



EUROPEAN COMPLIANCE
ACADEMY

SPEAKERS

DR SVEN M. DEUTSCHMANN
Roche Diagnostics, Germany

PROF DR WOLFGANG FRIESS
LMU, Germany

DR FIONA GREER
MScan, UK

DR STEFFEN GROSS
Paul-Ehrlich-Institut, Germany

DR THOMAS HÄMMERLE
Baxter, Austria

DR HILTRUD HORN
Horn Pharmaceutical
Consulting, Germany

DR HOLGER KAVERMANN
Roche Diagnostics, Germany

**PD DR HANNS-CHRISTIAN
MAHLER**
F. Hoffmann-La Roche,
Switzerland

DR ANDREAS NECHANSKY
Vela Laboratories, Austria

**PROF DR CHRISTIAN
SCHÖNEICH**
Kansas University, USA

DR INGO SPREITZER
Paul-Ehrlich Institut, Germany

DR MATTHEW VAN HOOK
United States Pharmacopoeia,
USA

DR JAN MARIUS VISSER
Sandoz, Czech Republic

DR HARALD WEGELE
Roche Diagnostics, Germany



Including

- Site Visit at Roche Diagnostics in Penzberg
- Academic Poster Session

Bio Production Forum

Development, Impurities and Biosimilars

Munich, Germany, 19 – 21 June 2012

HIGHLIGHTS:

- Protein- Formulation, Packaging Material Interactions and Degradation
- Impurities and Contaminants in Biopharmaceuticals e.g. DNA, Endotoxins, Host Cell proteins
- Capability of Impurity Analytics
- New Legal Pathways for U.S. Approval of Biologics/Biosimilars
- Development and Characterisation of Biopharmaceuticals and Biosimilars
- European Requirements on Biosimilars

Exclusive Media Partner:



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The University of Munich, Germany / Chair for Pharmaceutical Technology and Biopharmaceutics at the Department of Pharmacy-Center for Drug Research

The Center for Drug Research is dedicated to training in all areas of pharmaceutical technology for undergraduate and graduate students and to research in the field of parenteral dosage forms, colloidal systems and has a specific focus on protein drug formulations.

The Center conducts research projects with a number of biotech drugs. Further research topics are drug delivery systems for topical delivery as well as systemic depot forms and targeting approaches using nano-scaled technologies. Process technologies in the area of freeze drying, spray drying, nanoparticle and liposome formulation etc. are applied and further developed.



ETH Zurich – A science and technology university with an outstanding research record

ETH Zurich is the study, research and work place of 20,000 people from 80 nations. About 370 professors in 16 departments teach mainly in the engineering sciences and architecture, system-oriented sciences, mathematics and natural sciences areas and carry out research that is highly valued worldwide.

As an internationally oriented institution of higher education and a nationally grounded one this forward-looking task is fulfilled in service to the Swiss nation.



Schweizerische Gesellschaft der Pharmazeutischen Wissenschaften (SGPhW) / Swiss Society of Pharmaceutical Sciences (SAPhS)

The society promotes as a principal goal Pharmaceutical Sciences in Switzerland. For this purpose the society has assumed the function of an academy pursuing the following mission:

- Unifying and coaching the national and regional societies linked to the discipline of Pharmaceutical Sciences
- Promotion of national and international scientific contacts and of cooperations with other scientific societies and academies
- Public promotion of Pharmaceutical Sciences
- Promotion of the communication of eminent pharmaceutical findings and realizations in science, research, development, industry, health care and public society
- To award distinguished persons for their merits in Pharmaceutical Science



Cilag AG

Founded in 1936 in Schaffhausen, Switzerland, CILAG's creative and innovative approach has resulted in the continuous introduction of new products, processes and technologies. Today, the company is a worldwide strategic development, launch and production center of APIs (active pharmaceutical ingredients) and drug products within the Johnson & Johnson Pharmaceuticals Group, the world's most comprehensive and broadly based manufacturer of health care products, as well as a provider of related services, for the consumer, pharmaceutical and professional markets.



University of Leiden

Leiden University is the oldest university in the Netherlands. It was founded in February 1575, as a gift from William of Orange to the citizens of Leiden who had withstood a long siege by the Spaniards. In Leiden there are approximately 17,000 students and 4,000 staff members. The University consists of nine faculties, a School of Management and a School of Education. The University houses faculties of Archaeology, Arts, Creative and Performing Arts, Law, LUMC (Leiden University Medical Center), Mathematics and Natural Sciences, Philosophy, Social and Behavioural Sciences, and Theology.



