



EUROPEAN COMPLIANCE  
ACADEMY

#### AUTHORITY SPEAKERS

**BRYAN S. RILEY**

FDA, USA

**THOMAS MONTAG**

Paul-Ehrlich-Institut, Federal  
Institute for Vaccines and  
Biomedicines

#### INDUSTRY SPEAKERS

**ERIC ABACHIN**

Sanofi Pasteur, France

**BJÖRN BRETH**

Greiner Bio One, Germany

**LOTHAR BOMBLIES**

L+S AG, Germany

**SVEN M. DEUTSCHMANN**

Roche, Germany

**LILIANA DOGARU**

Bayer Corporation, USA

**JÖRG DRESSLER**

PMT GmbH, Germany

**SYLVIE GUYOMARD**

ACM Pharma, France;  
Member of Group 1 of the  
European Pharmacopoeia

**ALAN HOFFMEISTER**

Charles River, UK

**BENGT LJUNGQVIST**

KTH, The Royal Institute of  
Technology, Sweden

**ANNA MILLS**

Celsis, Belgium

**GUNTER NEUER**

BD Diagnostics Europe,  
Germany

**BERIT REINMÜLLER**

KTH, The Royal Institute of  
Technology, Sweden

**SCOTT SUTTON**

The Microbiology Network  
Inc., USA

**MIEK VAN LOON**

Janssen Pharmaceutica,  
Belgium

**GEERT VERDONK**

Schering Plough,  
The Netherlands

**FRIEDRICH VON  
WINTZINGERODE**

Roche, Germany



■ With Representatives from  
European and US Authorities

# Rapid Microbiological Methods Conference

## Developments, Systems Implementation

8 - 9 December 2010, Budapest, Hungary

#### HIGHLIGHTS:

- US Regulatory View
- European Regulatory View
- Results of ECA's Survey to chapter 5.1.6
- Case by Case Risk Assessment
- MALDI TOF Implementation
- Case Studies: Industrial Experiences with RMM Implementation
- Mycoplasma Testing
- Bacterial Endotoxin Testing



## Invitation



Until today, traditional microbiological methods are used in most pharmaceutical QC laboratories. Rapid Microbiology Methods (RMMs) provide significant advantages for pharmaceutical companies to obtain data with higher accuracy and precision compared to traditional methods, testing may be more cost effective, and the use of RMM allow for coordinated process analytical technologies to be fully integrated within the manufacturing processes.

In the past decade, many research and development activities focused on the study and implementation of improved methods for isolation, early detection, characterization, and enumeration of microorganisms.

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 share 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:

- Regulatory View
- New Methods
- Implementation in Industry
- Laboratory Experiences

It is also the aim of this conference to support you with information about Mycoplasma testing, experiences in fields near to pharmaceutical microbiology 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 regulatory authorities and industry.

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

A handwritten signature in blue ink, which appears to read "S. Deutschmann". The signature is fluid and cursive.

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 RMMs as well as the experiences in validation and implementation of the new methods. Furthermore you will hear about the regulatory view in Europe and USA.

## Background

Microbial contaminations poses enormous risks to pharmaceuticals and their consumers. To minimize the safety risk, pharmaceutical and biopharmaceutical manufacturers take thousands of samples a year with following incubation, counting of colonies and identification of micro organisms. The traditional culture methods need a long processing time 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 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 RMMs.

Several new systems for real-time microbial identification of samples from environmental monitoring, sterility testing, for mycoplasma detection, bacterial endotoxin testing are available at the market or in validation. The regulatory authorities like FDA, EMA or MHRA assist the implementation of RMM, e.g. with documents like USP chapter <1223> or EP chapter 5.1.6.

