

**SPEAKERS MYCOPLASMA
TESTING CONFERENCE**

DR DMITRIY VOLOKHOV
FDA, USA (invited)

DR SVEN M. DEUTSCHMANN
Roche Diagnostics, Germany

DR PIETA C. IJZERMAN-BOON
MSD, The Netherlands

DR HOLGER KÜHN
BioChem, Germany

DR DIETMAR MAYER
IDT Biologika, Germany

PROF RENATE ROSENGARTEN
*Mycoplasma Biosafety Services,
Austria*

HENRIK SALLING
Novo Nordisk, Denmark

SPEAKERS RMM CONFERENCE

JAN-OLIVER KARO
*PEI – German Federal Institute for
Vaccines and Biomedicines*

DR ERIKA PFEILER
FDA, USA

DR ANDREW BARTKO
Battelle Institute, USA

DR ARNAUD CARLOTTI
IDmyk, France

DR SVEN M. DEUTSCHMANN
Roche Diagnostics, Germany

JÖRG DRESSLER
PMT, Germany

DR WOLFGANG EDER
Roche Diagnostics, Germany

PROF EDWIN VAN DEN HEUVEL
*Eindhoven University of
Technology, The Netherlands*

KERSTIN KLEINSCHMIDT
Novartis, Switzerland

KEVIN LUONGO
Shire, USA

LEN VAN LIN
MSD, The Netherlands

ROCCO PETRIZZO
TSI GmbH, Germany

DR BENOIT RAMOND
Sanofi, France

DR DAVID ROESTI
Novartis

DR ALEXANDRA SCHOLZ
*Sartorius Stedim Biotech,
Germany*

DR MELANIE STÖRMER
University of Cologne, Germany

DR EMILIANO TOSO
Merck Serono, Italy

Two European Conferences:

Mycoplasma Testing & Rapid Microbiological Methods

9 and 10/11 December 2014,
Heidelberg, Germany





Dear Colleagues,

With the programme at hand I would like to invite you to the „Rapid Microbiological Methods Conference” and the “European Mycoplasma Testing Conference 2014” organised by the European Compliance Academy (ECA). ECA's RMM Working Group will provide you again a possibility to get familiar with the current development of Mycoplasma Testing and of Rapid Microbiological Methods.

This two conferences should give the possibility to become acquainted with ongoing regulatory requirements, the development of microbiological methods in quality and process control.

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

- Regulatory Expectations
- Newly developed Systems
- Global Implementation
- Routine use
- Pros, Cons and possible Pitfalls

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 a 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 Heidelberg. It promises to be an outstanding experience.

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

Mycoplasma Testing Conference

9 December 2014, Heidelberg, Germany

Objectives

This conference will review the current knowledge about mycoplasma detection strategies for quality control in biopharmaceutical manufacturing.

This one-day meeting provides the opportunity to discuss the recent advances in the area of the newest technological developments for mycoplasma detection and control, as well as practical aspects and concerns of meeting the regulatory requirements. State-of-the-art presentations from authority speakers, as well as industrial and academic experts in the field of Mycoplasma with particular focus on the current methodologies of mycoplasma detection, their implementation and validation will provide an in-depth overview.

Background

The scientific progress in the field of cellular and molecular biotechnology led to a fast development of biopharmaceuticals, tissue engineered applications and advanced therapy medicinal products (ATMPs). Against this background, the safety of such new technologies, products and applications becomes more importance. One important topic in the focus of risk assessment and safety is the contamination with mycoplasmas and its detection, prevention and control.

Target Audience

This conference is of interest to professionals from

- Biotechnological & Biopharmaceutical Companies
- Contract Service Laboratories
- Academic Research Institutions and Organizations
- Government Agencies
- Cell Culture Collections
- Supplier Detection Systems

with responsibilities in Manufacturing, Quality Assurance, Quality Control, Regulatory Affairs Research & Development, Process Development, Validation.

