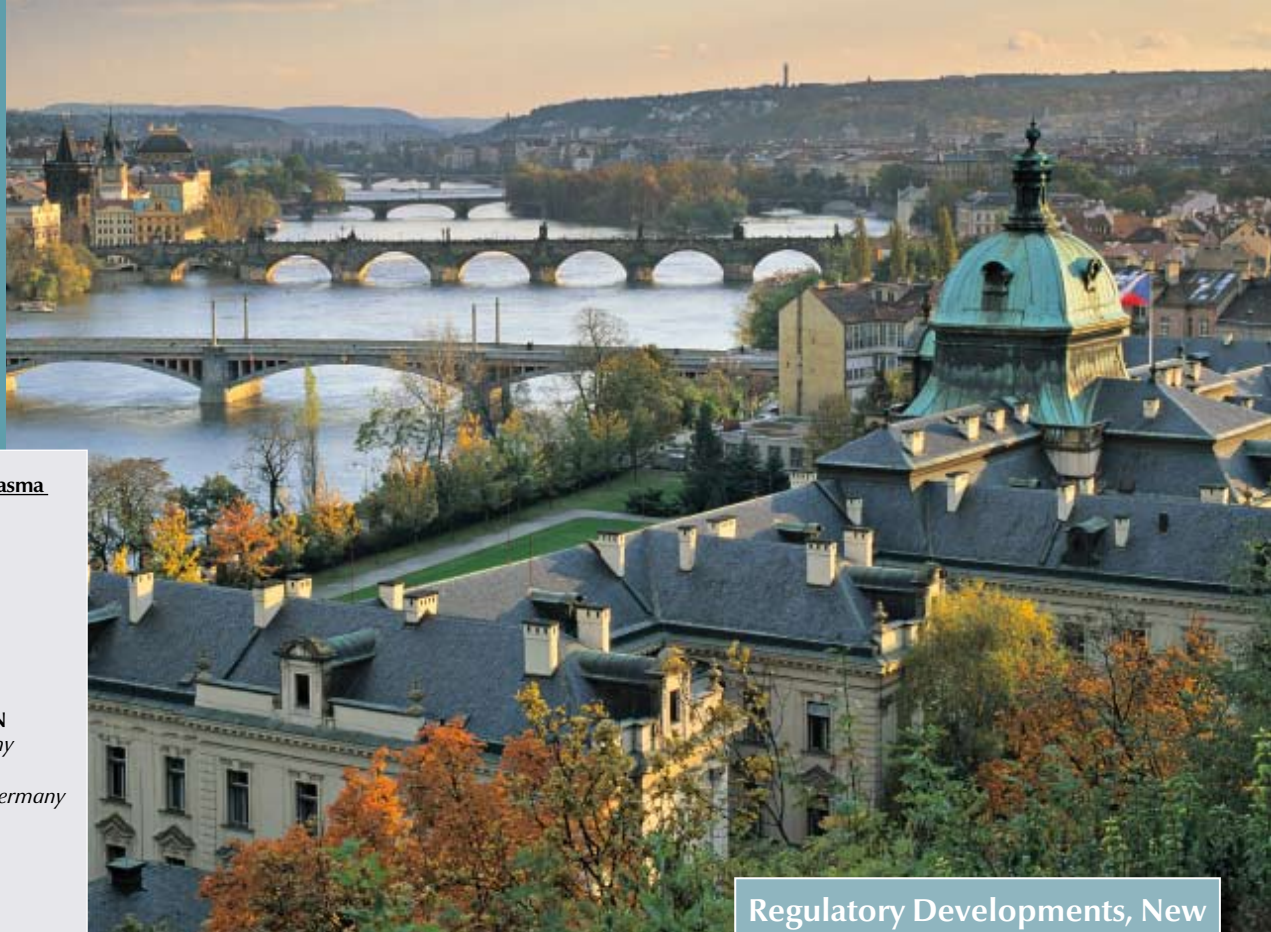




EUROPEAN COMPLIANCE
ACADEMY



Speakers European Mycoplasma

Testing Conference:

