees on Microbiology, and Toxicology. He represents USP on PDA expert task forces and committees related to Microbiology and Sterility Assurance and on AAMI expert Working groups related to Microbiology, Sterility Assurance and Biocompatibility. He holds a Ph.D. degree in Biochemistry.

MARY-ANNE WEATHERHEAD, QUALIFIED PERSON, PFIZER, HAVANT, UK

Currently Mary-Anne Weatherhead is a release QP at Pfizer in Havant (Hampshire). She started her working life 28 years ago as a Microbiologist working on Animal feed and progressed to Non-sterile and Sterile pharmaceuticals. She has had a varied career working as a team leader in tablet manufacture, a consultant on European regulations in Sterile production, a planner/scheduler for the Chemistry and Microbiology lab and Microbiology Manager and also spent time number crunching in the QA department before becoming a QP. She was previously a Director of the Pharmaceutical Microbiology Interest Group and is passionate about Microbiology.

Social Event

On 7 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.

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
Workshop Bioburden
Tuesday, 06 May 2014, 09.00 - 17.00 h
(Registration and coffee 08.30 – 09.00 h)

Microbiology Conference
Wednesday 07 May 2014, 09.00 – 18.00 h
(Registration and coffee 08.30 – 09.00 h)
Thursday, 08 May 2014, 08.30 – 16.30

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

Fees*
Pre-Conference Workshop Bioburden
ECA Members € 790.-
Non-ECA Members € 890.-
APIC Members € 840.
EU GMP Inspectorates € 445.-

European Microbiology Conference
ECA Members € 1,590.-
APIC Members € 1,690.-
Non-ECA Members € 1,790.-
EU GMP Inspectorates € 895.-

Pre Conference Workshop Bioburden combined with European Microbiology Conference
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 7 May, lunch on all three days 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
CONCEPT HEIDELBERG
P.O. Box 10 17 64
D-69007 Heidelberg, Germany
Phone +49 (0) 62 21/84 44-0
Fax +49 (0) 62 21/84 44 34
info@concept-heidelberg.de
www.concept-heidelberg.de

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 Jessica Stürmer (Organisation Manager) at +49-62 21/84 44 43 or per e-mail at stuermer@concept-heidelberg.de.

*Fees per delegate, + VAT

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

_____

_____

_____

_____

_____

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

69007 Heidelberg
Germany

Reservation Form (Please complete in full)

+49 6221 84 44 34

☐ **Workshop Bioburden**
6 May 2014, Prague Czech Republic

☐ **European Microbiology Conference**
7-8 May 2014, Prague Czech Republic

☐ **Workshop Bioburden AND European Microbiology Conference**
6 -8 May 2014, Prague Czech Republic

☐ Mr ☐ Ms

Title, first name, surname

Company Department

Important: Please indicate your company's VAT ID Number **Purchase Order No. if applicable**

Street / P.O. Box

City Zip Code

Country

Phone / Fax

E-Mail (Please fill in)

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 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)

wa/vers1/110102012