Mycoplasma Testing Conference

9 December 2014, Heidelberg, Germany

Programme

Recent Advances and New Developments in Mycoplasma Control of Biologicals, Biopharmaceuticals and ATMPs

- PCR-based assays for mycoplasma detection: recent achievements, current trends and existing concerns
- Current knowledge on cell culture-adapted highly fastidious cultivar strains and their detection
- "Universal" mycoplasma culture media for rapid mycoplasma enrichment prior to PCR-based analysis
- Pros and cons of rapid mycoplasma testing by combined culture and PCR hybrid approaches

Renate Rosengarten, Mycoplasma Biosafety Services,

Cultivable and "Non-Cultivable" Cell Culture-adapted Mycoplasmas

Dr Dmitry Volokhov, FDA (invited)

NAT for Mycoplasma Detection in Release Testing according to Ph. Eur.

- Method Validation of in House Method
- Real-Time vs Classical PCR approach
- Pitfalls in Contract Testing

Holger Kühn, BioChem

A Newly Developed Real-Time PCR-based Test System for Mycoplasma Detection

Dietmar Mayer, IDT Biologika

Strategy for Designing a Multi-Primer Mycoplasma qPCR Assay for Release Testing

- Choosing PCR target and designing primers
- Bioinformatic tools
- Designing controls
- Assay performance

Henrik Salling, Novo Nordisk

Validation approach for a rapid Mycoplasma qPCR detection method using statistical methods

Dr Pieta C. IJzerman-Boon, MSD, The Netherlands

Validation of a Fully-Automated PCR-Based Mycoplasma Detection Method"

- Introduction
- Method Validation
- Comparability Study

Dr Sven M. Deutschmann, Roche Diagnostics

Moderators

Prof. Renate Rosengarten, Mycoplasma Biosafety Services

Axel H. Schroeder, Concept Heidelberg

Rapid Microbiological Methods Conference

10-11 December 2014, Heidelberg, Germany

Objectives

This two day conference offers 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

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

Programme

Rapid Microbiological Methods in Pharmaceutical Manufacturing – Perspectives from the FDA

- FDA's policy on the use of rapid microbiological testing methods
- Suggested approaches to validating your rapid microbiological testing method
- Regulatory pathways to approval of rapid microbiological testing methods
- Case studies from FDA review of rapid microbiological testing methods

Dr Erika Pfeiler, FDA

Microbial Safety of Advanced Therapy Medicinal Products – The Impact of Rapid Methods

- Regulatory framework for ATMPs
- Microbiological challenges and characteristics of ATMPs
- The role of rapid microbiological methods: What do we need for ATMPs?
- Case studies from the microbiological assessment of ATMP applications

Jan-Oliver Karo, Paul Ehrlich Institut

Qualitative Detection of Microbial Contamination in cell-therapeutic processes based on real-time PCR

- Need of RMMs for microbiological quality control of cell-therapeutic processes
- Real-time PCR as a possible alternative
- Detection of low-level contamination possible
- Validation concept designed

Kerstin Kleinschmidt, Novartis

ROADMAP to PCR-Based Adventitious Agents Testing

- Problem Statement "Current Cell-Based or Culture-Based Methods"
- Intended Replacements
- Long Range Implementation Plan

Sven M. Deutschmann, Roche

Rapid Microbiological Methods Conference

10-11 December 2014, Heidelberg, Germany

Programme, cont'd

Validation of Milliflex Quantum for bioburden analysis and global implementation strategy

Len van Lin, MSD and Edwin van den Heuvel, Eindhoven University of Technology

dblast for rRNA Gene Sequence Analysis

- Identification concept of microorganisms at Roche
- New dblast database for identification of bacteria and fungi
- Validation of the dblast database

Dr Wolfgang Eder, Roche

Identification of Single Bacteria by Micro-Raman Spectroscopy"

- Technical background - Raman Spectroscopy
- Raman Spectroscopy in the micrometer scale
- Identification of particles in the micrometer scale
- Identification of bacteria, the spectroscopic concept
- Technical setup for a Raman spectrometer focussing on the needs of the pharmaceutical industry
- Discussion of field data

Dr Andrew Bartko, Battelle Institute Columbus and Joerg Dressler, PMT GmbH

NGS preliminary data on Biosafety Quality Control

- Application Strategy
- Sensitivity and Specificity checks
- Future perspectives

Emiliano Toso, Merck Serono

Rapid identification of environmental bacteria by MALDI-TOF Mass Spectrometry

- 302 isolates representing 50 genera and 138 species found most frequently in routine in pharmaceutical environments were analyzed on the VITEK MS Plus system.
- Identifications obtained were compared in each case to almost full gene16S rRNA gene sequencing data and for some cases to multilocus comparative sequencing data.
- All results include isolates in concordance with the reference identification (Genus+species), presence or absence of the target species in the closed database, and the intra-species variability.

