

Up-to-date lecture:
Mycoplasma PCR gets FDA Approval
Dr Sven M. Deutschmann, Roche Diagnostics

Authority Speaker

DR RAJESH GUPTA
CBER, FDA, United States

Speakers from Research and Industry

DR MAURO ANGLANA
Merck Millipore, Italy

DR SVEN M. DEUTSCHMANN
Roche Diagnostics, Germany

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

BARBARA GERTEN
Merck Millipore, Germany

OLIVER GORDON
Novartis, Switzerland

DAVIDE GRIONI
RIGEL Life Sciences S.r.l.

PIETA C. IJZERMAN-BOON
MSD, The Netherlands

DR STEFFEN KOCH
CellTool GmbH, Germany

ANNA MILLS
Rapid Micro Biosystems, USA

ANNET VAN MERODE
Bactimm, The Netherlands

DR MICHAEL MILLER
Microbiological Consultants, USA

DR C. MOISL-EICHINGER
University of Regensburg, Germany

DR MICHA NÜBLING,
Paul-Ehrlich-Institut, Germany

PROF DR DR H.C. ROB A. SAMSON
Fungal Biodiversity Center, The Netherlands

DR EMILIANO TOSO
Merck Serono, Italy

DR GEERT VERDONK
MSD, The Netherlands

CLAUDIA WEVER
Apotheek Haagse Ziekenhuizen, The Netherlands

Optional Workshop "Statistics for Validation of Microbiological Test Methods" on 13 December 2012

Rapid Microbiological Methods Conference

11-12 December 2012, Munich, Germany

Workshop "Statistics for Validation of Microbiological Test Methods" on 13 December 2012, Munich, Germany

HIGHLIGHTS:

- CBER's Expectations for the Use of RMM
- RMM in Clinical Phases
- Raman Spectroscopy
- Fungi Identification
- Rapid Airsampling
- Mycoplasma Detection



EUROPEAN COMPLIANCE ACADEMY



Rapid Microbiological Methods Conference

11-12 December 2012, Munich, Germany

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 2012“, organised by the European Compliance Academy (ECA). ECA's RMM Working Group will again provide you the possibility to get familiar with the current development of Rapid Microbiological Methods.

Speakers from Authority as well as from industry and vendors will present new methods, new applications and their experiences on implementation and validation.

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

- Regulatory Expectations
- New developed Systems
- Different possibilities of application
- Fungi identification
- 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 Munich. 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. 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

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

Moderators

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

A Novel Bacterial Contamination in Cell Culture Production: *Leptospira licerasiae* - Case Study -

- Development of a *Leptospira licerasiae*-specific PCR
- Validation of the *Leptospira licerasiae*-specific PCR

Dr Sven M. Deutschmann, Roche Diagnostics

CBER's Expectations and Experience with RMM in Product Testing

- Role of RMM in testing of Biological Products
- CBER's Expectations for Equivalency with Compendial Methods
- Examples, Rapid Sterility Test with Rapid Milliflex, Genomics methods and other commercial RMM
- Examples, Rapid Mycoplasma Testing with Genomics based methods

Dr Rajesh Gupta, CBER

Update on WHO Project for Mollicutes NAT standardization.

- Worldwide collaborative study,
- inclusion of different NAT methods,
- relative amplification efficiency for different Mollicutes species,
- WHO International standard for Mollicutes NAT

Dr Claudius Michael Nübling, Paul-Ehrlich-Institut

Universal Strain Identifiers – a unique system of identifiers for Reference Strains

- Background of Universal Strain Identifiers
- New WDCM system for Reference Strains from different Culture Collections

Barbara Gerten, Merck Millipore

Short Presentation: Validation of a fluorescence based system for rapid microbiological enumeration: Milliflex Quantum

- RMM adoption and expectations
- Quantum procedure and key distinctive principles
- Validation Approach

Dr Mauro Anglana, Merck Millipore

Validation and implementation of a new rapid microbiological enumeration method

- Introduction to the hemodiafiltration and water treatment
- Importance of getting rapid microbiological test results
- Validation of alternative (rapid) enumeration methods according to the European Pharmacopeia
- Milliflex Quantum implementation: Validation plan

Claudia Wever, Laboratory for pharmaceutical microbiology, Apotheek Haagse Ziekenhuizen

Raman micro spectroscopy for detection of microorganisms

- Principle of Raman micro spectroscopy
- The Bioram System
- Photonic fingerprinting of biological specimen

Dr Steffen Koch, CellTool, Dr. Oliver Gordon, Novartis

Molecular strategies for the determination of abundance and physiological status of microbial cells and spores encapsulated in spacecraft polymers

- Planetary Protection and spacecraft polymers
- Physiological staining of spores
- Quantitative PCR in combination with propidium monoazide masking

Dr Christine Moissl-Eichinger, Institute for Microbiology, Regensburg University

Sterility testing of pharmaceuticals and biologics using rapid microbiological method BACTEC FX & validation

- Sterility testing
- The why of a rapid method for sterility testing
- Different rapid microbiological method
- Validation of the BACTEC FX method
- Practical approach Bactimm BV

Dr Annet Ede Jantje van Merode, Bactimm B.V.