Merck Serono

Merck Serono is the division for innovative prescription pharmaceuticals of Merck KGaA, Darmstadt, Germany, a global pharmaceutical and chemical company. Headquartered in Geneva, Switzerland, Merck Serono discovers, develops, manufactures and markets innovative small molecules and biopharmaceuticals to help patients with unmet medical needs. In the United States and Canada, EMD Serono operates through separately incorporated affiliates. For more information, please visit www.merckserono.com or www.merck.de.



Boehringer Ingelheim

The Boehringer Ingelheim group is one of the world's 20 leading pharmaceutical companies. Headquartered in Ingelheim, Germany, it operates globally with 142 affiliates in 50 countries and more than 41,500 employees. Since it was founded in 1885, the family-owned company has been committed for 125 years to researching, developing, manufacturing and marketing novel products of high therapeutic value for human and veterinary medicine. Today, Boehringer Ingelheim is one of the world's leading companies for contract development and manufacture of biopharmaceuticals. All types of services from mammalian cell line or microbial strain development to final drug production can be delivered within a one-stop-shop concept. Boehringer Ingelheim delivers services for pre-clinical development up to global market supply with a strong commitment to its customers at its manufacturing facilities for mammalian cell culture and microbial fermentation. Boehringer Ingelheim has brought 17 molecules to market and has many years of experience in multiple molecule classes such as monoclonal antibodies, recombinant proteins, interferons, enzymes, fusion molecules and plasmid DNA. Furthermore, high-titer platform technologies for new antibody mimetic formats such as scaffold proteins and antibody fragments are available for the manufacture of customer products. To find further details please visit www.biopharma-cmo.com.



Roche

Roche is a leader in research-focused healthcare with combined strengths in pharmaceuticals and diagnostics. Roche is the world's largest biotech company with differentiated medicines in oncology, virology, inflammation, metabolism and CNS. Roche is the world leader in in-vitro diagnostics, tissue-based cancer diagnostics and a pioneer in diabetes management. The personalised healthcare strategy aims at providing medicines and diagnostic tools for improvements in the health, quality of life and survival of patients.

Objectives

Dear Colleagues,



During the last years, the Bio Production Forum became a fixed component in the calendar of many scientists and industrial representatives and emerged to one of the most important events in the field of biopharmaceutical manufacturing.

In 2011 we started bringing together academic sciences, industrial R&D and commercial manufacturing and we continue to offer a platform for young academics and researchers, to present their work to academic and industrial scientists and managers by a poster session.

This year, amongst the current development in protein formulation and degradation, we will focus on the considerable role of impurities in biopharmaceuticals and current status of Biosimilars.

I'm very pleased, that Roche give us the chance to highlight our conference program with a visit to their Biotechnology site in Penzberg. Therefore, this year we moved the conference to Munich. But everyone will remember the roots of the Bio Production Forum in Schaffhausen and the enormous efforts of the Swiss supporting organisations to realize the first five Bio Production Forums.

We are very happy that leading experts from science and industry accepted our invitation and will discuss with you the latest trends that have a major impact on development and manufacturing of biopharmaceuticals and biosimilars.

Please use this unique opportunity to keep abreast of these developments. We wish you a successful and interesting conference.

Yours sincerely,



Dr Sven M. Deutschmann
Chairman of the ECA Rapid Microbiological Methods Working Group
Director Quality Control, Micro- and Cellbiology
Roche Diagnostics GmbH, Penzberg, Germany

Target Audience

Vice Presidents, Directors, Heads of, Managing Directors and Managers responsible for:

- Manufacturing
- Quality
- Compliance
- Supply Chain
- Process Management
- Research and Development

Moderators

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

Scientific Advisory Board

Prof Dr Wim Jiskoot, Leiden University
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Dr Friedrich Haefele, Boehringer Ingelheim
Dr Sven M. Deutschmann, Roche

Poster Session

Our industrial partners esp. **Cilag AG** grants free-of-charge participations to young scientists from Universities, Research Institutes, etc. to present at the poster session and to attend the conference.

We encourage young scientists to apply for these grants! Please contact Axel H. Schroeder at schroeder@concept-heidelberg.de for details.

