ECA
European Compliance Academy

- With Representatives from EDQM and FDA

Rapid Microbiological Methods Conference

Regulatory Development, Testing of Sterile and Non-Sterile Products, Water Testing

7 - 8 December 2011, Berlin, Germany

Authority Speakers

BRYAN RILEY
FDA, USA

CHARLOTTA GUSTAFSSON
EDQM, France

Speakers from Research and Industry

SVEN M. DEUTSCHMANN
Roche, Germany

DR ANNE BAUMSTUMMLER
Merck Milipore

ROBERT BIRD
Pall, United Kingdom

MICHELE BOSI
Chiesi Farmaceutici, Italy

PRAFUL BHUSARI
Medimmune, USA

HANS VAN DOORNE
University Groningen, The Netherlands

ALESSIO FANTUZZI
Chiesi Farmaceutici, Italy

OLIVER GORDON
Novartis, Switzerland

SUBHO GOSWAMI
BD, USA

BENJAMIN JUNGE
BIOTECON Diagnostics, Germany

DANIEL LARSEN
Bavarian Nordic, Denmark

NEIL LEWIS
Procter & Gamble, USA

STEFAN MEINZINGER
Life Technologies, Germany

ANNA MILLS
Rapid Micro Biosystems, USA

KAREN PINKSTON
bioMérieux, USA

EMILIANO TOSO
Merck Serono, Italy

GUIDO VOGEL
Mabritec, Switzerland

ERIC WARD
Pfizer, USA

HIGHLIGHTS:

- FDA Experiences with Implementation and Approval of Alternative Microbiological Methods
- The Role of the European Pharmacopoeia in the Use of Alternative Microbiological Methods
- ISO Standards – Experiences from Food
- Testing of Non-Sterile Products
- Water Testing
- Mass Spectroscopy Systems
- Implementation of Phenotypic Identification
- Implementation Genotypic Identification
- Bacterial Flora associated with SPF Eggs Used in Vaccine Production

This conference is recognised for the ECA GMP Certification Programme „Certified Microbiological Laboratory Manager“. Please find details at www.gmp-certification.eu

Rapid Microbiological Methods Conference

7-8 December 2011, Berlin, Germany

Invitation to the Rapid Microbiology Methods Conference

Dear Colleagues,

The fast development in the field of Rapid Microbiological Methods (RMM) still goes on. During the last year, a lot of suppliers and pharmaceutical companies started to evaluate and implement new RMM.

With the programme at hand I would like to invite you to the „Rapid Microbiological Methods Conference 2011", organised by the European Compliance Academy (ECA). This conference intends to provide a microbiological update in the development of new RMM and to introduce experiences from authorities, consultants and pharmaceutical companies implementing such new technologies and getting them approved. The conference is one part of the activities of the ECAs RMM Working Group.

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

- Regulatory Requirements of US and European Authorities
- New developed Systems
- Testing of Non–Sterile Products
- Water Testing
- Experiences of Related Industries

Furthermore this conference will 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 it will be an unique possibility to discuss the state-of-the-art and the 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 become an outstanding experience.

Dr Sven M. Deutschmann
Chairman of the ECA RMM Working Group

Objectives

This two day conference offers you a unique possibility to evaluate the new developments in RMM systems to extend the **experiences in validatio**n and **implementation** of these systems in pharmaceutical industry. Furthermore you will learn more about the expectations of European and US authorities and developments in regulatory requirements.

Background

Microbial contamination poses enormous risks to pharmaceuticals and their consumers. To minimize the quality and financial risk, pharmaceutical and biopharmaceutical manufacturers collect thousands of samples for bioburden or sterility testing a year. The classic culture methods are often laborious and require long incubation times. In the field of some biopharmaceuticals, ATMP and other modern products, it is often not possible to wait 7 or more days for a result. RMMs provide the ability to reduce time and costs for microbial detection and increase the safety level of the products.
In the meantime several new systems for the detection of microbial contaminants and new identification systems are available at the market or in validation. The regulatory authorities like FDA, MHRA or EDQM assist the implementation of RMMs e.g. with the revision of the related guidelines or pharmacopoeias.

