ECA
European Compliance Academy

Two European Conferences

Regulatory Developments
New Methods
Practical Experiences

Mycoplasma Testing and Microbiology

Speakers of the European Mycoplasma Testing Conference:

JEAN-POL CASSART
GSK Vaccines, Belgium

VLADIMIR CHIZHIKOV
FDA, USA

SVEN M. DEUTSCHMANN
Roche Diagnostics, Germany

RENATE ROSENGARTEN
Mycosafe, Austria

OLAF STAMM
Charles River Laboratories, Germany

GEERT VERDONK
MSD, The Netherlands

DIRK VOLLENBROICH
Minerva Biolabs, Germany

Speakers of the European Microbiology Conference:

ANDY BAILEY
ViruSure, Austria

DR JÖRG DEGEN
BSL, Germany

BARBARA GERTEN
Merck, Germany

ROMAN KARASEV
Gedeon Richter, Russia

BETTINA LAUER
Vetter, Germany

DI MORRIS
MHRA, UK

MICHAEL RIETH
Merck, Germany

DAVID ROESTI
Novartis Pharma Stein, Switzerland

TIM SANDLE
Bio Products Laboratory, UK

LAURE VALOGNES
Merck Biodevelopment, France

CHRISTIAN VOGT
Novartis Pharma Basel, Switzerland

FRIEDRICH VON WINTZINGERODE
Roche Diagnostics, Germany

European Mycoplasma Testing Conference

23 April 2013,
Copenhagen, Denmark

HIGHLIGHTS:

- WHO International Standard for Mycoplasma NAT
- Recent Advances in Detection of Mycoplasma Contamination
- Mycoplasma Reference Strains for NAT Validation
- Combined Cell Culture Enrichment and qPCR Methods
- Evaluation of the Test Performance of a Commercial PCR Assay

European Microbiology Conference

24 and 25 April 2013,
Copenhagen, Denmark

HIGHLIGHTS:

- Experiences of European Authorities
- Implementation of Microbiological Methods
- Monitoring and Trending
- Microbial Safety Aspects

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These conferences are 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 2013 in Combination with European Mycoplasma Testing Conference

Dear Colleague,

I would like to invite you to the European Microbiology Conference and Mycoplasma Testing Conference 2013 organised by the European Compliance Academy (ECA).

In 2008, ECA organised the First Microbiology Conference and the First Mycoplasma Testing Conference in Berlin, Germany. Attendants, Speakers and Exhibitors gave a very good response to this events. Until today, these conferences become regularly events and 2013 The pharmaceutical microbiologist plays a key role in all aspects of development, manufacture and control of medicinal products, and their components. Therefore, the conference is intended to provide microbiological updates and "real life" experiences to support their activities.

These conferences will focus on aspects of:
- Regulatory Developments and Experiences in Europe and US
- Current experiences with equipment and methods
- Experiences in the daily business in laboratory and manufacturing

Experts from the pharmaceutical industry, regulatory authorities and international academia will present various microbiological aspects of the above topics.
It is the aim of this conference 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 Copenhagen.

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

European Mycoplasma Testing Conference
European Microbiology Conference

Objectives

These two conferences offer you 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, from regulatory bodies and consulting 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

These conferences are 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

European Mycoplasma Testing Conference

23 April 2013, Copenhagen, Denmark

Programme

Chaired by Prof Renate Rosengarten, Mycosafe

Recent Advances in Culture- and NAT-based Approaches for Detection of Mycoplasma Contamination

- Emerging issues of mycoplasma contamination and strategies for control
- Detection of cultivable and "non-cultivable" mycoplasmas
- Design and application of mycoplasma culture reference standards
- Performance validation of NAT-based mycoplasma detection systems and comparison to current culture assays

PROF DR RENATE ROSENGARTEN, MYCOSAFE

WHO International Standard for Mycoplasma NAT

- Worldwide collaborative study,
- Inclusion of different NAT methods,
- Relative amplification efficiency for different Mollicutes species,
- WHO International standard for Mollicutes NAT

DR SVEN DEUTSCHMANN, ROCHE DIAGNOSTICS

Mycoplasma Reference Strains for NAT Validation – An International Collaborative Study

- Study aims and design
- Mycoplasma reference strains preparation
- Methods employed for panel evaluation
- Study results and lessons

DR VLADIMIR E. CHIZHIKOV, FOOD AND DRUG ADMINISTRATION, USA

A Combined Cell Culture Enrichment and qPCR Method for a Broad Spectrum Detection of Mycoplasma Contamination

- Design of a Mycoplasma-specific quantitative PCR assay in a Mycoplasma genetic signature
- Electronic and experimental evaluation of the Q-PCR coverage
- Specificity against closely related sequences and experimental confirmation
- Mycoplasma growth kinetics in cell culture
- Ability of the procedure to detect 1-10 CFU/ml

