SPEAKERS:

Alison Armstrong  
BioReliance, UK

Björn Breth  
Greiner Bio-One, Germany

Sven Deutschmann  
Roche Diagnostics, Germany

Dr Marco Gut  
Applied Biosystems, Switzerland

Thomas Hämmerle  
Baxter AG, Austria

Barbara Potts  
Genentech, USA

Fahd Ramdhani  
Millipore MicroSafe Services, The Netherlands

Renate Rosengarten  
Mycosafe Diagnostics, Austria

Laure Taconet  
EDQM, France

Ann Warford  
Bayer HealthCare, USA

Helena Windsor  
Mycoplasma Experience, UK

European Mycoplasma Testing Conference

Berlin, Germany  
20-21 November 2008

Highlights:

Validation of NAT-based Commercial Mycoplasma Detection Systems

PCR Assay for the Detection of Mycoplasma

EP View of PCR Methods

Rapid Methods

FDA Regulatory Experience with a Touchdown PCR Assay
Objectives

This conference will review the current knowledge of the biology of mycoplasmas and their interactions with eukaryotic cells, and will particularly address current requirements and emerging new mycoplasma detection strategies based on nucleic acid amplification techniques (NAT) for quality control in biopharmaceutical manufacturing.

This one and a half day meeting provides the opportunity to discuss the recent advances in the area of mycoplasma infection biology, the newest technological developments for mycoplasma detection and control, as well as practical aspects and concerns of meeting the regulatory requirements. State-of-the-art presentations from academic experts in the field of mycoplasmology on the biological features of mycoplasmas and the consequences of a mycoplasma infection are combined with presentations from industry experts and from regulatory authorities on current mycoplasma testing methodologies and regulatory requirements.

The focus of the conference will be on the EP-compliant validation of newly developed NAT-based mycoplasma detection systems and their comparison with the current culture methods. NAT-based approaches for mycoplasma biosafety assurance of biological and biopharmaceutical products have been considered for many years as the most promising alternatives to the traditional culture methods due to their ability to significantly reduce the time required for testing. According to the latest EP guidelines, NAT may now be officially approved as replacements for the culture methods if they demonstrate in validation and comparability studies to be equivalent to or better than the current culture methods.

Background

The progress of the scientific in the field of cellular and molecular biotechnology, is leading to faster development of biopharmaceuticals, cell therapy, tissue engineering and advanced therapy. Safety of such new technologies, products and applications is of extreme importance. One special topic in the focus of risk assessment and safety is the contamination with mycoplasmas.

Moderator

Axel H. Schroeder, Concept Heidelberg

Target Audience

This conference is of interest to professionals from:
- Biotechnological & Biopharmaceutical Companies
- Contract Service Laboratories
- Academic Research Institutions and Organizations
- Government Agencies
- Cell Culture Collections
- Detection Systems Suppliers
  with responsibilities in:
- Manufacturing
- Quality Assurance
- Quality Control
- Regulatory Affairs
- Research & Development
- Process Development
- Validation

Programme

Mycoplasmas as Infectious Agents and Cell Culture Contaminants – An Introduction
- Mycoplasma biology, ecology, biodiversity and pathogenicity
- Interactions of mycoplasmas with host cells in vitro and in vivo
- Emerging issues of mycoplasma contamination and strategies for control
Renate Rosengarten
Mycosafe Diagnostics GmbH

Mycoplasma Testing of Biologicals: NAT Versus Current Culture Methods
- Pros and cons of mycoplasma testing by culture methods and NAT
- NAT as mycoplasma detection methods: Current regulations, trends and concerns
- EP-compliant performance validation of NAT-based mycoplasma detection systems and comparison to culture methods (examples)
Renate Rosengarten
Mycosafe Diagnostics GmbH

A History of Mycoplasma Contamination
- Mollicutes - the inevitable contaminant
- A history of mycoplasma testing
- Acholeplasma laidlawii ; an old organism, a new threat
- Future testing requirements - can cultural testing ever be defunct?
Helena Windsor
Mycoplasma Experience
Mycoplasma testing in the European Pharmacopoeia
Laure Taconet
EDQM