CHRISTINE ARBESSER

Baxter, Austria

VLADIMIR CHIZHIKOV

FDA, USA

MICHAEL BREWER

Life Technologies, USA

SVEN M. DEUTSCHMANN

Roche Diagnostics, Germany

GERHARD HAAKE

Sartorius Stedim Biotech, Germany

THOMAS MEINDL

L+S AG, Germany

RENATE ROSENGARTEN

Mycosafe, Austria

SÉVERINE TASKER

University of Bristol, United Kingdom

Regulatory Developments, New
Methods, Practical Experiences

Two European Conferences

Mycoplasma Testing and Microbiology

Speakers European Microbiology

Conference:

GERO BECKMANN

Institute Romeis, Germany

SVEN M. DEUTSCHMANN

Roche Diagnostics, Germany

STEPHEN FORSYTHE

*Nottingham Trent University,
United Kingdom*

BARBARA GERTEN

Merck, Germany

BODO HOLTkamp

Biotech, Germany

BETTINA LAUER

Vetter Pharmaceuticals, Germany

THOMAS MEINDL

L+S AG, Germany

SEBASTIEN RIBAUT

Milipore, France

TIM SANDLE

BPL, United Kingdom

DONALD SINGER

GlaxoSmithKline, USA

FRIEDRICH VON RHEINBABEN

Ecolab, Germany

BJÖRN WIESE

Cilag, Switzerland

**FRIEDRICH
VON WINTZINGERODE**

Roche Diagnostics, Germany

3 May 2011, Prague, Czech Rep.

European Mycoplasma Testing Conference

HIGHLIGHTS:

- Mycoplasma Testing of Biologicals – The Current US Regulatory View, Trends and Concerns
- WHO Standard
- Pros and Cons of different Tests
- Evaluation /Validation of a Mycoplasma Test
- How do we diagnose Haemoplasma Infections?

4–5 May 2011, Prague, Czech Rep.

European Microbiology Conference

HIGHLIGHTS:

- Current Changes in European and US Regulatory
- Development of Microbiological Methods
- Challenges in Daily Laboratory and Manufacturing Business

Book both conferences and save up to € 400,-!



These conferences are recognised for the ECA GMP Certification Programme „Certified Microbiological Laboratory Manager“. Please find details at www.gmp-certification.eu

**Invitation to the
European Microbiology
Conference 2011 in
Combination with the
European Mycoplasma
Testing Conference**



Dear Colleague,

I would like to invite you to the European Microbiology Conference and Mycoplasma Testing Conference 2011 organised by the European Compliance Academy (ECA).

In 2008, ECA organised the First Microbiology Conference and the First Mycoplasma Testing Conference in Berlin, Germany. Attendants, Speakers and Exhibitors gave a very good response to these events. Until today, these conferences have become regular events and 2011 ECA offers the unique possibility to participate both in combination.

The pharmaceutical microbiologist plays a key role in all aspects of development, manufacture and control of medicinal products, and their components. Therefore, the conference is intended to provide microbiological updates and "real life" experiences to support their activities.

These conferences will focus on aspects of:

- Regulatory Activities in Europe and US
- Current new developments in equipment and methods
- Experiences in the daily business in laboratory and manufacturing

Experts from the pharmaceutical industry, regulatory authorities and international academia will present various microbiological aspects of the above topics.

It is the aim of this conference to equip the pharmaceutical microbiologist with practical knowledge and "know how" which can be applied within the daily business. In addition it will provide a forum for interesting and open discussion between presenters, regulators and your colleagues from the industry.

It would be a great pleasure for me if you could join us in Prague.



Dr Sven M Deutschmann
Chairman of ECA's RMM Working Group

Objectives

These two conferences offer you a unique possibility to become acquainted with ongoing regulatory requirements, the development of microbiological methods for quality and process control as well as with the recent experiences in microbial contamination control.