Dr Arnaud Carlotti, Eurofins IDmyk, France

Short Presentation: BioTrak Applications

The Evolution to Acceptance in the Pharmaceutical Manufacturing Environment

Rocco Petrizzo, M.Sc, TSI

Biotrak – Evaluation of a Real Time System

- Biotrak a laser induced fluorescence system (LIF) capable to detect viable particles
- What about the discrimination between viable & non-viable particles?
- What is the scope of applications in the environmental monitoring?
- Real time monitoring dream or reality?
- Supportive data on the potential of Biotrak in Grades A, B, C and D from feasibility studies made within Sanofi.

Benoit Ramond, Sanofi Aventis

An Initial Evaluation of a Novel Rapid Micro Detection System

- Assessment of Quantitative Specificity and Limit of Detection
- Assessment of Qualitative Limit of Detection
- Operational Observations (Ease of Use)
- Potential Applications in the Biopharmaceutical Industry

Kevin Luongo, Shire, USA

Efficient Mycoplasma and Leptospira concentration techniques for increasing Real-time PCR sensitivity in large sample volumes

- Standard NAT methods process relatively low sample volumes which results in a lack in sensitivity
- Devices and methods are presented for concentrating up to 70 mL of liquid samples prior PCR testing
- Even low cell concentrations in large volumes can be detected
- Data of samples with and without pre-concentration step are compared showing the efficiency of this method

Dr Alexandra Scholz, Sartorius

Rapid Methods for the Microbial Safety of Blood Products - Requirements, Development and Installation in the Blood Centers Routine Setting

- Overview of current rapid methods for microbiological control of cellular products (pros and cons)
- Authorities requirements
- Development of rapid methods and validation
- Challenges for the routine setting

Dr Melanie Störmer, University of Cologne

Detection of Microbial Growth in Vials with a Gas Headspace Analyzer

- Oxygen and Carbon Dioxide measurements
- Large variety of stressed microorganisms tested
- What happens with damaged vials?
- Is the method advantageous in terms of time to results?

Dr David Roesti, Novartis

Speakers of both Conferences

Dr Andrew Bartko, Battelle Memorial Institute, USA

Dr Andrew P. Bartko received a B.S. from the University of Pittsburgh and a Ph.D. in physical chemistry. He is a senior scientist in Battelle's Technology Development Group, the manager and technical leader of an interdisciplinary team that is developing Battelle's Resource Effective Bioidentification System (REBS).

Benoit Ramond, Sanofi, France

Benoit Ramond is Doctor in Pharmacy at the University of Paris XI in France and obtains a PhD in Microbiology. He has 25 years of experiences in the Pharmaceutical Industry. Since 2004 he is microbiology expert in Sanofi group. In his function he has also a leading role in the RMM strategy development within Sanofi group.

Dr Arnaud Carlotti, Eurofins IDmyk, France

Arnaud Carlotti completed his PhD at the University of Lyon, France, with a speciality in Microbiology. In 2000, he established the IDmyk service company. Arnaud Carlotti is president of the Eurofins IDmyk company, a competence center for detection, identification and typing of micro-organisms in pharma industries.

Jan-Oliver Karo, Paul-Ehrlich-Institut, German Federal Institute for Vaccines and Biomedicines

Oliver studied biology at the Technical University in Darmstadt with focus on microbiology. Since 2009 he is at the Paul-Ehrlich-Institut, in the Division Microbial Safety. He is quality assessor and national expert advisor for the microbial safety of advanced therapy medicinal products (ATMPs) and member of the "Cell Therapy Products" Working Party of the German Pharmacopoeia Commission.

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 several national and international Pharmacopoeial Expert Groups and chairman of the advisory board of the ECA "Rapid Microbiological Methods Working Group".

Jörg Dressler, PMT GmbH, Germany

Joerg Dressler studied physics at the University Düsseldorf. 1999 he joined PMT - Particle Measuring Technique where he became head of sales and marketing. Since 2003, he is a member of the company management and responsible for all activities in sales, marketing and service.

