ECA
ROPEAN COMPLIANCE ACADEMY

Including
New Developments in the Pharmacopoeias

Rapid Microbiological Methods Conference

10-11 December 2013
Barcelona, Spain

With optional Workshop "Statistics for Validation of Microbiological Test Methods" on 12 December 2013

Speakers

DR TONY CUNDELL
MSD, USA

DR SVEN M. DEUTSCHMANN
Roche Diagnostics, Germany

DR MAITRY GANATRA
Pall Life Sciences, USA

DR MARCEL GOVERDE
MGP Consulting, Switzerland

OLIVER GORDON
Novartis, Switzerland

DR FRANZ GRUBER
Baxter, Austria

PROF DR EDWIN VAN DEN HEUVEL
University Medical Center Groningen, The Netherlands

DR PIETA IJZERMAN-BOON
MSD, The Netherlands

DR DAVID JONES
Rapid Micro Biosystems, USA

JUDY MADDEN
Celsis, USA

DR MICHAEL MILLER
Microbiological Consultants, USA

JEANNE MOLDENHAUER
Excellent Pharma Consulting, USA

DR DAVID MYATT
BTF, Australia

DARRICK NICCUM
TSI, USA

DR SEBASTIEN RIBAULT
Merck Biodevelopment, France

DR EMILIANO TOSO
Merck Serono, Italy

GEERT VERDONK
MSD, The Netherlands

STEPHEN WICKS
EDQM, France

DR ERIK WILKENS
Novartis, Switzerland

HIGHLIGHTS:

- Pharmacopoeial Developments
- Rapid Sterility testing
- IPC
- Method Validation
- Mycoplasma and Leptospira Detection

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

10-11 December 2013, Barcelona, Spain

Invitation to the Rapid Microbiology Methods Conference

Dear Colleagues,

With the programme at hand I would like to invite you to the „Rapid Microbiological Methods Conference 2013", organised by the European Compliance Academy (ECA). ECA's RMM Working Group will provide you again the possibility to get familiar with the current development of Rapid Microbiological Methods. Speakers from pharmacopoeial expert groups as well as from industry and vendors will present new methods, new applications, implementation and validation and their experiences in routine use.

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

- Pharmacopoeial changes in US and Europe
- New developed systems
- Different possibilities of application
- Routine use
- Experiences of Related Industries

The conference will be rounded off by an optional **Workshop about the necessary statistical data management for validation.**

Furthermore this conference will support you with information about regulatory requirements and approval processes 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 Barcelona. It promises to be an outstanding experience.

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

Objectives

This two day conference and the additional workshop offer you a unique possibility to evaluate the new developments in RMM systems to extend the experiences in validation as well as implementation of these systems in pharmaceutical industry. Furthermore you will learn more about the expectations of authorities and developments in regulatory requirements. Experts will give an insight view in the routine use of RMM and furthermore, an after conference workshop will provide you practical examples and information about the use of the microbiological data.

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, Advanced Therapy Medicinal Products 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, EDQM or MHRA 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

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

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Programme

Microbial Identification and Rapid Microbial Methods - USP Point of View

- USP<1113> Microbial characterization, identification and strain typing
- 21 CFR 610.12 Sterility Tests and the revision of USP <1223> Validation of alternative microbiological methods
- USP <71> Sterility Tests and products with short shelf lives – suitable methods

Tony Cundell, MSD USA

Rapid microbiological methods in the European Pharmacopoeia

- Current status of the revision of chapter 5.1.6
- Status of RMM in the European Pharmacopoeia
- Revision of chapter 5.1.6
- Future developments

Stephen Wicks, EDQM, France

A Comprehensive Review of the New PDA TR33 - Validation and Implementation of Alternative and Rapid Microbiological Methods

- Understand the most significant changes from the original 2000 guidance document
- Review recent regulatory expectations and policies
- Discuss validation strategies for qualitative, quantitative and identification methods
- Describe examples of successful implementation case studies

Michael Miller, USA

Rapid Sterility Testing - Why have so many companies abandoned their approved methods

- Overview of the methods approved for sterility testing with RMMs
- Types of methods approved in the early submissions
- Reasons for companies becoming disillusioned and discontinuing these methods
- How to prevent this type of occurrence

Jeanne Moldenhauer, USA

Shortpresentation: Celsis Rapid Detection System; Applications and Equivalency to Compendial Methods

Judy Madden, USA

Validation of a Rapid Sterility Test by Direct Inoculation with the Celsis Advance

- Introduction to the system
- Validation approach
- Results

Erik Wilkens, Switzerland

Short presentation: Growth Direct – the Second Generation

David Jones, Rapid Micro Biosystems

The 2nd Generation Growth Direct System for Environmental Monitoring – First experiences from a user's perspective

- Introduction to the system
- Beta study results
- Implementation strategies

Oliver Gordon, Switzerland

Summary Presentation: Helpful literature on Implementation and Validation of RMMs

- Overview – What is available
- How useful are these articles
- Where can you find them

Marcel Goverde, Switzerland

Short Presentation: Real-Time Viable Particle Detection: Road to Acceptance

Darrick Niccum, USA

Programme (cont.)

