



EUROPEAN COMPLIANCE
ACADEMY

SPEAKERS:

FROM AUTHORITIES:

JOHN METCALFE
FDA, USA

THOMAS MONTAG
Paul-Ehrlich-Institut, Germany

FROM INDUSTRY:

CORNELIA BODINET
Schaper and Brümmer,
Germany

HANS JÜRGEN BUSSE
University of Veterinary
Medicine Vienna, Austria

OLIVIER CHANCEL
Merial, France

ANTHONY CUNDELL
Schering Plough, USA

SVEN M. DEUTSCHMANN
Roche, Germany

BARBARA GERTEN
Merck, Germany

BETTINA LAUER
Vetter Pharma-Fertigung,
Germany

MEHUL DINESH PATEL
Accugenix Inc., USA

**FRIEDRICH VON
RHEINBABEN**
Ecolab, Germany

MIKE SADOWSKI
Baxter, USA

MANUEL STEIN
Heipha/Biotest, Germany

BIRGITTA STEINBORN
Cilag, Switzerland

MICHEL THIBAUDON
RNSA Laboratoire, France

HANNELORE WILLKOMMEN
Regulatory Affairs & Biological
Safety Consulting, Germany

**FRIEDRICH VON
WINTZINGERODE**
Roche, Germany



3rd European Microbiology Conference

With two parallel Sessions

Barcelona, Spain

4 – 5 May 2010

HIGHLIGHTS:

- Parametric Release
- Water Activity Applications
- New Developments and Experiences in Media Fill
- Harmonised Methods and Herbal Medicinal Products
- Culture Media in Pharmacopoeias
- Virus/TSE Safety
- Paperless Lab – LIMS in Microbiology
- Disinfection and Gassing
- Rapid Methods Application

Invitation

Dear Colleague,



With the following programme I would like to invite you to the Third Annual European Microbiology Conference organised by the European Compliance Academy (ECA) in Barcelona.

The pharmaceutical microbiologist has a key role in all aspects of development, manufacture and control of medicinal products and their components. For that reason the conference intends to provide updates and practical experiences to support the microbiologist in today's microbiological developments and challenges in pharmaceutical and biopharmaceutical manufacturing.

This conference will focus on microbiological aspects of:

- Parametric Release
- Water Activity Applications
- Special Cases of Harmonisation
- Virus Safety
- Disinfection
- News from Media and Media Fill
- Development in Taxonomy and Identification
- LIMS and Paperless Lab

In three sessions experts from the pharmaceutical industry, regulatory authorities and international academia will present various microbiological aspects of these topics.

It is the conference's goal to equip the pharmaceutical microbiologist with practical knowledge and "know-how" which can be applied in his daily work. In addition it will provide a forum for interesting and open discussions between presenters, regulators and your colleagues from the industry.

It would be a great pleasure for me if you joined us in Barcelona for what promises to be an exhilarating experience.



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

Objectives

During this two-day conference, speakers from different fields of microbiology, research and development, quality control and manufacturing as well as regulatory bodies and consulting will provide you with the opportunity to discuss the different views on versatile microbiological topics. It will be a chance to become acquainted with current development in optimising microbiological methods, laboratory work and ongoing regulatory requirements.

Background

The role of pharmaceutical microbiology has become more and more important in the last years. It is more focused on 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 month, and promises possibilities to optimise the factors time and money in microbiological in-process-control and release.

Thus classic topics, like cleaning and disinfection, become important again because of the new European regulatory requirements on chemical products, like the EU Guideline 98/8 EG for Biocides or the REACH, the new European Community Regulation on chemicals and their safe use. New experiences in the field of media fill, room gassing and other topics will open new opportunities to optimise processes in microbiological laboratory, manufacturing and quality control.