## 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

**ECA's Survey to EP Chapter 5.1.6.**

- Structure of survey
- Applications of RMM
- Percentage of Approvals
- Comments to Chapter 5.1.6

**DR SVEN M DEUTSCHMANN, Roche**

**Rapid Microbiological Methods: Requirements, Validation, and Implementation – A Regulatory View**

- Process Analytical Technology and Rapid Microbiological Methods
- Validation of Rapid Microbiological Methods
- FDA Regulatory Submission Requirements for Rapid Microbiological Methods

**DR BRYAN S. RILEY, FDA**

**Rapid Methods: Ph. Eur. member and European user view**

- Philosophy of the EP chapter 5.1.6
- Direct methods versus growth based methods
- Sterility and microbial limit test applications
  - Validation purpose

**SYLVIE GUYOMARD, ACM Pharma, Member of the Group 1 and MMM Ph.Eur.**

**Short presentation: The Biovigilant System**

- Auto fluorescence for viable counting
- Representative molecules for detection
- Optical setup

**JÖRG DRESSLER, PMT GmbH**

**Comparison of Data required during Simultaneous Measurements by Standard OPC, STA-Sampler and IMD-A**

- Active sampling of airborne particles; general principles
- Evaluation of the efficiency with regard to sampling location
- Results from simultaneous sampling with different methods – Impaction and Instantaneous Microbiological Detection
- Discussion on the application of new rapid methods in Grade A and B (EU Guidelines to Good Manufacturing Practice)

**BERIT REINMÜLLER, BENGT LJUNGQVIST, both KTH, The Royal Institute of Technology, Sweden**

**Short Presentation: BACTEC FX/EpiCenter Systems**

- Principles of the procedure
- Choice of media
- Workflow
- Data management

**DR GUNTER NEUER, BD Diagnostics Europe**

**Implementation and Approval of BACTEC 9240 for In-process Sterility Test**

- Bactec 9240 and in-process sterility test at Bayer
- Validation Overview
- Further challenging the system for sterility release test

**LILIANA DOGARU, Bayer Health Care LLC**

**Short Presentation: PTS rapid Endotoxin System**

- Endosafe®-PTS and MCS development considerations
- Technical features of the Endosafe® Pre-calibrated cartridge based systems
- System applications

**ALAN HOFFMEISTER, Charles River**

**Implementation of the PTS Rapid Endotoxin Detection system in a Manufacturing Environment**

- Comparison of the Endosafe®-PTS with a conventional kinetic endotoxin detection system
- Endosafe®-PTS and Process Analytical Technologies (PAT) alignment
- Efficiencies associated with Endosafe®-PTS implementation

**GEERT VERDONK, Schering Plough**

## Programme (cont.)

### Case by Case Risk Assessment

- Background
- Key aspects of CCRA approach
- Application of CCRA approach
- Outlook

FRIEDRICH V. WINTZINGERODE, *Roche Diagnostics*

### Short Presentation: How an Adenylate Kinase based Bioluminescence Test can apply to Quality Control

- Overview of Celsis technology: The theory behind Bioluminescence
- ATP Bioluminescence vs AKuScreen™
- Overview of Applications: Bioburden, Microbial Limits Testing and Sterility Testing
- Introduction to a Validation Project for Sterility Testing Using Celsis AKuScreen™ Technology

ANNA MILLS, *Celsis*

### Experiences with Celsis System – RMM Development and Validation – A Case Study

- Replacement for traditional microbial limit test
- Method development and validation
- Techniques for optimisation

MIEK VAN LOON, *Janssen Pharmaceutica*

### Short Presentation: The Microarray Technology – Benefits for the pharmaceutical Industry

- Test principle and assay development
- Validation acc. current guidelines
- Advantages compared to other rapid methods
- Case studies and customer feedback

DR BJÖRN BRETH, *Greiner*

### Alternative Mycoplasma testing by NAT: Results of prevalidation study

- Evaluation of alternative Mycoplasma assay for Mycoplasma contamination detection on our vaccine matrices.
- Prevalidation study carried out 9 Mycoplasma strains
- Objective: to validate an alternative Mycoplasma by following regulatory requirements

ERIC ABACHIN, *Sanofi Pasteur, France*

### Rapid Microbiological Methods in the pharmaceutical Industry

- Is there a need?
- Can these needs be defined?
- Can the needs be met?
- Is there a place for rapid methods in the pharmaceutical industry?