Speakers from different scopes of pharmaceutical microbiology – from regulatory bodies and consulting – will give you the chance to get to know the different views on versatile microbiological topics and you will have ample opportunity to discuss specific issues with speakers and other participants.

Background

The role of pharmaceutical microbiology has been getting more and more important in the last years. It is more focused by the regulators during product submission and inspections. With the harmonisation of the different pharmacopoeias the harmonised methods must be implemented and the challenge is therefore to satisfy regulatory requirements alongside financial expectations of the management.

Furthermore the field of Rapid Microbiological Methods developed very fast in the last years, and promises possibilities to optimise the factors time and money in microbiological in-process-control and release.

Target Audience

This conference is of interest to professionals in microbiology from

- Pharmaceuticals and Biopharmaceutical companies
- Academic Research Institutions
- Government Agencies
- Contract Service Laboratories

who are involved in

- Quality Affairs
- Research and Development
- Validation
- Regulatory Affairs
- Hygienic Aspects
- Mycoplasma Testing

European Mycoplasma Testing Conference

3 May 2011, Prague, Czech Republic

Chaired by Prof Dr Renate Rosengarten, Mycosafe

Programme

Key Note – Current Developments in Mycoplasma Detection, Prevention and Control
PROF DR RENATE ROSENGARTEN, Mycosafe

International Standards and Guidances

- WHO Standards
- PDA Technical Report 50

DR SVEN DEUTSCHMANN, Roche Diagnostics

Mycoplasma Testing of Biologicals – The Current US Regulatory View, Trends and Concerns

- Current mycoplasma testing methods and regulations
- Recent changes and novel trends in mycoplasma testing
- Alternative methods: challenges and factors affecting comparison
- Mycoplasma standards and reference materials

DR VLADIMIR E. CHIZHIKOV, Center of Biologics Evaluation and Research, Food and Drug Administration, USA

Short Presentation:

Use of Rapid Molecular Contaminant Detection for In-Process Monitoring during Cell Culture Manufacturing

- Implementation
- Validation Strategies

MICHAEL BREWER, Life Technologies

Implementation and Application of Mycoplasma Testing in a Contract Laboratory

- Validation Strategies
- Requirements on a Mycoplasma Testing System
- First Steps of Implementation
- Validation and Integration in classic Methods
- Possibilities and Limits

DR THOMAS MEINDL, L+S

Short Presentation: *Acholeplasma laidlawii* Membrane and Agar Evaluation

- Experimental setup
- Evaluation results

GERHARD HAAKE, Sartorius Stedim Biotech

Mycoplasmas in the Pharmaceutical Industry

- Challenges
 - Where can we find them?
 - How can we get rid of them?
 - Influence on product/processes?
- Preventive Measure

DR CHRISTINE ARBESSER, Baxter

NAT-based Mycoplasma Detection: additional Approaches

- Alternative purification approaches
- Alternative detection approach

DR SVEN DEUTSCHMANN, Roche Diagnostics

Haemoplasmas – The “new” Group of Mycoplasmas and we detect them

DR SÉVERINE TASKER, School of Veterinary Sciences & Langford Veterinary Services, University of Bristol, UK

European Microbiology Conference

4 – 5 May 2011, Prague, Czech Republic

Programme

Module 1: Current Regulatory Developments

CHAired BY BARBARA GERTEN

USP Microbiological Best Laboratory Practices <1117> Revised

- Intent is for guidance and practical considerations for infrastructure of microbiological testing
- Second version has added more valuable information for microbiology laboratories
- New topics are Sample Handling, Media Incubation Times, and Resources

DR DON SINGER, *GSK*

Update of European Regulatory

- Changes to microbiological monographs in the European Pharmacopoeia and United States Pharmacopoeia
- ISO cleanroom standards
- PIC/S and regulatory developments and other applicable standards
- Potential future developments

TIM SANDLE, *BPL*

Standardisation and Validation at ISO

- The process of standardization at ISO
- ISO standards for validation of alternative microbiological methods
- ISO standards for quality control of culture media for drinking water and food