JEAN-POL CASSART, GLAXOSMITHKLINE VACCINES, BELGIUM

Challenges Associated with Rapid Detection Methods of Mycoplasma Contaminations used in QC applications for different product types

- Validation aspects which are associated with the use of commercially available Mycoplasma detection systems
- Special considerations which need to be taken in account for different product types

DR OLAF STAMM, CHARLES RIVER LABORATORIES

Mycoplasma NAT proficiency tests and consequences for sample preparation

- Evaluation of proficiency test results for typical pitfalls in mycoplasma PCR testing
- Testing large sample volumes for mycoplasma combining membrane filtration with qPCR

DIRK VOLLENBROICH, MINERVA BIOLABS

Validation of a Culture and qPCR Hybrid Approach for Mycoplasma Detection

- Challenging Reference Standards
- Validation according European Pharmacopoeia
- Challenges of multisite implementation

GEERT VERDONK, MSD, THE NETHERLANDS

Mycoplasma-PCR: Interaction with Agencies

- Update on Q & A

DR SVEN DEUTSCHMANN, ROCHE DIAGNOSTICS

European Microbiology Conference

24-25 April 2013, Copenhagen, Denmark

Module 1: Current Regulatory Developments

Chaired by Barbara Gerten

Microbial Identification and USP<1113>

- Summary of USP<1113> requirements
- Comparison between EP 5.1.6. Subchapter 3.-4. and USP<1113>
- Proposed strategy for the lab

FRIEDRICH VON WINTZIGERODE, ROCHE

Microbiology Best Laboratory Practice USP <1117>: Supplementation of practical information by ISO standards

- Media preparation, storage and shelf life testing
- Physical-chemical and microbiological quality control of media
- Preparation and maintenance of microbiological cultures
- Sample handling including water samples

BARBARA GERTEN, MERCK MILLIPORE

Module 2: Current Development in Microbiological Methods

Effects of various incubation parameters on growth characteristics of selected microorganisms

- Studies using reference strains and in-house isolates
  - to confirm current incubation regime and
  - to generate data for harmonization of different incubation regimes.

BETTINA LAUER, VETTER

Alert levels / trending based on statistical evaluation of historical data

- The challenge of trending microbiological data or assessing alert/ expectation levels based on historical results
- Definition of expectation levels for microbiological examination of non-sterile products
- Trending of environmental monitoring data based on target values

DAVID ROESTI, NOVARTIS

Biologics Drug Substance production: Safety aspects of bioburden contaminations of non-sterile process intermediates.

- Health Authority requirements
- Concept of “Objectionable organisms” or “bad bug lists” do not help
- Case by Case Assessment of Bioburden (CCAB)

FRIEDRICH VON WINTZIGERODE, ROCHE

Microbiology in Sterility Test and Production Isolators

- Bringing an isolator under microbiological control
- How to achieve a state of “practically free of microorganisms”
- Control of an isolator with physical and microbiological monitoring
- Maintenance aspects and integrity checks of isolator systems
- Validation of an filling isolator with media fills
- Microbiological problems in isolators

CHRISTIAN VOGT, NOVARTIS

Sterility Testing of Combination Products

- Medical Devices and Drug Products
- Drug Products with Applicator
- Requirements of the different Gudieleines for medical Devices and Medicinal Products
- Special Challenges and Pitfalls

DR JÖRG DEGEN, BSL

Rapid Enumeration Test

- Detection using direct fluorescent staining
- Principle of operation
- Milliflex Quantum System
- Rapid method versus compendial method
- Method validation
- Performance examples

MICHAEL RIETH, MERCK

Module 3: Challenges in Daily Laboratory and Manufacturing Business

Chaired by Dr Sven M. Deutschmann

OOS in Microbiology

- The microbiological OOS procedure
- Planning investigations
- The investigation process
- Take away messages

DI MORRIS, MHRA, UK

Understanding risk management when dealing with virus contamination

- Case studies using recent contamination incidences in GMP manufactured biopharmaceuticals

ANDY BAILEY, VIRUSURE

Hygiene monitoring for non-sterile area

- Environmental monitoring program for non-sterile area
- Selection of the sample – sites
- Alert and action level for non-sterile area

ROMAN KARASEV, GEDEON RICHTER, RUSSIA

Fungal contamination in pharmaceutical products and cleanroom risks

- A review of fungal contamination relating to pharmaceutical drug recalls
- Fungal contamination sources
- Fungi and environmental monitoring
- Fungi and disinfectant efficacy testing
- Review: why the characterisation of fungi matters