Alternative Mycoplasma Testing According to the Current Guidelines
■ Current guidelines
■ Methodological approach
■ Potential pitfalls and issues
Thomas Hämmerele
Baxter Bioscience

Rapid Detection Methods for Examination of Mycoplasma Species During Biosafety Testing of Biotechnological Products
■ Rapid molecular testing methods for detection of mycoplasma
■ Current regulatory guidance for rapid microbiological methods
■ Cultivation vs molecular end point assays
■ Validation parameters for lot release testing
Alison Armstrong
BioReliance

Development, Validation and FDA Regulatory Experience with a Touchdown PCR Assay for the Detection of Mycoplasma
■ The touchdown PCR assay is equivalent to the culture assay (FDA Points To Consider and E.P.2.6.7) with the detection of 0.1CFU/mL in both methods.
■ This assay was developed as a 5-8 hour method to be used during the CHO bioreactor process to aid in decision making for further processing.
■ The primers used in the assay detect all major Mycoplasma species
■ A troubleshooting matrix for multiple analysts and testing sites based on materials, method, machines and people will be shared.
Barbara Potts
Genentech Inc.

Mycoplasma PCR: Method, Validation, and Regulatory Concerns.
■ Description of the mycoplasma PCR testing performed at Bayer HealthCare, Berkeley CA.
■ Description of the improved method which was developed.
■ Details on validation of the method
■ Responses to concerns raised by regulatory agencies worldwide
Ann Warford
Bayer HealthCare

Validation of a Mycoplasma PCR Assay acc. E. P.-chapter 2.6.7
■ Details on validation of the method
Sven M. Deutschmann
Roche Diagnostics GmbH

Short Presentations of Detection Systems Suppliers:
Advanced Mycoplasma Testing Using CytoCheck®
Björn Breth, Greiner Bio-One

Real-Time PCR-based Method for a Broad Detection of Mycoplasma in Cell Culture
Marco Gut, Applied Biosystems, Switzerland

Mycoplasma Testing Requirements
F. Ramdhani, Millipore GmbH

Social Event
On 20 November 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

**Allison Armstrong**  
*BioReliance, United Kingdom*  
Dr Armstrong joined the BioSafety Testing division of BioReliance UK in 1999. BioReliance is a contract research company which provides non-clinical testing, development and manufacturing services for biologics and pharmaceutical companies worldwide. Dr Armstrong had overall responsibility for the microbiology and molecular biology operational divisions at BioReliance Stirling and the Microbiology division based in Glasgow, Scotland. These divisions provide specialist biosafety testing packages designed to assist client specific products pass the regulatory approval process. Recently Dr Armstrong was appointed Scientific director at BioReliance with specific responsibility for maintenance of scientific excellence and regulatory expertise within the global divisions of Microbiology and molecular biology. Dr Armstrong holds an Honours degree in Microbiology, MSc by thesis in Medical Science and a PhD in molecular virology from the University of Glasgow.

**Dr Sven M. Deutschmann**  
*Roche Diagnostics GmbH, Germany*  
Sven M. Deutschmann studied biology (major: microbiology, biochemistry and biotechnology) at the University of Braunschweig where he obtained his PhD in cell culture technology. In 1993 he joined Boehringer Mannheim GmbH, now Roche Diagnostics GmbH, as Manager QC. He was responsible for the microbiological and cell biological analytics of QC- and in-process control samples in the production of biotechnological derived active pharmaceutical ingredients and for the environmental monitoring program in the production areas. Since 2001 he is Director of the Microbiology QC Department. Sven M. Deutschmann is member of the Microbiology Commission and the Working Party „Pyrogen tests“ of the German Pharmacopoeia Commissions and specialist resp. member in the Working Parties „Monocyte Activation Test“ and „Bacterial Endotoxins“ of the European Pharmacopoeia Commissions.

**Thomas Hämmerle**  
*Baxter AG, Austria*  
Dr Haemmerle joined Immuno AG – now part of Baxter – in Vienna, Austria, in 1992 as a staff scientist. He is currently head of the Department of Molecular Biological Control of the Baxter Vaccine AG located at the Baxter facility in Orth, Austria.