Programme

Day 1 Development and Analytic

Key Note: Biopharmaceutical Manufacturing
N.N. Roche

Challenges in antibody formulation and drug product manufacture

- Formulation principles
- Current Issues, e.g.
 - Polysorbate Degradation
 - Frozen Storage Degradation

PD DR HANNS-CHRISTIAN MAHLER, Roche

Poster Presentations

Understanding Protein– Packaging Material Interactions

- Mechanisms of protein-glass vial interactions;
- mAb adsorption at siliconized surfaces;
- Changes of mAbs at the vial surface;
- New vial coatings

PROF DR WOLFGANG FRIESS, Department of Pharmacy – Center for Drug Research, LMU

Chemical degradation of proteins: novel pathways probed during accelerated stability studies

- Chemical degradation of proteins can target all amino acids
- Novel oxidation and cleavage pathways during exposure to oxidizing conditions and light
- Formation and detection of oxidation products, which can promote aggregation
- Formation of new covalent crosslinks during disulfide degradation

PROF DR CHRISTIAN SCHÖNEICH, University of Kansas

Poster Presentations

Capability of Impurity Analytics – crucial factor of safety and quality

- Overview of assays
- Performance and Design
- Pitfalls

DR ANDREAS NECHANSKY, Vela Laboratories

Host Cell Proteins

- ECP and CHOP
- Immunogenicity
- Patient safety
- Manufacturing consistency

DR HARALD WEGELE, Roche

Day 2 Impurities and Contaminants of Biopharmaceuticals

DNA Impurity Quantitation and Qualification in Biotechnology Products.

- Methodological approaches,
- Evaluation and Qualification of data,
- Guidelines including recent developments.

DR THOMAS HÄMMERLE, Baxter

Endotoxin and Pyrogens – alternative Testing regarding the expected new requirements

- Pyrogen testing: MAT basics
- Endotoxin testing: new LAL (BET) developments
- Relevance of Non-Endotoxin Pyrogens
- Implications of the new EU-DIRECTIVE 2010/63/EU on the protection of animals used for scientific purposes

DR INGO SPREITZER, Paul-Ehrlich-Institut

Adventitious Agents

- Viral Risk Mitigation Strategies
- Molecular and Cell Based Virus Testing

DR HOLGER KAVERMANN, Roche

Programme (cont.)

Introduction to the site visit

- Facts and details for the following site visit

DR SVEN M. DEUTSCHMANN, Roche

Site visit at Roche Diagnostics GmbH, Penzberg, Germany



Penzberg is Roche Diagnostics GmbH's location near Munich, Bavaria. It is one of the largest biotech centers in Europe and the only Roche location performing research, development and production for both divisions: Diagnostics and Pharmaceuticals.

Diagnostics' strengths include system platforms for immunology, clinical chemistry, genetic and cellular analysis, as well as reagents and systems for the life sciences market. Over 40 years of experience in biotechnological production make this site a pioneer of industrial biotechnology. Roche at Penzberg, employing about 4,800 people, is an important economic factor in the region.

Intensive cross-networking between the two divisions creates synergies. These are proving particularly useful for driving forward initiatives such as stem cell research or the Roche "Personalised Healthcare" program. The goal is to offer custom-tailored patient therapy with greater safety, efficacy and yet good tolerability. Personalised Healthcare is a key element of Roche's corporate strategy.

As a pharmaceutical production location, Penzberg makes great contributions to the therapy of important diseases like cancer and anemia. Four biotechnologically manufactured active pharmaceutical ingredients (API) are produced at the Pharma Biotech production. Recently, the capacity of research and technical development of therapeutic proteins was significantly enlarged which in turn will further enhance the value chain, from early research on active substance candidates to the production of protein drugs for the market.

Day 3 Requirements on Biopharmaceuticals and Biosimilars

New Legal Pathways for U.S. Approval of Biologics/Biosimilars

- Under new U.S. law all drugs considered a "biologic product," not just biosimilars, will be required to obtain a BLA biologics license (not an NDA under the mainstream Food, Drug, and Cosmetic Act)
- There are differences in the regulatory approval standards for BLAs and NDAs, but all are equally subject to the same fundamental requirements, such as conformance to GMPs and compendial quality standards (e.g. nonproprietary naming/identity; strength, quality, purity)
- The new biosimilars 351(k) marketing pathway has some parallels with the EU comparability approach; remains to be seen how "abbreviated" it will prove in practice, and whether applicants will seek to obtain an FDA finding of "biosimilar" or "interchangeable," or instead tend to continue to use the old 351(a) BLA pathway