IPC testing by traditional, innovative and next generation methods to avoid Large Scale Contaminations
- Rapid Molecular Methods perceptions and trends affected by public incidents
- Development of a successful GMP platform: lessons learned
- qPCR & NGS technology revolutions

Emiliano Toso, Italy

Long-term experience regarding alternative mycoplasma testing according to European Pharmacopoeia
- NAT mycoplasma testing - methodology for nucleic acid extraction and amplification
- Validation of a NAT mycoplasma method according to European Pharmacopoeia
- Long-term experience using a reference preparation: handling, storage, and stability
- Relations between reference preparations

Franz Gruber, Austria

Validation and Global Implementation of a PCR-based Leptospira Detection Method - A Journey From a Trouble-Shooting Tool to a Routine IP-Test
- Method Development and Validation
- Global Change Request
- Global Roll-Out and Implementation

Sven M. Deutschmann, Germany

Short presentation: The Value of Precise Quantitative Controls in Validation of Alternative Microbiological Methods.
David Myatt, BTF – BioMerieux, Australia

Statistical reflections on microbiological method validation
Edwin van den Heuvel, The Netherlands

Is there really a need for rapid methods as IPC during Biotech processes ?
- Biotech processes and RMM: Is faster always better?
- Rapid methods in Process Development vs Rapid Methods in Production
- How rapid should be rapid?
- Impact of RMM on projects timelines

Sebastien Ribault, France

Workshop "Statistics for Validation of Microbiological Test Methods"
12 December 2013, Barcelona, Spain

Speakers

Pieta C. IJzerman-Boon, Principal Statistician MSD
Geert Verdonk, Principal Scientist Microbiology, MSD
Edwin van den Heuvel, Professor Medical Statistics, UMCG

Abstract

For the validation of rapid microbiological test methods several experiments must be performed to demonstrate that the new method is capable of detecting and counting organisms in test samples and at least as good as the compendial method. To quantify the performance statistical methods form an indispensable tool. This workshop will provide information on the types of experiments and the statistical analyses that may be performed to estimate the validation parameters of the new rapid methods. The methods will be illustrated with real cases on the validation of rapid microbiological test methods.

Programme

Introduction
- Validation parameters
- Equivalence
- Guidelines measurement systems
- Basic statistics

Accuracy & Precision
- Pseudo reference material (BioBalls)
- Recovery
- Repeatability
- Intermediate Precision
- Analysis of variance

Sensitivity & Specificity
- False positives
- False negatives
- Chi-square statistic and Fisher exact test

Linearity & Range

Limit of Detection & Limit of Quantitation
- Most probable number (MPN)
- Most probable limit of detection (MPL)
- Pearson's minimum chi-square estimator

Robustness

Equivalence
- Types of equivalence
- Wilcoxon rank sum test
- Confidence intervals

Speakers

Dr Tony Cundell, Senior Principal Scientist, MSD, U.S.A.
Tony Cundell worked in different microbiological positions for the NY Blood Center, Wyeth and Schering-Plough. Since 2012 he holds the position of a Senior Principal Scientist at MSD and provides technical expertise and leadership to the Merck Research Laboratories in the area of microbiology. He is Senior Technical Advisor to the Merck Microbiology Center of Excellence. Furthermore, he is a member of the USP Microbiology and Sterility Assurance Committee of Experts.

Dr Sven M. Deutschmann, Roche Diagnostics GmbH, Germany
Sven is Director of the Micro- and Cellbiology QC Department in the Pharma Division at Roche Diagnostics GmbH. He is member of the German Pharmacopoeia Commission, the Microbiology Committee and the Working Party "Pyrogen tests" of the German Pharmacopoeia Commissions as well as member in the Working Parties "Monocyte Activation Test", "Bacterial Endotoxins", "Modern Microbiological Methods" and "Mycoplasma" (this Working Party is chaired by him) of the European Pharmacopoeia Commissions. In 2009 he was appointed as commissioner of the Central Commission for Biological Safety, a brains trust of the Federal Office of Consumer Protection and Food Safety. In addition, he is member of two PDA's Task Forces, the "Mycoplasma Task Force" and the "Bioburden and Biofilm Task Force", and chairman of the advisory board of the ECA "Rapid Microbiological Methods Working Group".