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

Moderators

Dr Sven M. Deutschmann, *Roche, Germany*
Axel H. Schroeder, *Concept Heidelberg*

Programme
Tuesday, 4 May 2010

Plenary Session

Current Bacterial Taxonomy

- Short introduction in bacterial systematic and bacterial diversity
- Classical taxonomy
- Polyphasic approach
- Future trends of bacterial taxonomy

DR FRIEDRICH VON WINTZINGERODE

Parametric Release: A CDER Perspective

- The information to provide CDER when submitting applications requesting parametric release of parenteral drug products
- Current CDER perspectives involving a parametric release program

DR JOHN METCALFE

Parametric Release, Industrial View and Experiences

MIKE SADOWSKI

Water Activity Applications in Pharmaceutical Microbiology

- Concept of water activity
- Water activity measurement
- Effects of water activity on microorganisms
- Water activity and drug product formulation
- Role of water activity measurement in microbial risk assessment, specification setting and release and stability testing

DR ANTHONY CUNDELL

Proteotypic – A New Method in Microbial Identifications using MALDI-TOF

- Overview and evaluation of various technologies used for microbial identification- Genotypic, Proteotypic and Phenotypic
- Accuracy and Performance of Proteotypic MALDI-TOF microbial identifications
- Importance/relevance of having dynamic microbial libraries for identification
- Evaluation of Proteotypic MALDI-TOF technology for routine identifications

MEHUL PATEL

Harmonised Methods in the microbiological Examination of herbal medicinal Products

- Ph. Eur. requirements and acceptance criteria for the quality of herbals – actual developments
- Implementation of the methods (culture media, test strains, TAMC, TYMC, test for specified microorganisms)
- Experiences from the product-specific suitability tests
- Prospects and further steps

DR CORNELIA BODINET

Virus/TSE Safety – Current Questions

- In contrast to bacteria – viruses grow only in living organisms
- Virus detection requires complex systems
- Prevention of contamination is the best way to assure TSE safety
- Inactivation/removal of virus/TSE infectivity requires specific considerations

DR HANNELORE WILLKOMMEN

Wednesday, 5 May 2010

Session 1:

Specific Culture Media for special Purposes

- Isolation of injured („stressed“) microorganisms
- Chromogenic media for detection of specific microorganisms
- Validation of specific alternative culture media

BARBARA GERTEN

An innovative solution for rapid airborne contamination control : cleanrooms and indoor air case studies

- Environmental monitoring : the complexity of airborne bio-contamination
- The current method for air sampling
- Focus on cyclonic method
- Case studies : indoor environments control

MICHEL THIBAUDON

Vegetable Bouillon for Media Fill

- Reasons for the implementation of a vegetarian bouillon
- Requirements market research
- Preliminary tests
- Tests
- Implementation and experiences

DR BETTINA LAUER

Case Study: New growing Broth for Media Fill Test with rapid Test Reading

- Visual inspection – the bottleneck in workflow
- A new culture medium with a microbiological colour indicator for higher performance.
- Contamination and turbidity detection with an irreversible colour change after incubation reducing the risk of false positive.
- MFT validation run with innovative culture medium - acceptance from the QC and production staff
- Future perspective

DR OLIVIER CHANCEL

Identification of Specific Microorganisms

- Identification of bacterial isolates based on the phenotype
- Identification of bacterial isolates based on the genotype
- Epidemiological approaches
- Recommendations from a taxonomist for classification of environmental strains

DR HANS JÜRGEN BUSSE

Session 2:

Case Study: Decontamination of Cleanrooms with H₂O₂ – A New Approach of Room Disinfection

- Design and technical requirements
- Cycle design for different rooms
- Acceptance criteria and comparison to manual disinfection
- Cycle development and selection of testing positions
- Verifying cycles and monitoring plan

DR BIRGITTA STEINBORN

Virus Activity of Chemical Disinfectants

- Structure of viruses
- Behaviour against disinfectants
- Right choice of disinfectants
- Legal situation in Europe

DR DR FRIEDRICH VON RHEINBABEN

Approaches for Growth-based Rapid Sterility Testing

DR THOMAS MONTAG

Paperless Laboratory – LIMS in Environmental Monitoring

- Hygiene monitoring concept of heipha Dr Müller GmbH as a manufacturer of culture media
- Field report to implement LIMS in the environmental monitoring
- System requirements (Hard- and Software, Data-Matrix-Code, Scanner)
- Basic principles, implementation and benefits

MANUEL STEIN

Paperless Laboratory – LIMS in In-Process-Control

DR SVEN M. DEUTSCHMANN

Social Event



On Tuesday, 4 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.