TIM SANDLE

Single Use Equipment vs Microbial Contamination

- Case Study including a comparison of Stainless Steel traditional systems vs Single Use equipment

LAURE VALOGNES, MERCK MILLIPORE

Social Event

As a delegate of the European Microbiology Conference or of both the European Mycoplasma Testing Conference and the European Microbiology Conference you are cordially invited to a social event on 24 April 2013. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

Speakers of both Conferences

DR ANDY BAILEY, VIRUSURE GMBH, AUSTRIA

Dr Bailey has been actively involved in the pathogen safety of biopharmaceuticals for over 11 years. Originally a Biochemist, Dr Bailey served for nine years at the MRC Virology Unit in Glasgow, Scotland. In 1995, he moved as Director of Virus Validation services to Q-One Biotech Ltd, and in 2001 to the Pathogen Safety group of Baxter Healthcare in Vienna, Austria. He was the main founder of ViruSure GmbH, a specialist virus safety testing company in Vienna, Austria, in 2005. Over the last 10 years, Dr. Bailey has presented at numerous regulatory agencies on virus and prion safety, either in support of products or as an invited speaker at expert workshops, including the UK MHRA, German PEI, French AFFSAPS, US FDA, EMA and JMHLW (Japan).

DR JEAN-POL CASSART, GLAXOSMITHKLINE VACCINES, BELGIUM

Jean-Pol Cassart obtained his PhD in Molecular Genetics at the University of Namur (Belgium) in 1996. He joined the GSK Vaccines R&D department in 1998 where he was initially involved in cancer and virology research programmes: genetic characterization of vaccines and development of molecular clinical read-outs. Currently, he is working in Quality Control. He is responsible for the development and the implementation of novel analytical methods for QC testing.

DR VLADIMIR CHIZHIKOV, CBER, FDA, UNITED STATES

Vladimir Chizhikov is presently a Senior Investigator at the Laboratory of Methods Development of the Center for Biologics Evaluation and Research (CBER), US Food and Drug Administration. He received his Ph.D. in Chemistry/Biochemistry from the National Research Center of Virology and Biotechnology "Vector" (NRC V&B), Russia. Prior to joining CBER in 1999, he held research positions at the National Research Center of Virology and Biotechnology "Vector" (1977-1993, Kotsovo, Russia), Centers for Disease Control and Prevention (1993-1997, Atlanta, GA), and National Institute of Allergy and Infectious Diseases, NIH (1997-1999, Bethesda, MD).

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

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.

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.

DR ROMAN KARASEV, CJSC GEDEON RICHTER RUS, RUSSIAN FEDERATION

Roman Karasev studied Microbiology at the Ryazan State Medical University, where he obtained his PhD in medicine. In 2006 he joined the Gedeon Richter Rus in Moscow, as Head of Microbiological laboratory. He is responsible for validation activities, hygiene monitoring, testing of non-sterile products and authorities audits.

DR BETTINA LAUER, VETTER PHARMA FERTIGUNG GMBH & CO. KG, 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.

DI MORRIS, MHRA, UK

GMP Inspector for Medicines and Healthcare products, Regulatory Agency (MHRA) UK.

DR MICHAEL RIETH, MERCK KGAA, GERMANY

After the study of biology at University Göttingen and his degree, Michael Rieth was employed at biosyn pharmaceuticals in Stuttgart as head of quality control and service laboratory. From 1990 to 1998 he was employed in different positions of QC and QA as head of laboratory. Since 1999 works at Merck, Darmstadt in the microbiological quality control of the pharmaceutical production.

Speakers (cont'd)

DR DAVID ROESTI, NOVARTIS PHARMA STEIN AG, SWITZERLAND

David holds a PhD in microbial ecology from the University of Neuchâtel, Switzerland and has 14 years experience in the field of microbiology within various domains. Currently, David is leading the RMM team and the Novartis Pharma expert network in microbiology at Novartis Pharma AG in Stein Switzerland. Prior to this assignment, David was the laboratory supervisor for the microbiological testing of non-sterile drug products at Novartis Pharma Stein AG.

PROFESSOR DR RENATE ROSENGARTEN, MYCOSAFE DIAGNOSTICS GMBH, AUSTRIA

Renate Rosengarten's academic career with research focus on mycoplasmas took her to the School of Veterinary Medicine Hannover, the University of Missouri-Columbia and the Hebrew University Hadassah Medical School in Jerusalem. Since 1996 she is Professor of Bacteriology and Hygiene and Head of the Institute of Bacteriology, Mycology and Hygiene at the University of Veterinary Medicine Vienna. She is a member of the Board of the Austrian Society for Hygiene, Microbiology and Preventive Medicine (ÖGHMP) since 1996 and was acting as ÖGHMP President from 2008 to 2010. She was Board member of the International Organization for Mycoplasmology (IOM) for 10 years, holding the Chair position from 2004 to 2006. She is the Founder and the Managing Director of Mycosafe Diagnostics GmbH, a GMP- certified contract research organization specialized in mycoplasma testing and related activities.