Target Audience

This conference is of interest to professionals in Quality, Microbiology and Validation from

- Pharmaceutical and Biopharmaceutical Companies
- Contract Service and Research Laboratories
- Government Agencies
- Cell Culture Collections

Moderators

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

Programme

The Role of the European Pharmacopoeia in the Use of Rapid Microbiological Methods

- Results from the EDQM enquiry among industry and authorities
- Current status of the revision process of chapter 5.1.6 and other Ph. Eur. chapters involving rapid microbiological methods.

Charlotta Gustafsson, ***EDQM and*** **Hans van Doorne,** ***University of Groningen***

Short Presentation: Basic Function of the MicroCount

- Technology Overview
- Application and Uses
- Instrumentation, Software and Examples

Subho Goswami, ***BD USA***

Application of Flow Cytometry for Rapid Bioburden Screening – From Concept to Implementation

- In-process measurements of microbiological quality are critically important in aseptic processing of vaccines and biologics
- Culture based methods of bioburden detection require considerable turn around time necessiating intermediate inventory hold-time
- Rapid Microbiological Methods can provide timely results to facilitate uninterrupted processing
- A Flow cytometry based rapid method was developed and implemented for process control bioburden screening in Influenza vaccine manufacturing.

Praful Bhusari, *Medimmune*

Short Presentation: Rapid Mycoplasma Detection

Stefan Meinzinger, ***Life Technologies***

Mycoplasma Rapid Testing Overview

- Detection methods (qPCR, touchdown PCR, Microarrays, RT PCR, enrichment based PCRs ecc),
- Health authority requirements and challenges
- Validation strategies and guidelines (EP, USP, PTC, PDA TR 50 ecc)

Emiliano Toso, ***Merck Serono***

Short Presentation: New Genotypical Water Testing System for the Pharmaceutical Industry

- Technology Overview
- Application and Uses

Benjamin Junge, ***BIOTECON Diagnostics***

A Diversity Study on the Bacterial Flora associated with SPF Eggs used in Vaccine Production

- The identification methods used. (500R DNA sequencing and Ribotyping)
- Microbiological flora obtained from the surface of the eggs
- Microbiological flora obtained from the inside of the eggs
- Impact of the flora on the production of a live vaccine

Daniel Larsen, ***Bavarian Nordic***

Water Testing with the Growth Direct – Experiences and User View

- Validation approach
- Experiences and challenges during validation
- Implementation in routine use

Oliver Gordon, ***Novartis Pharma Stein AG***

Short presentation: Introduction to a novel qPCR System for pharmaceutical Microbiology testing

Robert Bird, ***Pall***

Development and Aualification of alternative Methods for the Release of non-sterile and sterile Products

- Key benefits and critical factors for the Implementation
- Qualification and Validation data
- Experience and strategy for the Regulatory submission

Michele Bosi and Alessio Fantuzzi, ***Chiesi Farmaceutici***

Programme (cont.)

An FDA Perspective on Rapid Microbiology Methods
- Experience and strategy for the Regulatory submission
- Selection of a Rapid Microbiology Method (RMM)
- Validation of a RMM
- FDA Regulatory Pathways for RMM implementation

Bryan Riley, ***FDA***

Case Study: Strain Typing of B. subtilis-Isolates
- Different approaches for strain typing using different molecular-besed methods such as rDNA-Sequencing, AFLP or full genome sequencing

Sven M. Deutschmann, ***Roche***

Short presentation: Miliflex Quantum – use for Cell-based Products
Dr Anne Baumstummler, ***Merck/Millipore***