**Barbara Potts**  
*Genentech, USA*  
Dr. Barbara Potts received her B.Sc. and M.Sc. in Zoology from Montana State University in Bozeman, Montana in 1967 and 1970 and a Ph.D. in Experimental Pathology from the University of California, School of Medicine, at San Francisco, CA in 1981. She was a Staff Fellow and Senior Staff Fellow at the NIH for six years in the NICHD and NIAID conducting basic research on pestiviruses and retroviruses. From 1989 to 1999 Dr. Potts was a Principal Scientist and Director in the biotechnology industry and at the University of Minnesota where she was a project leader for HIV-1 monoclonal and vaccine programs and xenodiagnostics. During this time she served as an AIDS and Related Research study section member for the NIH Division of Research Grants. Barbara joined Genentech Inc. in July of 2000 as Director of QC and now is a Principal Scientist in Quality Control. Barbara continues to serve on various NIAID Special Emphasis Panel review panels for Novel HIV Therapies and HIV Vaccine Development. She has over 42 publications in virology, pathogenesis studies, immunology, HIV vaccine development and three patents.

**Professor Renate Rosengarten**  
*Mycosafe Diagnostics GmbH, Austria*  
Renate Rosengarten’s academic career as a microbiologist 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. In 1996 she was appointed as Professor of Bacteriology and Hygiene at the University of Veterinary Medicine Vienna (VUV). She is Head of the Institute of Bacteriology, Mycology and Hygiene at VUV, current Chair of the Austrian Society for Hygiene, Microbiology and Preventive Medicine, Past-Chair of the International Organization for Mycoplasmology, and Founder and Managing Director of Mycosafe Diagnostics GmbH, a contract service and research organization specialized in the area of mycoplasma bioquality control in biopharmaceutical manufacturing. By working as a consultant for biopharmaceutical and biotechnology companies and by organizing international meetings on mycoplasmas, she is actively engaged to promote the area of Industrial Mycoplasmology.

**Laure Taconet**  
*EDQM, France*  
Mrs Taconet is the scientific administrator at EDQM, responsible for the Ph. Eur. Mycoplasma Working Party.

**Ann Warford**  
*Bayer HealthCare, USA*  
Initially a board-certified infectious disease laboratory director in microbiology/virology from 1980-1999 at Stanford University Medical Center, UCLA and Kaiser Medical, I transitioned into medical devices via positions at Cepheid, Johnson and Johnson. I joined at Bayer HealthCare in 2001 as a senior microbiology manager. All of my publications have concentrated on the enhanced detection of infectious agents with new methodologies since 1980. During the period from 2003 to present, I have lead validations and implementation for Bactec 9240 Sterility testing, ScanRDI Laser and BioVitesse microbial detection methods, LaCalhene Sterility Isolators, modified viral detection, Vitek-2 Compact, MIDI- GC ID System, and Mycoplasma PCR (in collaboration with Barbara Potts, Genentech).

**Helena Windsor**  
*Mycoplasma Experience Ltd., United Kingdom*  
Helena Windsor began her career as a trainee technician at the Wellcome Research Laboratories, Beckenham in 1972, joining the Mycoplasma Section in 1974. From 1977 she worked on the development of media formulations to support fastidious mycoplasmas. She obtained a BSc (Hons) in Applied Biology from North East London Polytechnic in 1979. David and Helena Windsor established Mycoplasma Experience in 1988, offering contract Mycoplasma testing for cell cultures and biologicals and, in response to industry demand, began producing and selling their unique media products for in-house testing. In 1999 Helena isolated a new human Mycoplasma species, Mycoplasma amphoriforme from the sputum of an immunocompromised patient with chronic bronchopneumonia using the growth medium developed at Mycoplasma Experience and she continues to be directly involved in media production and Mycoplasma testing. Helena Windsor was appointed Member at Large on the International Organisation of Mycoplasmology (IOM) Board of Directors for the 2006 – 2008 biennium and is currently Team Leader of the Cell Culture/Diagnostics Team of the International Research Program on Comparative Mycoplasmology (IRPCM). She is also a member of the PDA Mycoplasma task force.
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 course. Please use this form for your room reservation or be sure to mention "VA 5696 ECA Course" to receive the specially negotiated rate for the duration of your stay. Reservation should be made directly with the hotel not later than 22 October 2008. Early reservation is recommended.