Maitry Ganatra, Pall Life Sciences, USA
Maitry Ganatra is Director, Global Marketing with Pall Life Sciences and is responsible for managing the process monitoring product portfolio and directing global cross functional team on new products. She has more than 10 years of experience in healthcare and pharmaceuticals including scientific research, process validation, and business development for laboratory products. Prior to joining Pall, she led Microbiology Program at Claris Life Sciences. Dr Ganatra holds a Diploma in Pharmacy, Ph.D. in Microbiology and MBA from Long Island University. She has authored 14 scientific publications and is committee member of PDA Task force for Revision of Technical Report No. 13 on Environmental Monitoring.

Oliver Gordon, Novartis Pharma Stein AG, Switzerland
Since 2010, Oliver Gordon is working at Novartis Pharma AG in Switzerland in the QA/QC Microbiology department in the Launch Center for Rapid Microbiological Methods. He is also advisory board member of the ECA Working Group on Rapid Microbiological Methods.

Dr Marcel Goverde, MGP Consulting, Switzerland
Marcel Goverde has attended the University of Basel, where he majored in biology. After one year of working for the agro biological department of Novartis, he led a development project on sustainability and education in Costa Rica. After returning to Switzerland he earned his PhD in ecology at the University of Basel where he subsequently was employed as an academic tutor. 2002 to 2010 he was leading the quality control lab for non-sterile products as well as the lab for research & development of microbiological methods at F. Hoffmann-La Roche Ltd in Basel. Furthermore he is a member of the working party for Modern Microbiological Methods (MMM) from the European Directorate for the Quality of Medicines (EDQM).

Dr DI Franz Gruber, QC - Molecularbiological Control, Baxter AG, Vienna Austria
Franz Gruber studied biochemical technologies and food chemistry at the technical University Vienna. After his graduation at the TU Vienna and the Agricultural University Wageningen, he joined Baxter. He is responsible for the inhouse development PCR methods for implementation in QC.

Prof Dr Edwin R. van den Heuvel, Professor Medical Statistics, University Medical Center Groningen
In 1996 he started a professional career as consultant at the Institute for Business and Industrial Statistics (IBIS UvA). After several years he obtained also a part-time position as associate professor at the mathematics department of the University of Amsterdam. In 2002 he became departmental head of the statistical department of MSD (formerly Organon). He was offered a part-time position as professor in statistics for life sciences at the mathematics department of the University of Groningen in 2008 and he became a full professor in medical statistics at the same university in 2010. Over the years he has published (among others) several articles on statistical techniques for the evaluation and validation of different types of measurement methods. His research interest include (linear, generalized, and non-linear) mixed models and related techniques for medical and pharmaceutical applications.

Dr Pieta C. Ijzerman-Boon, Senior Statistician, MSD, The Netherlands
After her Ph.D. Ms Ijzermann-Boon joined MSD Oss (formerly Organon), where she started her career in the field of clinical statistics. In 2011 she moved to the non-clinical statistics group in the company, where she currently works as a senior statistician at the Center for Mathematical Sciences. She focuses (among others) on statistical methodology for biological and microbiological test methods.

Speakers cont'd

Dr David Jones, Rapid Micro Biosystems, USA
David studied at Brunel University and University of London. After positions at Anagen, Chemunex and Wyeth Biotech, he joined 2005 Rapid Micro Biosystems as Technical Director Services.

Judy Madden, Vice President Corporate Development, Celsis
Judy studied at the University of Western Ontario. During her career, she hold positions at Baxter and Advanced Bionics. 2044 she joined Celsis and her current position is Vice President Development.

Dr Michael Miller, , Microbiology Consultants, LLC, United States
For more than 22 years, Michael has held numerous R&D, manufacturing, quality, and consulting and business development leadership roles at Johnson & Johnson, Eli Lilly and Company, Bausch & Lomb, and Pharmaceutical Systems, Inc. In his current role, Dr. Miller consults with multinational companies in providing technical, quality and regulatory solutions for pharmaceutical manufacturing, contamination control, QC, barrier isolator technology and microbiological PAT. she is the Field Application Specialist of Rapid Micro Biosystems Inc. for Europe.

Jeanne Moldenhauer, Vice President Excellent Pharma Consulting, USA
Jeanne has over 25 years consulting in the pharmaceutical industry. She is the founder of the Rapid Micro User's Group in the United States. During her career, she has been a significant promoter of the use of rapid micro methods.

