



MARY-BETH ANHEUSER
bioMerieux, USA

ARNAUD CARLOTTI
idmyk, France

MARCO GUT
Applied Biosystems,
Switzerland

BODO HOLTkamp
Biotest, Germany

DAVID JONES
Rapid Microbiosystems, USA

PETRA MERKER
Bayer Schering
Pharma, Germany

THOMAS MIKOSCH
Centocor Europe,
The Netherlands

GARY DU MOULIN
Genzyme Biosurgery, USA

RENATE ROSENGARTEN
Mycosafe Diagnostics, Austria

ANDREAS SCHLÖSSER
L&S AG, Germany

SILKE SCHNEEGANS
Biotecon, Germany

**HOLGER
SCHÖNENBRÜCHER**
Merck KGaA, Germany

ALEXANDRA STÄRK
Novartis Pharma
Stein, Switzerland

MIKE WADDINGTON
Accugenix, USA

ELIZABETH YOUNG
Baxter Healthcare, USA

Rapid Microbiological Methods Conference

- New Methods
- New Approvals

**- Implementation -
- Approval -
- Routine Use -**

**9 - 10 December 2008
Berlin, Germany**

Invitation

Dear Colleagues,



Over the last ten years, the importance of Rapid Microbiology Methods (RMM) for the pharmaceutical industry increased considerably, because RMM provide an opportunity to reduce time and costs in different fields of microbiological testing. During this period, there was a lot of confusion and a great uncertainty about the implementation and the regulatory requirements of such new technologies. But in 2008 several pharmaceutical companies issued news about approval of RMM.

With the programme at hand I would like to invite you to the „Rapid Microbiological Methods Conference“, organised by the European Compliance Academy (ECA). This conference intends to provide a microbiological update in RMM and to introduce experiences from pharmaceutical companies implementing such new technologies and getting them approved.

The focus of this conference will be on the different aspects of RMM in:

- Sterility Testing
- Environmental Monitoring
- Sterility Testing of Tissues
- Mycoplasma Tests

It is also the aim of this conference to support you with information about regulatory requirements and approval processes, practical knowledge in implementing the methods as well as future expectations relative to RMM.

In addition you will get the possibility to discuss the state-of-the-art and current experiences with RMM with speakers, suppliers and your colleagues from industry.

It would be a great pleasure for me to welcome you in Berlin. It promises to be an outstanding experience

Yours sincerely,

A handwritten signature in blue ink, appearing to read 'R.M. Bonner', written in a cursive style.

Richard M. Bonner
Director Regulatory Affairs,
European Compliance Academy (ECA)

Objectives

This two day conference offers you a unique possibility to evaluate the **new developments** in RMM systems as well as the experiences in validation and implementation of pharmaceutical manufacturers. Furthermore you will hear about RMM established in tissue-engineering and about cognitions in approval and licensing RMM.

Background

Microbial Contaminations poses enormous risks to pharmaceuticals and their consumers. To minimize the quality and financial risk, pharmaceutical and biopharmaceutical manufacturers sample thousands plates a year with following incubation, counting of colonies and identification of micro organisms. With classic culture methods, this needs a lot of time and money and in the fields of cell culture, tissues and tissue engineering it is often not possible to wait 7 or more days for a result. RMM provide the ability to reduce necessary time and costs for microbial detection. The increasing interest of pharmaceutical and biopharmaceutical companies in rapid microbiological methods caused a rapid development in the field of RMM.

Several new systems for real-time microbial identification of the samples from environmental monitoring, sterility testing, for mycoplasma detection, pyrogen and endotoxin testing are available at the market or in validation. The regulatory authorities like FDA or MHRA assist the implementation of RMM, e.g. with documents like USP chapter <1223>.