Speakers

DR CORNELIA BODINET, *Schaper & Brümmer GmbH, Germany*

Cornelia studied Biology with focus on Microbiology at University of Saarbrücken. and University Greifswald, Germany. Since 1986, she is at Schaper & Brümmer and today she is head of Division "Pharmaceutical Laboratories" and a member of the management board.

DR HANS JÜRGEN BUSSE, *University of Veterinary Medicine, Vienna, Austria*

Dr Busse is head of the working group of Bacterial Taxonomy and Environmental Microbiology at the Institute of Bacteriology, Mycology and Hygiene of the University of Veterinary Medicine Vienna.

DR OLIVIER CHANCEL, *Merial, France*

Doctor Pharmacist, graduated in technological pharmacy and management. Currently Technical Project Manager at Merial, Toulouse, France.

TONY CUNDELL, PH. D., *Schering-Plough Research Institute, Union, New Jersey, USA*

Dr Tony Cundell works in the Schering-Plough Research Institute in Union, New Jersey as the Director, Pharmaceutical Sciences Microbiology. He is a member of the 2005-2010 USP Microbiology and Sterility Assurance Committee of Experts.

Speakers (cont.)

DR SVEN M. DEUTSCHMANN, *Roche Diagnostics GmbH, Germany*

Sven Deutschmann studied biology (major: microbiology, biochemistry and biotechnology) at the University of Braunschweig. In 1995 he joined Boehringer Mannheim GmbH, now Roche Diagnostics GmbH, as Manager QC. Since 2001 he is Director of the Microbiology QC Department.

BARBARA GERTEN, *Merck KGaA, Darmstadt, Germany*

After her studies in microbiology and biochemistry, Barbara Gerten was employed in different companies responsible for QC and R+D of culture media. 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.

DR BETTINA LAUER, *Vetter Pharma-Fertigung GmbH & Co. KG, Ravensburg, Germany*

Dr Bettina Lauer graduated in 1994 as a Biologist, specialising in Microbiology. In 1999 she joined Vetter Pharma-Fertigung GmbH & Co. KG in Ravensburg, Germany. At present Dr Bettina Lauer is deputy head of Microbiology and works as a senior expert in Microbiology responsible for customer audits and authorities' inspections.

DR JOHN W. METCALFE, *REVIEW MICROBIOLOGIST, FDA/CDER/OPS, USA*

Dr Metcalfe holds a BA in biology from Merrimack College in Andover, MA, and a PhD. in microbiology from the University of Rhode Island. Following his graduate studies, he worked as a college professor for a total of 14 years at Potsdam College of the State University of New York and Salem State College in Massachusetts where he taught microbiology related courses. John began his career at CDER in January of 2003, where he works as a review microbiologist.

DR THOMAS MONTAG, *Paul-Ehrlich-Institut, Langen, Germany*

Thomas Montag studied medicine at the Humboldt-University Berlin and has specialised in medicinal microbiology. After spending some years in research work at the Charité in Berlin he has been employed at the Paul-Ehrlich-Institut since 1990. At present, Thomas Montag is heading the department of parasitology, diagnostics and microbial safety.

MEHUL DINESH PATEL, *Accugenix Inc.*

For over a decade, Mehul Patel has extensive experience in Research and Development, market analysis, technology and product development for the Biotech and Pharmaceutical industries. He obtained his B.S. degree in Cellular and Molecular Biology from the University of Michigan and his MBA degree in Finance from the University of Delaware. Mr Patel is currently responsible for all activities related to conceptualizing and implementing marketing strategies and achieving marketing targets in support of corporate goals at Accugenix, Inc.