Evaluation of the Millipore Milliflex Quantum™ Rapid Detection System
- Evaluation of the Millipore Milliflex Quantum™ Rapid Detection System
- Describes the principle of operation of the system
- Beta study data including testing of water system and cell culture samples
- Challenged post assay viability of challenge organisms
- Provides results of study including recommendations for potential applications of the system

Eric Ward, ***Pfizer***

Rapid testing of non-sterile Products with the Celsis Advance
- Business justification
- System evaluation
- Validation rationales

Oliver Gordon, ***Novartis***

Short presentation: Rapid Method based on Mass Spectroscopy
Karen Pinkston, ***bioMèrieux***

Implementation of a Maldi-TOF
- Identification system for the industrial setting
- Inclusion of highly pathogenic micro-organisms in the database

Guido Vogel, ***Mabritec, Switzerland***

Microbiology and Statistics: Would the compendial method pass validation?
- Regulatory background
- Necessary Statistical Concepts
- Hypothesis and Statistical Testing
- Discussion on Precision
- F-test

Anna Mills, ***Rapid Micro Biosystems***

Implementation of RMM at Procter & Gamble
- The thought processes and criteria for the selection of rapid methods
- Difficulties and issues during implementation
- Combination of rapid and traditional methods
- Need for an industry wide approach

Neil Lewis, ***Procter & Gamble***

Exhibition

Since 2008, many suppliers of Rapid Microbiological Methods and contact laboratories used the opportunity to present their products and services to the participants of Europe's biggest event on RMM in pharmaceutical microbiology.

Seize the unique chance to get in contact with specialists from science and industry and to present your company and service.

Extract of the exhibitors list: bioMerieux, Rapid Micro Biosystems, Celsis International, PMT, BD Europe, Lonza, AES Cheminex, Merck Millipore, Biotecon, Pall, Lifetechnologies, Accugenix and more.

Would you also like to present an exhibition stand?
You will find details on the conference website www.rmm-conference.org or you contact Ms Jessica Sturmer at phone + 49-6221/ 84 44 43, or per e-mail at stuermer@concept-heidelberg.de.

Lufthansa
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Special offer with Lufthansa – Discounted Travel for Rapid Microbiological Methods Conference Attendees

Lufthansa German Airlines offers a comprehensive global route network linking Berlin with major cities around the world. As the Official Airline to this event, Lufthansa offers special prices and conditions to all attendees.To make your reservation, please click on the link you will receive with your registration confirmation and enter the access code **DEZUPS** in the "Access to Event Booking" area. This will take you into an online booking platform that will automatically calculate the discount offered or provide you with an even better offer if another promotional fare is available.
Please note that you may have to enable pop-ups on this site – otherwise the booking platform window will not open.
These promotional fares are also available via your IATA / ARC Travel Agent. Travel Agents can obtain ticketing instructions via eMail lufthansa.mobility@dlh.de by quoting the access code as an event reference.

RMM Group
Rapid Microbiology Methods

The **ECA RMM Working Group** was founded on 7 June 2006 at the German Federal Agency for Sera and Vaccines by 11 representatives from the European Pharmaceutical Industry and the German Federal Agency for Sera and Vaccines, the Paul-Ehrlich-Institute (PEI). During its inaugural meeting the working group reviewed the current situation of RMMs in Europe and defined a work plan.

One of the current issues the group identified is the lack of standardisation for the submission of RMMs. The group also considers the integration of certain methods into the European Pharmacopoeia chapter 5.1.6 as critical because it possibly sets a wrong focus on these tests only. In addition, the use of RMMs for marketed products is discouraged by the Type II Change effort. The group also voiced concerns about the inappropriate methods occasionally requested by the authorities – like classical EP sterility tests for cell therapy products. In general it sees a clear forward path for using RMMs for new submissions.