BARBARA GERTEN, *Merck*

Module 2: Current Development in Microbiological Methods

CHAired BY DR SEBASTIEN RIBAUT

Microbiology challenges for Rapid Micro Methods

- Microbiology variations and their impact on rapid methods
- Which control make sense?
- Viable but non-culturable issues
- False positive challenges
- Challenges of the comparison Rapid/Compendial methods

DR SEBASTIEN RIBAUT, *Milipore*

Vegetable Bouillon for Media Fill

- Reasons for implementation of a vegetarian Bouillon
- Requirements
- Market research
- Preliminary experiments
- Experiments
- Implementation
- Future Prospects

DR BETTINA LAUER, *Vetter Pharmaceuticals*

Monocyte-Activation Test with Cryopreserved Human Blood

- Requirements of the European Pharmacopoeia 2.6.30
- Scope of pyrogenic substances detected
- Comparison to Rabbit Pyrogen Test (RBT) and Bacterial Endotoxin Test (BET)

DR BODO HOLTkamp, *Biotest*

Molecular Typing of Microorganisms using Amplified Fragment Length Polymorphism (AFLP)

- Experiences with the method from the point of view of a contract laboratory
- Applications of this method
- Comparison to other typing methods
- Correlation of classical microbiological methods and molecular typing

DR THOMAS MEINDL, *L+S*

CHAired BY DR SVEN M. DEUTSCHMANN

Myths and legends of the emergent bacterial pathogen Cronobacter (Enterobacter sakazakii)

- Association with severe infant infections
- Risk assessments by the FAO/WHO and revised guidelines for hygienic practices by WHO for infant feeding
- Understanding of the bacterial organism - achieved through genetic analysis; 16S rDNA sequencing, MLST and whole genome sequencing.
- Misunderstandings in the scientific community

PROF DR STEPHEN FORSYTHE, *Nottingham Trent University*

Risk Evaluation of Microorganisms – a Challenge for the Microbiologist in pharmaceutical Industries

- Background
- Pathogen or not
- What means an “objectionable organism” according USP?
- Practical Examples

DR GERO BECKMANN, *Institute Romeis*

16S-rDNA based microbial Identification (MID) at Roche.

Organization of a global Network

- Background and structure of the Roche global MID network
- Harmonization of MID acceptance criteria, qualifications and validations
- Evaluation of novel techniques

DR FRIEDRICH VON WINTZINGERODE, *Roche*

Environmental Monitoring sterile/non-sterile

- What is ‘environmental monitoring’?
- Regulatory requirements for monitoring
- Deciding what should be included in a monitoring programme
- The use of risk assessment in developing a monitoring programme: sample selection, locations for monitoring and frequencies
- The interpretation and assessment of monitoring data
- Consideration of out of limits results

TIM SANDLE, *BPL*

OOS Handling

- Regulatory Requirements
- Failure/Deviation System, Vetter
- Work Flow
- Level: Quality Control
- Level: Microbiology
- Case Studies

DR BETTINA LAUER, *Vetter Pharmaceuticals*

New Insights in Trending of Monitoring Results

- Finding the right sampling frequency
- Setting and revising alert and action levels
- What is a negative trend?
- How to defend a reduced monitoring program

DR BJÖRN WIESE, *Cilag*

Virus Activity of Chemical Disinfectants

- Structure of viruses
- Behaviour against disinfectants
- Right choice of disinfectants
- Legal situation in Europe

DR DR FRIEDRICH VON RHEINBABEN, *Ecolab*

Speakers of both conferences

DR CHRISTINE ARBESSER,

Baxter AG, Austria

Christine Arbesser is responsible for Quality Operations, focusing on microbiology and aseptic challenges, trouble shooting and audit support for Baxter BioScience Europe.

DR GERO BECKMANN,

Veterinary Specialist for Microbiology, Germany

Gero Beckmann has been with the Institut Romeis since 2009.

MICHAEL BREWER, Life Technologies, USA

Prior to joining Life Technologies Michael Brewer worked for over 20 years for a major Biopharmaceutical company.