Programme (cont.) Identification and detection of fungi – what are the modern methods bringing us?

- Why is identification of moulds so important
- What are the limitation of the identification methods
- What are the advantages and disadvantages of phenotypic versus molecular diagnosis of fungi

Prof Dr Dr h.c. Rob A. Samson, CBS-KNAW Fungal Biodiversity Centre

Short Presentation description and validation of a new application for the GD system

Anna Mills, Rapid Micro Biosystems

Mycoplasma PCR Detection: the biggest challenge of Molecular Biology QC

- Molecular Biology applications and vision in Pharma QC
- Mycoplasma alternative method overview
- Development and Validation checklist
- Health Authorities expectations

Dr Emiliano Toso, Merck Serono

Mycoplasma PCR gets FDA Approval

- Questions, Answers and Pitfalls

Dr Sven M. Deutschmann, Roche Diagnostics

Detection of Mycoplasma with qPCR: Statistical Considerations

- Limit of detection
- Recovery
- Ct Cut-off value
- Sensitivity and specificity
- Minimum culture time

Pieta C. IJzerman-Boon, MSD

Introduction to Azbil BioVigilant and Instantaneous Microbial Detection

- Scientific Principles,
- Testing and Applications

Davide Grioni, RIGEL Life Sciences S.r.l.

Real-Time Environmental Monitoring using Optical Spectroscopy Rapid Methods

- Benefits and support for QbD and PAT applications
- Review scientific principles and applications
- Support for Parametric release of aseptically-filled product
- Case studies in use in isolators and other controlled environments

Dr Michael Miller, Microbiological Consultants,

Workshop Statistics for Validation of Microbiological Test Methods

13 December 2012, Munich, Germany

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

Programme (cont.)

Sensitivity & Specificity

- False positive
- 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 Mauro Anglana, Regional Marketing, Europe, BioMonitoring, Merck Millipore

Graduated in Biology, he obtained his PhD degree in Applied Genetics at the University of Pavia, Italy. He has then conducted molecular research activity at the McMaster University, Hamilton, Canada, at the Pasteur Institute and at the Curie Institute in Paris, France and at the Department of Pharmacology of the University of Milan, Italy. In Merck Millipore he has worked as Validation Engineer and Technical Service representative and has been deeply involved in the support for the validation of systems and methods for classical and rapid microbiological monitoring. Since three years he is part of the team of Regional Marketing for all Europe. Within this role, among other activities he is also giving trainings in all Europe on Bioburden and Sterility testing.

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 "Pyrogentests" 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".

Barbara Gerten, Merck Millipore, Darmstadt, Germany

After her studies in microbiology and biochemistry, Barbara Gerten was employed in different companies responsible for QC and R+D. In 2008 she joined Merck KGaA and is now head of the laboratory Raw Materials and Regulations at Merck Millipore Biomonitoring R+D. She is a member in several national and international bodies of microbiological food and water testing in ISO and CEN.

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.

Davide Grioni, RIGEL Life Sciences S.r.l.

Rajesh K. Gupta, Ph.D. Deputy Division Director, CBER, FDA

Dr. Gupta has a Ph.D. in Microbiology and currently he is Deputy Director and Lab Chief in the Division of Biological Standards and Quality Control, Office of Compliance and Biologics Quality, CBER, FDA. He is responsible for lot release of biological products, regulatory reviews of applications and supplements and generation of standards and reagents used in the manufacture and testing of biological products. Dr Gupta has more than 30 years experience in the development, production, testing and regulation of biological products, working both in the public and private sectors.

Prof Dr Edwin R. van den Heuvel, University Medical Center Groningen, The Netherlands

Edwin received his M.Sc. degree in mathematics and his Ph.D. in statistics from the University of Amsterdam. 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.

Pieta C. IJzerman-Boon, Senior Statistician, MSD, The Netherlands

She received her education at the University of Twente, the Netherlands. In 1995 she obtained her M.Sc. degree in Applied Mathematics, followed by a Ph.D. in Statistics in 1999. After her Ph.D. she 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.