Dr Wolfgang Eder, Roche Diagnostics, Germany

Wolfgang studied and graduated in microbiology at the University Regensburg. After working at Diversa Corporation in USA, profos AG and University Regensburg, Germany, he joined 2006 Roche. Currently he is group leader QC EM and Cleaning at Roche Diagnostics, Penzberg, Germany.

Prof Dr Edwin R. van den Heuvel, Professor of Statistics at the mathematics department of the Eindhoven University of Technology

Edwin received his M.Sc. degree in mathematics and his Ph.D. in statistics from the University of Amsterdam. In 2002 he became departmental head of the statistical department of MSD (formerly Organon). He became a full professor in medical statistics at the University of Groningen in 2010 and from October 1, 2014, he will be Professor of Statistics at the mathematics department of the Eindhoven University of Technology (TU/e).

Dr Pieta C. IJzerman-Boon, MSD, The Netherlands

Pieta C. IJzerman-Boon 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. She joined MSD after her PhD. 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.

Dr Dietmar Mayer, IDT, Germany

He studied at Institute of Genetics, Department of Virology in Stuttgart-Hohenheim. He then worked as group leader at FEP and BioTeSys GmbH. Since 2005 he is Head of Molecular Biology Quality Control at IDT Biologika GmbH. Responsible for the development of product specific methods as release tests.

Speakers of both Conferences

Dr Holger Kühn, BioChem GmbH, Germany

Holger studied Biology at the Universities of Heidelberg and Glasgow. He graduated in Regensburg. 2008-2011 he worked at SGS Institute Fresenius as Project Manager. Since 2011 he is Head of Laboratory Microbiology and Molecular Biology at BioChem GmbH in Karlsruhe.

Dr Kerstin Kleinschmidt, Novartis Pharma Stein, Switzerland

Kerstin holds a Master's degree in Biotechnology from the Beuth Hochschule für Technik, Berlin (Germany). Currently, Kerstin is working as a PhD Student in the RMM team of Dr David Roesti at Novartis Pharma Stein AG, Switzerland.

Kevin Luongo, Shire, USA

Kevin Luongo has over 10 years of experience in the biopharmaceutical industry. He has a broad range of experience in the evaluation and implementation of new technologies into biopharmaceutical operations. He currently works for Shire as a Scientist based in Lexington, Massachusetts and has previously worked for both Pfizer and Wyeth.

Len van Lin, MSD, The Netherlands

Rocco Petrizzo, M.Sc., TSI GmbH, Germany

Rocco studied at the Universities of Modena, Catania and Barcelona. After working at Aldeasa he joined 2007 GE Healthcare as technical Support Specialist. Currently he is EMEA Contamination Control Application Specialist.

Dr Erika Pfeiler, FDA, United States

Erika has worked with FDA's Center for Drug Evaluation and Research for 3 years, and has review experience with rapid microbiological methods. Erika holds a Ph.D. from North Carolina State University and a B.S. in Agriculture from the University of Tennessee.

Dr David Roesti, Novartis Pharma Stein AG, Switzerland

David holds a PhD in microbial ecology from the University of Neuchâtel, Switzerland. Currently, David is leading the RMM team and the Novartis Pharma expert network in microbiology at Novartis Pharma AG in Stein Switzerland. Prior to this assignment, David was the laboratory supervisor for the microbiological testing of non-sterile drug products at Novartis Pharma Stein AG.

Prof Renate Rosengarten, DVM, PhD, University of Veterinary Medicine Vienna | CSO, COO - Mycoplasma Biosafety Services, Austria

Renate Rosengarten's academic career is for more than 35 years marked by a continuous interest in the infection biology of mycoplasmas. Since 1996 Renate Rosengarten is Professor of Bacteriology and Hygiene at the University of Veterinary Medicine Vienna in Austria. She was Founder and Managing

Director of the former Mycosafe Diagnostics GmbH, and is currently CSO and COO of the newly established biosafety company Mycoplasma Biosafety Services GmbH.

Dr Alexandra Scholz, Sartorius Stedim Biotech GmbH, Germany

Alexandra holds a Masters degree in Biotechnology from the Technical University of Braunschweig (Germany) and a PhD in Live Science from the University of Hannover (Germany). She did her PhD in cooperation with Sartorius Stedim Biotech where she started working as scientist in the department of R&D Microbiology in February 2014.