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. OLAF STAMM, CHARLES RIVER BIOSERVICES, GERMANY

Dr. Stamm holds a doctoral degree in molecular parasitology and a master degree in drug regulatory affairs from the University of Bonn, Germany. He joined Charles River (formerly NewLab) in 2003 and became responsible for the business development activities in Europe, Asia and the US. Prior to joining Charles River/NewLab he worked for Eurofins Scientific running their microbiological GMP testing laboratories in Switzerland.

LAURE VALOGNES, HEAD OF BIOPRODUCTION, MERCK BIODEVELOPMENT, FRANCE

Laure holds a Master of Science in Biotechnology. Between 1999 – 2000 and 2001, she worked as: Development Engineer at CEVA Santé Animale (Hungary) and a Research Engineer at. TEPRAL (France). Since 2001 she is employed at Serono/Merck Serono. Her current position is Head of Bioproduction.

GEERT VERDONK, SENIOR SCIENTIST QUALITY, MSD, THE NETHERLANDS

Mr Verdonk has been with MSD (formerly Organon Oss) since 1996. He worked for 15 years in the molecular biology research. For the past 7 years he managed the microbiological development group in Oss, the Netherlands. He was responsible for validation activities, development of new microbiological technologies (rapid microbiological methods) and troubleshooting microbiological contaminations in pharmaceutical production processes. His current position is Director of the global Center of Expertise Microbiology within Merck. Mr Verdonk is member of the expert group RMM from the European Pharmacopoeia and is co-author of chapter 5.1.6 in the EP. Also he is member of the Rapid Method Advisory Board of the ECA.

DR CHRISTIAN VOGT, NOVARTIS PHARMA AG, SWITZERLAND

Christian Vogt studied Biology at the University of Constance/Germany, ETH Zurich/Switzerland and at the Texas A&M University/USA, where he graduated in microbiology. He joined Novartis Pharma AG in 2006. From 2007 until 2011 he was responsible for sterility testing and microbiological QA and QC at the Novartis Pharma site in Stein, Switzerland. Since 2011 he is head of the microbiology department at Novartis Basel, Switzerland.

DR FRIEDRICH VON WINTZINGERODE, ROCHE, GERMANY

Friedrich studied biology with focus on Microbiology at Technical University Braunschweig. Diploma at German Strain Culture Collection (DSMZ), Braunschweig. Degree at Institute of Microbiology and Hygiene, Charité, Berlin. Since 2001 employed at Roche Diagnostics as group leader Environmental monitoring and cleaning analytics and since 2005 group leader microbiological IPC and analytics for release. Friedrich is Head of a global working group for microbial identification within Roche. He also acts as a global expert for endotoxin testing and assessments of microbial contaminations within Roche.

Easy Registration

Reservation Form:
CONCEPT HEIDELBERG
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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 Mycoplasma Testing Conference
Tuesday 23 April 2013 09.30 - 17.00 h
(Registration and coffee 08.30 - 09.00 h)

European Microbiology Conference
Wednesday, 24 April 2013, 09.00 – 18.00 h
(Registration and coffee 09.00 - 09.30 h)
Thursday, 25 April 2013, 08.30 – 16.00 h

Venue

Radisson Blu Scandinavia Hotel
Amager Boulevard 70
2300 Copenhagen S, Denmark
Phone +45 33 96 50 00
or 00 800 3333 3333
Fax +45 33 96 55 55

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.

Fees per delegate, + VAT

European Mycoplasma Testing Conference
ECA Members € 790.-
APIC Members € 840.-*
Non-ECA Members € 890.-
EU GMP Inspectorates € 445.-

European Microbiology Conference
ECA Members € 1,590.-
APIC Members € 1,690.-*
Non-ECA Members € 1,790.-
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European Mycoplasma Testing Conference
TOGETHER with the
European Microbiology Conference
ECA Members € 2,080.-
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Non-ECA Members € 2,280.-
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The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the 24 April, lunch on all three days and all refreshments during the conferences. VAT is reclaimable.

*does not include ECA Membership

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

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23 April 2013, Copenhagen, Denmark

☐ **European Microbiology Conference**
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European Microbiology Conference
23-25 April 2013, Copenhagen, Denmark

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1. We are happy to welcome a substitute colleague at any time.
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- until 2 weeks prior to the conference 10 %,
- until 1 weeks prior to the conference 50 %
- within 1 week prior to the conference 100 %.

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