Conference language

The official conference language will be English.

Organisation and Contact

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For questions regarding reservation, hotel, organisation etc.:
Marion Weidemaier (Organisation Manager) at +49-62 21/84 44 46 or per e-mail at weidemaier@concept-heidelberg.de.

GMP Certification Programme

This conference is recognised within the GMP Certification Programme. By attending selected seminars, the participant can acquire an additional certificate. We offer the following modules:

- Certified Quality Assurance Manager – Pharmaceutical Production (ECA)
- Certified Quality Assurance Manager – API Production (ECA)
- Certified Quality Control Manager (ECA)
- Certified Pharmaceutical Engineering Manager (ECA)
- Certified Computer Validation Manager (ECA)
- Certified Regulatory Affairs Manager (ECA)
- Certified Validation Manager (ECA)

On the internet at www.gmp-compliance.org you will find a text explaining which seminars are recognised for which certificates. Or you send an e-mail to info@gmp-compliance.org or a fax to +49-6221-84 44 64 with the request for information about the GMP Certification Programme. We will then send you our brochure on the topic.

About CONCEPT HEIDELBERG

Founded in 1978, CONCEPT HEIDELBERG is the leading organiser of seminars on pharmaceutical production, quality control, quality assurance and GMP in Europe. This year more than 240 events will be organised by CONCEPT HEIDELBERG. ECA has entrusted CONCEPT HEIDELBERG with the organisation of its events.

What Is ECA?

The European Compliance Academy (ECA) is an independent educational organisation chaired by a Scientific Advisory Board with members of the pharmaceutical industry and regulatory authorities. The ECA will provide support to the Pharmaceutical Industry and Regulators to promote the move towards a harmonised set of GMP and regulatory guidelines by providing information and interpretation of new or updated guidances.

What Are the Benefits of ECA?

First benefit: During the membership, you enjoy a 10 % discount on the regular participation fee of any European Conference organised by ECA in co-operation with CONCEPT HEIDELBERG.

Second benefit: The GMP Guidelines Manager CD ROM with a large number of guidelines, e.g. EC Directives, FDA Guidelines, ICH Guidelines, will be forwarded to you when you are using your membership for a conference registration.

How Do You Become Member of ECA?

By participating in one of the European Compliance Conferences or Courses marked with ECA, you will automatically become a member of ECA for two years – free of charge. There are no obligations for the member! Conferences and Education Courses organised by ECA will be realised in co-operation with CONCEPT HEIDELBERG. More information about ECA can be obtained on the Website http://www.gmp-compliance.org.
Thursday, 20 November 2008, 09.30 – 17.30 h

Registration and coffee 09.00 – 09.30 h

Friday, 21 November 2008, 09.00 – 13.00 h

Venue
Steigenberger Hotel Berlin
Los-Angeles-Platz 1
10789 Berlin
Germany
Phone +49 (0)30 2127 0
Fax +49 (0)30 2127 799

Fees
Non-ECA Members EUR 1,690.- per delegate plus VAT
ECA Members EUR 1,521.- per delegate plus VAT
APIC Members EUR 1,605.- per delegate plus VAT
EU GMP Inspectorates EUR 845.- 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.

Registration
Via the attached reservation form, by e-mail or by fax message.
Or you register online at www.gmp-compliance.org

General Terms of Business
1. 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 fee will be calculated as soon as possible and will be refunded as full refund of fees.

   - until 2 weeks prior to the conference: 10 % of the registration fee.
   - until 1 week prior to the conference: 50 % of the registration fee.
   - within 1 week prior to the conference: 100 % of the registration fee.

2. 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. CONCEPT HEIDELBERG will not be responsible for discount airfare penalties or other costs incurred due to a cancellation.

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