Target Audience

This conference is of interest to professionals from

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

with responsibilities in

- Quality Assurance
- Quality Control
- Research and Development
- Process Development
- Validation
- Regulatory Affairs

Moderator

Axel H. Schroeder, Concept Heidelberg

Programme

Regulatory Expectations – Filling-Variations-Enforcement, Licensing
SPEAKER INVITED

RMM for Microbial Identification – Case Study:
MicroSEQ Implementation Strategy
DR THOMAS MIKOSCH, *Centocor Europe B.V., The Netherlands*

Evaluations of a Novel Technology for the Automated Rapid Enumeration of Microorganisms
ELIZABETH YOUNG, *Baxter Healthcare Corporation, USA*

New Rapid Sterility Test
DR ALEXANDRA STÄRK, *Novartis Pharma Stein AG, Switzerland*

Rapid Methods in Mycoplasma Detecting
PROF RENATE ROSENGARTEN, *Mycosafe Diagnostics, Austria*

Automated rapid microbiological Detections for the Pharmaceutical Industry: Experience with Validation and Implementation for an autologous Cell Therapy Product
DR GARY DU MOULIN, *Genzyme Biosurgery, USA*

Outsourcing and Optimizing of Microbial Identification
DR ANDREAS SCHLÖSSER, *L&S AG, Germany*

Validation and Implementation of a Real-Time PCR System for Microbial Identification Comparative Study
DR PETRA MERKER, *Bayer Shering, Germany*

Molecular Identification in the microbiology Laboratory: Pluses, Perils and Pitfalls
DR ARNAUD CARLOTTI, *idmyk, France*

Requirements for Validation of Real-time PCR Assays as Alternative Methods
DR HOLGER SCHÖNENBRÜCHER, *Merck KGaA, Germany*

State-of-the-art and future Developments in cGMP-compliant, Genetic Microbial Identification
MIKE WADDINGTON, *Accugenix, USA*

Short Presentations

Automated Alternative to Compendial Sterility Testing
MARY-BETH ANHEUSER, *bioMerieux, USA*

The Growth Direct, a rapid, non-destructive Enumeration System
DAVID JONES, *Rapid Microbiosystems, USA*

Micro Compass – Quantitative Detection of Bacteria, Yeast and Mould
N.N., *Lonza Group*

MicroSEQ – Molecular Identification Systems
DR MARCO GUT, *Applied Biosystems, Switzerland*

Real Time PCR Microbial Screening - Interlaboratory Test
SILKE SCHNEEGANS *Bioteccon, Germany*

New Real-Time PCR kit for Mycoplasma Detection
DR BODO HOLTkamp, *Biotest AG, Germany*

Social Event



On 9 December 2008, 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.

Date

Tuesday, 9 December 2008, 09.30 h – 17.30 h
(Registration and welcome coffee 09.00 h – 09.30 h)
Wednesday, 10 December 2008, 08.30 h – 17.00 h

Venue

Steigenberger Hotel Berlin
Los-Angeles-Platz 1
10789 Berlin
Germany
Phone +49 30 2127 0
Fax +49 30 2127 117

Conference fees

Non-ECA Members € 1,690.- per delegate plus VAT
ECA Members € 1,521.- per delegate plus VAT
APIC Members € 1,605.- per delegate plus VAT
(does not include ECA membership)
EU GMP Inspectorates € 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.

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 5694 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 8 November 2008. Early reservation is recommended.

Registration

Via attached reservation form, by 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
69007 Heidelberg, GERMANY
Phone +49 (0) 62 21/84 44-0
Fax +49 (0) 62 21/84 44 34
E-mail: info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content:

Axel H. 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.:

Jessica Stürmer (Organisation Manager) at +49-62 21/84 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:

Reservation Form (Please complete in full)

Rapid Microbiological Methods Conference

9 – 10 December 2008, Berlin, Germany

Mr Ms

Title, first name, surname

Company

Department

Important: Please indicate your company's VAT ID Number

Please indicate the Purchase Order Number, if applicable

Street / P.O. Box

City

Zip Code

Country

Phone / Fax

E-Mail (Please fill in)

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

69007 Heidelberg
Germany

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 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 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!)