Extract of the activities:

- 2007: First Good Practice Paper: MicroSeq for Microbial Identification
- 2008: The Working Group organises the first Conference on RMM as a meeting point for interested industrial microbiologists, suppliers and scientists from contact laboratories,
- 2009: the group established on their website a RMM database and searching engine which includes information about different Rapid Micro Methods
  - Second Good Practice Paper: VITEK2 – Microbial Identification
  - Second RMM Conference
- 2010: The Working Group supported EDQM's survey related to a revision of EP chapter 5.1.6. with the feedback of approx. 70 members.
  - Database now includes 20 systems
  - Third RMM Conference
- 2011: Current survey to the group members about their activities
  - Database increased to 27 systems
  - New course about validation of molecular biological methods

Speakers

Dr. Sven M. Deutschmann, Roche Diagnostics GmbH, Germany
Sven is Director of the Microbiology QC Department in the Pharma Division at Roche Diagnostics GmbH. He is member of the German Pharmacopoeia Commission, the Microbiology Committee and different Working Parties. In addition, he is member of the PDA "Mycoplasma Task Force" and chairman of the advisory board of the ECA "Rapid Microbiological Methods Working Group".

Dr Anne Baumstummler, Merck/ Millipore GmbH, Germany
After graduating as an Engineer in Biotechnology, Anne Baumstummler joined Millipore in 2008. While working as a Research Scientist, she did a PhD thesis on rapid microbiology. Since 2011, Dr Baumstummler is employed by Merck Millipore as a Rapid Microbiology Senior Scientist, with a focus on the development of new rapid detection technologies.

Praful Bhusari, Medimmune Inc., USA
Praful Bhusari studied Microbiology at the University of Wyoming and Management Science at the California State University. He has over eighteen years of experience in Biotechnology, Pharmaceutical and Consumer Product Microbiology. Had the opportunity to work at several companies in the San Francisco Bay area. Since 2001 he is Associate Scientist, MedImmune, Inc.

Robert Bird, Pall, United Kingdom
Mr Robert Bird is currently the European Business Development Manager for Rapid Microbiology Systems within Pall Life Sciences. Originally graduating from Queens University of Belfast with an honours degree in Biochemistry he subsequently worked on virology research in both academia and industry.

Michele Bosi, Chiesi Farmaceutici, Italy
He had a degree in Industrial Chemistry in 1991 at Bologna University (Italy). In 1997 he joined Chiesi Pharmaceutical assuming responsibilities into the different fields of quality control operations in: Chemical, Packaging Materials and Microbiological Laboratories, Stability and Analytical Development. From 2001 he is in charge as Quality Control Manager.

Dr Hans van Doorne, University Groningen, The Netherlands

Dr Alessio Fantuzzi, Chiesi Farmaceutici, Italy
He had a degree in Biology at Parma University (Italy) in 2000. He has acquired experience within the Microbiology Laboratory in Chiesi Group, Parma plant, covering positions of increasing responsibility. Currently is in charge for Microbiology Analytical Development.

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.

Subho Goswami, BD, USA

Charlotta Gustafsson, EDQM, Straßbourg, France
Ms Charlotta Gustafsson studied biotechnology And she joined the European Directorate for the Quality of Medicines & HealthCare (EDQM) in 2007.. She is involved in the Scientific Secretariat to the microbiology Group of Experts as well as the Working Parties on modern microbiological methods and microbial contamination of herbal drugs.

Benjamin Junge, BIOTECON Diagnostics, Germany
Benjamin Junge studied Biology with focus on Molecular Biology and Biochemistry and Marketing and Management. Currently, he is employed at BIOTECON Diagnostics as Product Manager for PCR based Rapid Methods.

Dr Daniel Larsen, Manager QC Microbiology, Infectious Disease Division, Bavarian-Nordic A/S
From 1998-2000 Daniel Larsen was QC Scientist at Colgate, Palmolive and from 2000-2005 Manager QC Microbiology and Analytical Science. In 2005 he joined Carlsberg-Denmark as Head Microbiologist QC/Production. From 2008 - present he is Manager QC Microbiology at Bavarian-Nordic A/S.