DR MATTHEW B. VAN HOOK, USP

Development of Biotech Products: From Lab to Patient

- Key Aspects for EU and US
- GMP and Regulatory Challenges
- Strategies for Success

DR HILTRUD HORN, Horn Pharmaceutical Consulting

Challenges for Characterisation of Biopharmaceuticals and Biosimilars"

- Physicochemical characterisation- primary and higher order structure
- Post translational Modifications
- Comparability against the Innovator Product

DR FIONA GREER, M-Scan

Target-Directed Development of Biosimilars

- A general introduction to biosimilars and the need for global development
- Biosimilar development, aimed at targeting the originator quality attribute ranges (goal posts), results in "highly similar" biopharmaceuticals
- A comprehensive comparability exercise, including analytical & biological characterization and pre-clinical and clinical comparative studies, provides the proof of the pudding for biosimilarity
- Biosimilars are as safe and efficacious as their originator products and increase patient access to essential, high quality biopharmaceuticals

DR JAN MARIUS VISSER, Sandoz Biopharmaceuticals

Requirements for demonstrating biosimilarity of monoclonal antibodies

- Necessary Comparability Exercises in term of Quality, Safety, Efficacy
- Clinical and Non Clinical Requirements
- The step-wise approach to evaluate mAbs

DR STEFFEN GROSS, *Paul-Ehrlich-Institut*

Social Event

On 19 June 2012 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

DR SVEN M. DEUTSCHMANN, *Roche Diagnostics GmbH, Germany*

Sven Deutschmann obtained his PhD in cell culture technology. In 1995 he joined Boehringer Mannheim and has been Director of the Microbiology QC Department since 2001. In addition, he is member of several national and international Pharmacopoeial committees and Working Groups of the Central Commission for Biological Safety (CCBS).

PROF DR WOLFGANG FRIESS, *Department of Pharmacy – Center for Drug Research , Pharmaceutical Technology and Biopharmaceutics, Ludwigs-Maximilians-Universität (LMU), Munich*

Dr Wolfgang Frieß has been Professor for Pharmaceutical Technology and Biopharmaceutics at the LMU since 2001.

DR FIONA M. GREER, *SGA M-Scan, United Kingdom*

Dr Greer was appointed Director of Biochemical Services in 1988. At the same time, she was instrumental in establishing a facility in the United States. She is now Global Director for Biopharma Services Development.

DR STEFFEN GROSS, *Scientific Assessor and Laboratory Head, Section Monoclonal and Polyclonal Antibodies, Paul-Ehrlich Institut, Germany*

Dr Gross is Deputy Head of the Section Monoclonal and Polyclonal Antibodies, Laboratory Head and Scientific Assessor (Quality, Pre-clinic) at the Paul-Ehrlich Institute.

DR THOMAS HÄMMERLE, *Manager QC-Molecularbiological Control, Baxter AG, Vienna, Austria*

Thomas is currently heading the Department of Molecularbiological Control at the Baxter site in Orth/Danube Austria. He is also a member of the EDQM Mycoplasma and CTP working parties, a member of the USP Residual DNA working party and co chair of the PDA Mycoplasma Task Force Testing Subgroup.

DR HILTRUD HORN, *Horn Pharmaceutical Consulting, Germany*

Dr Horn is managing director of HORN PHARMACEUTICAL CONSULTING. Prior positions include QA and Regulatory Affairs at Hoffmann-La Roche, Knoll AG and at Cap Gemini Ernst & Young, where she was the responsible consultant for questions concerning biotechnology and life sciences.

DR HOLGER KAVERMANN, *Roche Diagnostics GmbH, Germany*

Dr Kavermann joined Roche Diagnostics in 2003. Today, he is responsible for the microbiological and cell biological analytics of QC- and In-Process-Control-samples in the production of biotechnological derived active pharmaceutical ingredients.

PD DR HANNS-CHRISTIAN MAHLER, *F. Hoffmann-La Roche Ltd., Switzerland*

DR ANDREAS NECHANSKY, *Vela Laboratories, Austria*

Dr Nechansky is Founder/COO of Vela Laboratories and responsible for analytical operations.

PROF DR CHRISTIAN SCHÖNEICH, *Chair Department of Pharmaceutical Chemistry, University of Kansas*

Dr Schöneich is the Takeru Higuchi Distinguished Professor and Chair in the Department of Pharmaceutical Chemistry.