Dr Steffen Koch, Application Specialist, CellTool GmbH, Tutzing, Germany

Steffen Koch studied biology at University Bonn and graduated at the University of Stuttgart, Institute of Interfacial Engineering, c/o Fraunhofer-Institute of Interfacial Engineering and Biotechnology (IGB). From 2010 – 2011 he was employed as Scientific associate at IGB. 2011 he joined CellTool GmbH as Raman application specialist.

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.

Anna Mills, Application Specialist, Rapid Micro Biosystems, USA,

Anna has BSc (Hons) in Biological Sciences from the University of Plymouth and a postgraduate 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..

Dr Christine Moissl-Eichinger, Institute for Microbiology, Regensburg University, Germany

Christine Moissl-Eichinger is a specialist in the field of general microbiology and microbial ecology with focus on Archaea and extremophilic Bacteria, and their interactions with biotic and abiotic environments. Main focus: Planetary protection and the analysis of spacecraft-associated environments with respect to their microbial diversity and presence of multi-resistant, extremophilic microorganisms that could possibly survive a spaceflight and even on other planets; Analysis of cold-water ecosystems and their microbial diversity, with main focus on Archaea

Priv.-Doz. Dr. Claudius Micha Nübling, Paul-Ehrlich-Institut, 63225 Langen (Germany)

Dr Nübling has been with the Paul-Ehrlich-Institut since 1990 – the German Federal Institute for Vaccines and Biomedicines in Langen. Since 1996, he is Deputy Head of Virology Division. He is a Member of different committees like the Biological Reference Preparations (BRP) Program of the European Pharmacopoeia, the OMCL Proficiency Testing Program of the EDQM, the WHO Working Group on Hepatitis and HIV Diagnostic Kits, and the EU Working Group on Common Technical Specifications (CTS) for in vitro diagnostic (IVD) medical devices

Prof Dr h.c. Rob A. Samson, Head of Applied and Industrial Mycology, CBS-KNAW FUNGAL BIODIVERSITY CENTRE

Rob Samson studied Biology at the University of Utrecht. From January 1970 he was appointed as junior scientist at the CBS Fungal Biodiversity Centre in Utrecht. After postdoctoral studies at the universities of Austin, Gainesville and Bloomington, he returned to CBS and became 1983 the head of applied research. Currently he is head of the Department applied and Industrial Mycology

Emiliano Toso, PhD, Merck Serono Ivrea (Turin), Italy

He is head of the Molecular Biology group in the GMP Biological Quality Control department. He has a PhD on Human Biology: molecular and cellular basis at Turin University. Since 2000 he has set up and validated PCR and qPCR detection of viruses, retroviruses and mycoplasma in cell banks and bulk harvests, as well as genotypic characterization tests of recombinant cell lines, microbial identification with genotypic methods, residual DNA detection by qPCR, and human cell line DNA profiling.

Dr 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.

Claudia M. Wever, Senior Analyst, Apotheek Haagse Ziekenhuizen

Over thirteen years of in depth experience in quality control of pharmaceuticals. Responsible for development, validation, implementation and process improvement of testing methods and procedures -both analytical as well as microbiological- at a renowned laboratory. Teacher and trainer in executing pharmaceutical microbiological tests and procedures.

Social Event



On 11 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.



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

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.



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

11 December 2012, 09.30 – 18.00 h
(Registration and coffee 09.00 -09.30 h)
12 December 2012, 08.30 – 16.00 h

Workshop Statistics for Validation of Microbiological Test Methods

13 December 2012, 08.30 – 17.00 h
(Registration and coffee 08.00 -08.30 h)

Venue

Holiday Inn Munich -City Centre
Hochstraße 3
81669 Munich, Germany
Phone +49 (0)89 - 4803 0
Fax +49 (0)89 - 448 7170

Fees

Conference only

ECA Members € 1,590.-*
APIC Members € 1,690.-* (does not include ECA Membership)
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.-* (does not include ECA Membership)
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.-* (does not include ECA Membership)
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 or be sure to mention "E34" to receive the specially negotiated rate (single room € 159,- incl. breakfast) for the duration of your stay. Reservation should be made

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

directly with the hotel not later than 12 November 2012. Early reservation is recommended.

Conference Language

The official conference language will be English.

Organisation and Contact

CONCEPT HEIDELBERG
P.O. Box 10 17 64
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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.

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Germany

Reservation Form (Please complete in full)

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- Rapid Microbiological Methods Conference**
11-12 December 2012, Munich, Germany
- Workshop "Statistics for Validation of Microbiological Test Methods"**
13 December 2012, Munich, Germany

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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 %
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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)!