Henrik Salling, Novo Nordisk, Denmark

Graduated in 2010 from University of Copenhagen. Employed by "Statens Serum Institut" as a molecular biologist to design qPCR assays for detection of residual host cell DNA. Employed as a development scientist by Novo Nordisk A/S to design qPCR assays for detection of viruses and mycoplasma.

Dr Melanie Stoermer, University Hospital of Cologne, Germany

After studying at the University of Applied Sciences Lippe and Hoexter, Lemgo and at the University of Bielefeld, she worked at the Institute of Laboratory and Transfusion Medicine at the Heart and Diabetes Center North Rhine-Westphalia in Bad Oeynhausen, Germany. After her doctoral thesis she was employed at the Paul-Ehrlich-Institut, Federal Institute for Vaccines and Biomedicines, in the Division Microbial Safety. Since April 2011 she is working at the Institute for Transfusion Medicine at the University Hospital of Cologne and is responsible for the scientific work dealing with quality of blood products and stem cells.

Dr Emiliano Toso, Merck Serono Ivrea, 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.

Dmitriy V. Volokhov, D.V.M., Ph.D., DACVM. (invited)

Research Microbiologist, US Food and Drug Administration, Center for Biologics Evaluation and Research, USA

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.



Historic city center - Holy Ghost Church and Christmas Market

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

Mycoplasma Testing Conference

Tuesday 09 December 2014, 09.00 – 17.30
(Registration and coffee 08.30 - 09.00 h)

Rapid Microbiological Testing Conference

Wednesday, 10 December 2014, 09.00 – 18.00 h
(Registration and coffee 08.30 - 09.00 h)
Thursday, 11 December 2014, 08.30 - 16.30 h

Venue



Heidelberg Marriott Hotel
Vangerowstraße 16
69115 Heidelberg,
Germany
Phone +49 (0) 6221 908 0
Fax +49 (0) 6221 908 660

Heidelberg – Optimal Accessibility via Frankfurt

Airport Shuttle Service PCS
<http://www.pcs-hd.de/>
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TLS Airport Shuttle Service Heidelberg
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Lufthansa Bus Airport Shuttle
<http://www.transcontinental-group.com/en/frankfurt-airport-shuttles>
Tel. +49 (0)6152 – 97 69 099,
info@frankfurt-airport-shuttles.de

Train: You can get on the train directly at the airport. Trains leave up to two times per hour and it takes less than one hour to get to Heidelberg.
www.bahn.de

Fees (per delegate plus VAT. VAT is reclaimable)

European Mycoplasma Testing Conference

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

Rapid Microbiological Methods Conference

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.

European Mycoplasma Testing Conference & Rapid Microbiological Methods Conference

ECA Members € 2,080
APIC Members € 2,180
Non-ECA Members € 2,280
EU GMP Inspectorates € 1,140
Includes conference documentation, dinner on the second day, lunch on all three days 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

ECA has entrusted Concept Heidelberg with the organisation of this event.

CONCEPT HEIDELBERG
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69007 Heidelberg, Germany
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For questions regarding content:

Mr 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.:

Ms Jessica Stürmer (Organisation Manager) at
+49 (0) 62 21/84 44 43 or per e-mail at
stuermer@concept-heidelberg.de.

If the bill-to-address deviates from the specification to the right, please fill out here:

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

69007 Heidelberg
Germany

Reservation Form (Please complete in full)

+49 6221 84 44 34

- ☐ Mycoplasma Testing Conference
9 December 2014, Heidelberg, Germany
- ☐ Rapid Microbiological Methods Conference
10-11 December 2014, Heidelberg, Germany
- ☐ Both Conferences
9-11 December 2014, Heidelberg, Germany

☐ Mr ☐ Ms

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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 week prior to the conference 50 %
■ within 1 week prior to the conference 100 %.
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Terms of payment: Payable without deductions within 10 days after receipt of invoice.
Important: This is a binding registration and above fees are due in case of cancellation or non-appearance. If you cannot take part, you have to inform us in writing.

The cancellation fee will then be calculated according to the point of time at which we receive your message.
In case you do not appear at the event without having informed us, you will have to pay the full registration fee, even if you have not made the payment yet. Only after we have received your payment, you are entitled to participate in the conference (receipt of payment will not be confirmed)! (As of January 2012).
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