DR SCOTT SUTTON, *Consultant*

### Operation of a MALDI-TOF Mass Spectrometer for Microbiological Identification in a GMP Environment

- Principle of the Method
- Validation/Qualification
- Pros and Cons

DR LOTHAR BOMBLIES, *L+S AG*

## Social Event



On 8 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.

## Speakers

### **ERIC ABACHIN, PhD, Analytical R&D Department, Sanofi Pasteur, France**

He obtained his PhD degree in Molecular and Cells Biology from the University of Rene Descartes Paris V. Currently he is working as analytical scientist in Sanofi Pasteur R&D department. His research is focused on developing and validation of molecular biology methods and bacteriology methods in order to control both commercialized vaccines and new vaccines.

### **DR BJÖRN BRETH, Greiner Bio-One GmbH, Germany**

Björn holds a Master degree in biology and a PhD in biotechnology working on pro- and eukaryotic fermentation processes and drug characterization. Since he joined Greiner Bio-One GmbH he is responsible for the development of bacterial, viral, and human identification systems for the biopharmaceutical industry.

### **DR LOTHAR BOMBLIES, L+S AG, Bad Bocklett, Germany**

Dr Lothar Bomblies obtained his degree in biology from Regensburg University. He prepared his thesis at the Max-Planck-Institut für Biochemie in Martinsried Germany. After a year as postdoctoral fellow at the Ludwig-Maximilians-Universität München he joined Labor L+S AG, a pharmaceutical contract laboratory as microbiologist in 1994. Since 2003 he was member of the board of directors. Since 2001 he is member of the Committee for Microbiology of the German Pharmacopoeia Commission.

### **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.

### **LILIANA DOGARU, Bayer Corporation, Berkeley, USA**

Liliana earned her Bachelor of Science in Romania, from University of Bucharest, Department of Biochemistry. She also has a Biotechnology Certificate from California State University, Hayward. She worked in research for the National Institute for Food Research in Bucharest. She is employed with Bayer Corporation, in Microbiology Department in Quality Control since 2002.

### **DIPL. PHYS. JÖRG DRESSLER, PMT GmbH, Germany**

Mr Jörg Dressler obtained his degree in laser physics from Düsseldorf University. In 1999 he joined PMT Partikel-Messtechnik GmbH, where he was in charge of managing the sales and marketing departments. Since 2003 Mr Dressler is member of PMT's board of directors, with responsibility for marketing, sales and service.

### **SYLVIE GUYOMARD, ACM Pharma, France; Member of Group 1 of the European Pharmacopoeia**

Dr. Sylvie Guyomard earned her Master in biological control and PhD in Microbiology from the University of Paris V (Paris, France). With over 20 years of experience in pharmaceutical microbiology labs (Sanofi Aventis, Biowittaker), where she developed rapid methods, she works from 2010 for ACM Pharma as Pharmacist and consultant. She also managed her own consultancy and training in Pharmaceutical microbiological control through ubioPharma. She is French member of Ph.Eur group 1 (Microbiology) and MMM (alternative methods in microbiology) working group.

### **ALAN HOFFMEISTER, Charles River, UK**

### **DR BENGT LJUNGQVIST, KTH, Building Service Engineering, Stockholm, Sweden**

Dr B. Ljungqvist received his Ph.D. in 1978 and is, since 1986, Professor of Safety Ventilation at Kungl Tekniska Högskolan, Stockholm. He is past Chairman of the Nordic Association of Contamination Control (R3-Nordic) and international contact person for R3-Nordic and since 2007 honorary member in R3-Nordic. He is also active in the ISO TC 209 standardization work.

### **ANNA MILLS, Technical Support Manager (European Regulatory Liaison), Celsis, Belgium**

Anna Mills joined Celsis in 2005 as Technical Support Manager for UK, Ireland and Southern Europe. She brings significant industry experience to her role from her previous positions, including Application Specialist at BD and Account Manager at Lab M. She has BSC (Hons) in Biological Sciences from the University of Plymouth and a postgraduate degree (MPhil) in Microbiology from Northampton University in the UK.