VLADIMIR E. CHIZHIKOV,

Center of Biologics Evaluation and Research, FDA, USA

Vladimir Chizhikov is presently a Principal Investigator at the Laboratory of Methods Development of the Center for Biologics Evaluation and Research (CBER), US Food and Drug Administration. Prior to joining CBER in 1999, he held research positions at different institutes.

DR SVEN M. DEUTSCHMANN,

Roche Diagnostics GmbH, Germany

Sven Deutschmann joined Boehringer Mannheim GmbH, now Roche Diagnostics GmbH, as Manager QC in 1995. Since 2001 he has been Director of the Microbiology QC Department.

PROF STEVEN FORSYTHE,

Nottingham Trent University, United Kingdom

Currently, Steven Forsythe is professor in Microbiology at Nottingham Trent University. His research area is primarily into pathogenic bacteria associated with food poisoning.

GERHARD HAAKE,

Sartorius Stedim Biotech

BARBARA GERTEN,

Merck KGaA, Darmstadt, Germany

Barbara Gerten has been head of the laboratory RTU Media / Validation at Merck KGaA since 2008. She is a member in several national and international bodies of microbiological topics in ISO and CEN.

DR BODO HOLTkamp,

Biotest AG - GBU Microbiology

Bodo Holtkamp is working for Biotest since 1985. Actual he is Senior Director in the GBU Microbiology and head of the Dept. of Molecular Biology.

DR BETTINA LAUER,

Vetter Pharma Fertigung GmbH & Co. KG, Ravensburg, Germany

Bettina Lauer joined Vetter Pharma-Fertigung in 1999, and is presently deputy head of Microbiology, working as a senior expert in Microbiology responsible for customer audits and authorities' inspections.

DR THOMAS MEINDL,

L+S AG, Bad Bocklett, Germany

Dr Meindl researched in Oncology at SKM Oncology GmbH from 2003 to 2005. In 2005 he joined L + S AG as Division Manager.

DR DR FRIEDRICH V. RHEINBABEN,

Ecolab GmbH & Co. OHG, Düsseldorf

He has been working for Ecolab Company / Germany as Technical manager for Microbiology / Virology and Hygiene in the Research and Development Department since 2000.

DR SÉBASTIEN RIBAUT,

Head of Applied Biology, Biomonitoring R&D, Merck Millipore

Prior to joining Millipore, Sébastien Ribault worked as Research Scientist at Transgene, Strasbourg and then as head of the R&D Laboratory at Hemosystem.

PROF DR RENATE ROSENGARTEN,

Mycosafe Diagnostics GmbH, Vienna, Austria

Renate Rosengarten is Head of the Institute of Bacteriology, Mycology and Hygiene at VUW, current Chair of the Austrian Society for Hygiene, Microbiology and Preventive Medicine, Past-Chair of the International Organization for Mycoplasma, and Founder and Managing Director of Mycosafe Diagnostics GmbH.

TIM SANDLE,

Bio Products Laboratory, UK

Tim Sandle has over twenty years experience of working in the pharmaceutical industry. In addition, he has published over seventy articles and book chapters on the subject of pharmaceutical microbiology.

DR DONALD C. SINGER,

Global Lead Manager, Microbiology, R&D, GSK, USA

Donald C. Singer is a member of the USP Microbiology Committee of Experts and is Global Lead Manager, Microbiology R&D for GlaxoSmithKline.

DR SÉVERINE TASKER,

University of Bristol, United Kingdom

Séverine Tasker is currently Senior Lecturer in Small Animal Medicine at the University of Bristol where she is involved with the Feline Centre and the Molecular Diagnostic Unit of Langford Veterinary Services.

DR BJÖRN WIESE,

Cilag, Johnson&Johnson, Switzerland

Björn Wiese became responsible for Environmental Monitoring activities at the pharmaceutical production site of Cilag in Schaffhausen, Switzerland, in 2007. Since 2008 he is Head of QC Microbiology at Cilag.