Dr David Myatt, Program Director, BioBall BTF - A bioMérieux Company, Sydney, Australia
David studied microbiology at the University Queensland and marketing and international business at the university of New England. After that , he worked in different positions at BD Biosciences and at BioCompass Asia. 2010 he joined BioMerieux as Marketing Manager BTF. Today he is Program Director BioBall.

Dr Emiliano Toso, Merck Serono Ivrea (Turin), Italy.
He is Associate Director and Head of the Molecular Biology group in the GMP Biological Quality Control. He has a PhD on Human Biology: molecular and cellular basis at Turin University. Since 2000 he has set up qPCR based assays to detect biological contaminants as well as genotypic characterization tests of recombinant cell lines. In 2011 he presented to FDA a qPCR based alternative method to detect Mycoplasma contamination in a Type C meeting. He is invited speaker, moderator and chair at several international conferences in Europe, Asia and USA.

Geert Verdonk, Senior Scientist Quality, MSD, Oss, The Netherlands
Mr Verdonk has been with MSD (formerly Organon Oss and Schering Plough) since 1996. For the past 5 years he managed the microbiological development group in Oss, the Netherlands. He is responsible for validation activities, development of new microbiological technologies (rapid microbiological methods) and troubleshooting microbiological contaminations in pharmaceutical production processes.

Dr Stephen Wicks, European Pharmacopoeia Dept., European Directorate for the Quality (EDQM)

Dr Erik Wilkens, QA Specialist, QA/QC BMS (Biological & Microbiological Services), Novartis Switzerland
Since early 2012 he has been working at Novartis Pharma Stein AG, Switzerland, in the QA/QC Microbiology department. In his function as a Specialist in the Rapid Microbiological Methods Team he is involved in evaluation and validation of Rapid Microbiological Methods and their implementation in routine use, including method transfer to interested sites within the Novartis Group.

Social Event

On 10 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.

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.

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As an ECA course or conference attendee, you will receive up to 20% discounted travel fares (according to availability). And as Lufthansa German Airlines offers a comprehensive global route network linking major cities around the world you will most likely be able to benefit from these special prices and conditions.
And this is how it works: Once you registered for a course or conference you will receive a link together with your registration confirmation. Opening that link will take you to the Mobility Partner Program website where you can enter a code in the "Access to Event Booking" area you will also receive. 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.
We look forward to welcoming at the conference – and we already wish you a pleasant flight!

*Please note: You may have to enable pop-ups on the Mobility Partner Program website – otherwise the booking platform window will not open.

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

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

Dates

RMM Conference
Tuesday, 10 December 2013, 09.30 – 18.00 h
(Registration and coffee 09.00 -09.30 h)
Wednesday, 11 December 2013, 08.30 – 16.00 h

Workshop Statistics for Validation of Microbiological Test Methods
Thursday, 12 December 2013, 08.30 – 17.00 h
(Registration and coffee 08.00 - 08.30 h)

Venue

Barceló Sants
Placa dels Paisos Catalans, s/n
Estació de Sants
08014 Barcelona, Spain
Phone +34 93 503 53 00
Fax +34 93 490 60 45

Fees

Conference only
ECA Members € 1,590.-*
APIC Members € 1,690.-*
Non-ECA Members € 1,790.-*
EU GMP Inspectorates € 895.-*
Includes conference documentation, dinner on the first day, lunch on both days and all refreshments.

Conference AND Workshop
ECA Members € 2,080.-*
APIC Members € 2,180.-*
Non-ECA Members € 2,280.-*
EU GMP Inspectorates € 1,140.-*
Includes conference documentation, dinner on the first day, lunch on all three days and all refreshments.

Workshop only
ECA Members € 790.-*
APIC Members € 840.-*
Non-ECA Members € 890.-*
EU GMP Inspectorates € 445.-*
Includes documentation, lunch and all refreshments.

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 to receive the specially negotiated rate for the duration of your stay. Reservation should be made directly with the hotel. Early reservation is recommended.

Conference Language

The official conference language will be English.

Organisation and Contact

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 (0) 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 (0) 62 21/84 44 43 or per e-mail at stuermer@concept-heidelberg.de.

*per delegate plus VAT. The conference fee is payable in advance after receipt of invoice. VAT is reclaimable

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☐ **Rapid Microbiological Methods Conference**
10-11 December 2013, Barcelona, Spain
☐ **Workshop "Statistics for Validation of Microbiological Test Methods"**
12 December 2013, Barcelona, Spain
☐ **RMM Conference AND Workshop**
10-12 December 2013, Bacelona, Spain

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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 %
- within 1 week prior to the conference 100 %.

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