DR DR FRIEDRICH VON RHEINBABEN, *Ecolab GmbH & Co. OHG, Düsseldorf, Germany*

Studied Biology at the Rheinische Friedrich-Wilhelms University in Bonn / Germany, where he also made his PhD in Human Virology and Microbiology. Since 2000 he works for Ecolab Company, Germany as technical manager for Microbiology/Virology and Hygiene in the Research and Development Department.

MIKE SADOWSKI, *Baxter, Illinois, USA*

Mike Sadowski studied at Purdue University. Today he is Director, Sterile Manufacture Support at Baxter Healthcare in Illinois.

MANUEL STEIN, *heipha Dr Müller GmbH, Germany*

After his apprenticeship as assistant biological technician and his study of biotechnical engineer, he was more than 10 years employed in QC and QA of API. Since 2007, he is the head of QA at heipha Dr Müller GmbH, a media manufacturer.

DR BIRGITTA STEINBORN, *Cilag AG, Schaffhausen, Switzerland*

She studied Biology at University Freiburg. Since 2000 she is employed at Cilag, at first as head of global microbiology of J&J research and development, since 2005 in QA of sterile clinical trial products and responsible for the new building of the new aseptic filling line.

MICHEL THIBAUDON, *RNSA Laboratoire, France*

Michel Thibaudon is a pharmacist by training since 1975. From 1975 to 1991 she joined Pasteur Institute in Paris in different functions in laboratory of allergen and laboratory of aerobiology and becomes chief of French Aerobiology Network. Since 1992 he worked at Axcell Biotechnologies and 1996 as responsible pharmacist in a pharmaceutical industry. 2004 Michel becomes President of A.S.P.E.C. and 2005 Director of RNSA, and of RNSA Laboratoire.

DR HANNELORE WILLKOMMEN, *RBS Consulting, Germany*

Dr Hannelore Willkommen works as Consultant for Regulatory Affairs and Biological Safety of biopharmaceuticals and as Vice President Regulatory Affairs at NewLab BioQuality AG, Germany. She is active in international organisations like PDA (Parenteral Drug Association) and at present she leads PDA's Biotech Interest Group in Europe.

DR FRIEDRICH VON WINTZINGERODE, *Roche Diagnostics, Penzberg, Germany*

Friedrich studied biology with focus on Microbiology at Technical University Braunschweig. Degree at Institute of Microbiology, Charité, Berlin. Since 2001 employed at Roche Diagnostics as group leader Environmental monitoring and cleaning analytics and since 2005 head of microbiological IPC and analytics for release.

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.eu

Date

Tuesday 4 May 2010, 09.00 – 17.30 h
(Registration and coffee 08.30 – 09.00 h)
Wednesday, 5 May 2010, 08.30 – 15.30 h

Venue

NH Constanza
C/ Deu i Mata 69-99
28029 Barcelona
Spain
Phone +34 93 281 1500
Fax +34 93 281 15 25

Conference fees

Non-ECA Members € 1,890.- per delegate plus VAT
ECA Members € 1,701.- per delegate plus VAT
APIC Members € 1,795.- per delegate plus VAT
(does not include ECA Membership)
EU GMP Inspectorates € 945.- per delegate plus VAT
The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on both days and all refreshments. 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 conference.

Please use this form for your room reservation or be sure to mention "VA 6389 ECA Event" to receive the specially negotiated rate for the duration of your stay. Reservation should be made directly with the hotel not later than 5 April 2010. Early reservation is recommended.

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
69007 Heidelberg, GERMANY
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For questions regarding content:


Axel H Schroeder (Operations Director) at +49 6221/84 44 10
or per e-mail at schroeder@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc.:

Jessica Stürmer (Organisation Manager) at +49 6221/84 44 43
or per e-mail at stuermer@concept-heidelberg.de.

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

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3rd European Microbiology Conference

Barcelona, Spain, 4 – 5 May 2010

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1. We are happy to welcome a substitute colleague at any time.
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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)!