DR FRIEDRICH VON WINTZINGERODE,


Roche, Germany

Friedrich von Wintzingerode has been with Roche Diagnostics as group leader Environmental Monitoring and Cleaning Analytics since 2001. In 2005 he also became group leader microbiological IPC and analytics for release.

Dates	<p>European Mycoplasma Testing Conference Tuesday, 3 May 2011, 09.00 – 18.00 h (Registration and coffee 08.30 – 09.00 h)</p> <p>European Microbiology Conference Wednesday, 4 May 2011, 09.30 – 17.30 h (Registration and coffee 09.00 – 09.30 h) Thursday, 5 May 2011, 08.30 – 16.30h</p>
Venue	<p>Dorint Hotel Don Giovanni Prague Vinohradská 157A 130 20 Prague 3 Tel. +420 2 6703 1111 Fax +420 2 6703 6717</p>
Fees	<p>European Mycoplasma Testing Conference ECA Members EUR 790.- per delegate plus VAT Non-ECA Members EUR 890.- per delegate plus VAT EU GMP Inspectorates EUR 445.- per delegate plus VAT</p> <p>European Microbiology Conference ECA Members EUR 1,590.- per delegate plus VAT Non-ECA Members EUR 1,790.- per delegate plus VAT EU GMP Inspectorates EUR 895.- per delegate plus VAT</p> <p>European Mycoplasma Testing Conference TOGETHER with the European Microbiology Conference ECA Members EUR 2,080.- per delegate plus VAT Non-ECA Members EUR 2,280.- per delegate plus VAT EU GMP Inspectorates EUR 1,140.- per delegate plus VAT</p> <p>The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the 4 May 2011, lunch on all three days and all refreshments during the conferences. VAT is reclaimable.</p>
Accommodation	<p>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 "VA 6866-6868 ECA Event" to receive the specially negotiated rate for the duration of your stay. Reservation should be made directly with the hotel not later than 5 April 2011. Early reservation is recommended.</p>
Registration	<p>Via the attached reservation form, by e-mail or by fax message. Or you register online at www.gmp-compliance.org.</p>
Conference Language	<p>The official conference language will be English.</p>
Organisation and Contacts	<p>CONCEPT HEIDELBERG P.O. Box 10 17 64 D-69007 Heidelberg Germany Phone +49 (0) 62 21/84 44-0; Fax +49 (0) 62 21/84 44 34 E-mail: info@concept-heidelberg.de; www.concept-heidelberg.de</p> <p>For questions regarding content: Axel Schroeder (Operations Director) at +49-62 21/84 44 10 or per e-mail at schroeder@concept-heidelberg.de.</p> <p>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.</p>
Social Event	<p>As a delegate of the European Microbiology Conference or of both the European Mycoplasma Conference and the European Microbiology Conference you are cordially invited to a social event on 4 May 2011. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.</p>




Easy Registration

 Reservation Form:
CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg
Germany

 Reservation Form:
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 e-mail:
info@concept-heidelberg.de

 Internet:
www.gmp-compliance.org

Special offer with Lufthansa – discounted travel for European Mycoplasma Testing Conference & European Microbiology Conference attendees



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Please note that you may have to enable pop-ups on this site – otherwise the booking platform window will not open.

These promotional fares are also available via your IATA / ARC Travel Agent. Travel Agents can obtain ticketing instructions via eMail lufthansameetingsandevents.ber@dlh.de by quoting the access code as an event reference.

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Reservation Form (Please complete in full)

European Mycoplasma Testing Conference
3 May 2011, Prague, Czech Republic

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European Microbiology Conference
4 – 5 May 2011, Prague, Czech Republic

**European Mycoplasma Testing Conference AND
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3 – 5 May 2011, Prague, Czech Republic

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2. If you have to cancel entirely we must charge the following processing fees: Cancellation
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 - until 1 weeks prior to the conference 50 %
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possible and will receive a full refund of fees paid. CONCEPT HEIDELBERG will not be responsible for discount airfare penalties or other costs incurred due to a cancellation.

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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)!