### **DR THOMAS MONTAG, Paul-Ehrlich-Institut, Federal Institute for Vaccines and Biomedicines**

Thomas Montag studied medicine at the Humboldt-University Berlin and has specialised in medicinal microbiology. After spending some years in research work at the Charité in Berlin he has been employed at the Paul-Ehrlich-Institut since 1990. At present Thomas Montag is heading the department of parasitology, diagnostics und microbial safety.

### **DR GUNTER NEUER, BD Diagnostics Europe, Germany**

Dr Neuer studied Biology in Heidelberg, finished with degree at the Institute for Molecular Genetics in 1990. PhD in Biology 1994. From 1994 - 1998 he was sales representative at Life Technologies, Difco and BD. Since 1999 he is Application Specialist at BD, responsible for Europe/EMA.

### **DR BERIT REINMÜLLER, KTH, Building Service Engineering, Stockholm, Sweden**

Dr B. Reinmüller received her Ph.D. in 2001. She has spent 30 years in the pharmaceutical manufacturing field specializing in the areas of contamination control, environmental monitoring, validation, and microbiological risk assessment. She is employed as Senior Researcher in Building Services Engineering at Kungl Tekniska Högskolan in Stockholm.

### **DR BRYAN S. RILEY, FDA, USA**

Dr Riley earned his Masters Degree (Texas Tech University) and his Ph.D. in Microbiology (University of North Texas). Prior to coming to FDA in 1998, he directed a specialty clinical diagnostic microbiology laboratory. Dr Riley is currently a Senior Review Microbiologist in the Office of Pharmaceutical Science in the Center for Drug Evaluation and Research at FDA. He is involved in numerous scientific and regulatory issues relating to product quality microbiology.

### **DR SCOTT SUTTON, The Microbiology Network Inc., USA**

Dr Sutton earned his Masters and PhD in Microbiology from the University of Rochester (NY, USA). With over 20 years of laboratory leadership experience in the microbiology arena of the pharmaceutical and personal products industries, he consults until 2009 through Vectech Pharmaceutical Consultants, Inc. Dr Sutton also operates an information source on the Internet, The Microbiology Network ([www.microbiol.org](http://www.microbiol.org)). Today Scott manages his own consultancy.

### **MIEK VAN LOON, Janssen Pharmaceutica, Belgium**

Miek Van Loon joined Janssen Pharmaceutica in 2002 in the QC Microbiology Department. For the past 5 years she has gained experience in R&D Microbiology where she is responsible for the microbiological method development and validation of new products.

### **GEERT VERDONK, Schering Plough Oss, The Netherlands**


Mr Verdonk has been with Schering Plough (formerly Organon Oss) since 1996. He worked for 15 years in the molecular biology research. 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.

### **FRIEDRICH VON WINTZINGERODE, Roche, Germany**

Friedrich studied biology with focus on Microbiology at Technical University Braunschweig. Degree at Institute of Microbiology, Charité, Berlin. Since 2001 employed at Roche Diagnostics as group leader Environmental monitoring and cleaning analytics and since 2005 head of microbiological IPC and analytics for release.

## 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.microbiology-  
conference.org

### Date

Wednesday, 8 December 2010, 09.30 to 17.45 h

(Registration and coffee 09.00 – 09.30 h)

Thursday, 9 December 2010, 08.30 – 16.00 h

### Venue

Hilton Budapest WestEnd

Váci út 1-3

1062 Budapest, Hungary

Tel +36 1 288 5500

Fax +36 1 288 5588

### Conference fees

ECA Members € 1,521.- per delegate plus VAT

APIC Members € 1,605.- 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 has reserved a limited number of rooms in the conference hotel. Reservations should be made directly with

the hotel. Please use the following link and make your reservation via POG (Personalised Online Group Page) where you also can modify/cancel your reservation until 23 November 2010 without any penalty. Early reservation is recommended: <http://www.hilton.com/ECA071210>

### 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

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### 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](mailto: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](mailto: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)

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### Rapid Microbiological Methods Conference

8 – 9 December 2010, Budapest, Hungary

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### 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 %.

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**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)!