Speakers cont'd

Neil Lewis, Procter & Gamble, USA
Graduated in Microbiology and Parasitology 1979. Worked 12 years as site microbiologist for Max Factor and Revlon. He is currently responsible for the microbiological performance of some 70 manufacturing sites globally and the development of new microbiological techniques for QC.

Dr Stefan Meinzinger, Life Technologies, Germany
Based in Cologne, Stefan is responsible for Germany, Austria and Switzerland and provides customized training, support and implementation services to customers as Field Application Specialist for Pharma Analytics in Applied Markets. Stefan obtained his PhD degree in Biochemistry from the University of Cologne. After being Scientifc Application Specialist at Amaxa AG he worked for 3 years as Scientific Product Specialist for Lonza Cologne AG. Since joining Life Technologies in 2009, he was appointed European Expert for Bioassays.

Anna Mills, Application Specialist, Rapid Micro Biosystems, USA,
Anna has BSC (Hons) in Biological Sciences from the University of Plymouth and a post-graduate degree (MPhil) in Microbiology from Northampton University in the UK. Anna Mills joined Celsis in 2005 as Technical Support Manager for UK, Ireland and Southern Europe. Currently she is the Field Application Specialist of Rapid Micro Biosystems Inc. for Europe..

Bryan S. Riley, Ph.D., US Food and Drug Administration.
Dr Riley is a Senior Review Microbiologist in the Office of Pharmaceutical Science, Center for Drug Evaluation and Research at FDA. Prior to coming to FDA in 1998, he directed a specialty clinical diagnostic microbiology laboratory. Dr Riley is also a member of the FDA's Process Analytical Technology (PAT) team for Rapid Microbiology Methods (RMM).

Karen Pinkston, bioMérieux, USA

Emiliano Toso, Merck Serono, Italy
With RBM Merck Serono since 1999, Dr Toso has been the Head of the Molecular Biology Laboratory in the GMP Biological Quality Control department for the last three years. Since 2000, he set up and validated (GLP/GMP) PCR and qPCR methods for detection, characterization and identification of different microorganisms.

Guido Vogel, Mabritec AG, Switzerland
Guido Vogel studied Biochemistry at the University Bern. After three years as head of the Biosafety Laboratory Basel, he joined 1999 Mabritec AG. Today he is Chairman of the Administrative Board and Chief Scientific Officer.

Eric Ward, Pfizer, USA
Eric Ward is a Senior Supervisor in the Quality Analytical Development department at Pfizer Specialty Care in Andover, Massachusetts. In this role he provides scientific and strategic expertise for evaluating, validating and implementing microbiology methods and technologies.

Social Event

On 7 December, 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.rmm-conference.org

Date
Wednesday, 7 December 2011, 9.30 - 17.30 h
(Registration and coffee 9.00 – 9.30 h)
Thursday, 8 December 2011, 8.30 – 16.30 h

Venue
Esplanade Grand Hotel Berlin
Lützowufer 15
10785 Berlin, Germany
Phone +49 30 25478 0
Fax +49 3025478 8617

Conference fees
ECA Members € 1,490.- per delegate plus VAT
APIC Members € 1,590,- per delegate plus VAT
(does not include ECA membership)
Non-ECA Members € 1,690.- per delegate plus VAT
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 event. Please use this form for your room reservation or be sure to mention "ECA Event" to receive the specially negotiated rate (single room € 129,-/double room € 149,- incl. breakfast) for the duration of your stay. Reservation should be made directly with the hotel not later than 21 October 2011. Early reservation is recommended.

Conference Language
The official conference language will be English.

Organisation and Contact
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Reservation Form (Please complete in full)

Rapid Microbiological Methods Conference
7 - 8 December 2011, Berlin, Germany
☐ Mr ☐ Ms

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Department

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If you cannot attend the conference you have two options:
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 %
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