DR INGO SPREITZER, *Paul-Ehrlich-Institut, Langen, Germany*

Dr Spreitzer he has been working as a scientist at the Paul-Ehrlich-Institut since 2001. In October 2004 he was appointed Deputy of Section 1/3, "Microbial Safety and Parasitology". Duties: Pyrogen testing (rabbit and alternatives); LAL-Testing.

DR MATTHEW B. VAN HOOK, *Vice President and Assistant General Counsel, USP – United States Pharmacopeia, Rockville, Maryland, U.S.A.*

Mr van Hook received his J.D. from the University of Michigan Law School. Today, he is an attorney at USP, responsible for the legal aspects of USP compendial standard setting, including governance rules for the Expert Committees.

DR JAN MARIUS VISSER, *Head Global Analytical Characterization & Bioanalytics, Sandoz Biopharmaceuticals, Oberhaching, Germany*

Dr Visser assumed his current role at the end of 2010. In the 3 years before he was leading Technical Development at Sandoz Biopharmaceuticals Menges in Slovenia, pioneering and spearheading biosimilar drug substance development from gene to validation.

DR HARALD WEGELE, *Director Development Analytics, Roche Diagnostics, Germany*

At present, Dr Wegele is heading the Biochemical Development Analytics department at Roche Diagnostics (Penzberg, Germany).

Conference language

The official conference language will be English.

Organisation and Contact

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For questions regarding content:

Axel H Schroeder (Operations Director) at +49-6221/84 44 10, or per e-mail at schroeder@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc.:

Ms Jessica Stürmer (Organisation Manager) at +49-6221/84 44 43, or per e-mail at stuermer@concept-heidelberg.de.

About CONCEPT HEIDELBERG

Founded in 1978, CONCEPT HEIDELBERG is the leading organiser of seminars on pharmaceutical production, quality control, quality assurance and GMP in Europe. This year more than 240 events will be organised by CONCEPT HEIDELBERG. ECA has entrusted CONCEPT HEIDELBERG with the organisation of its events.

GMP Certification Programme

This conference is recognised within the GMP Certification Programme Module "Biotech Manager". By attending selected seminars, the participant can acquire an additional certificate. We offer the following modules:

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- Pharmaceutical Engineering/Production Manager (ECA)
- Computer Validation Manager (ECA)
- Regulatory Affairs Manager (ECA)
- Microbiological Laboratory Manager (ECA)
- Sterile Production Manager (ECA)
- Pharmaceutical Development Manager (ECA)
- Biotech Manager (ECA)



On the internet at www.gmp-compliance.org you will find a text explaining which seminars are recognised for which certificates. Or you send an e-mail to info@gmp-compliance.org or a fax to +49-6221- 84 44 64 with the request for information about the GMP Certification Programme. We will then send you our brochure on the topic.

What Is ECA?

The European Compliance Academy (ECA) is an independent educational organisation chaired by a Scientific Advisory Board with members of the pharmaceutical industry and regulatory authorities. The ECA will provide support to the Pharmaceutical Industry and Regulators to promote the move towards a harmonised set of GMP and regulatory guidelines by providing information and interpretation of new or updated guidances.

What Are the Benefits of ECA?

First benefit: During the membership, you enjoy a 200 EUR discount on the regular participation fee of any European Conference organised by ECA in co-operation with CONCEPT HEIDELBERG.

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How Do You Become Member of ECA?

By participating in one of the European Compliance Conferences or Courses marked with ECA, you will automatically become a member of ECA for two years – free of charge. There are no obligations for the member! Conferences and Education Courses organised by ECA will be realised in co-operation with CONCEPT HEIDELBERG. More information about ECA can be obtained on the Website www.gmp-compliance.org.

Special offer with Lufthansa – discounted travel for 8th Bio Production Forum 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 one of our next events – and we already wish you a pleasant flight!

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.bio-conference.org

Date

Tuesday, 19 June 2012, 09.00 – 18.00 h
(Registration and coffee 09.00 – 09.30 h)
Wednesday, 20 June 2012, 08.30 – 18.00 h
Thursday, 21 June 2012, 08.30 – 13.30 h

Venue

Holiday Inn Munich
Effnerstrasse 99
81925 München, Germany
Tel. +49 (0)89 927 98-0
Fax +49 (0)89 98 38 13

Fees

Option I: Day 1 and Day 2

Non-ECA Members EUR 1,590.- per delegate plus VAT
ECA Members EUR 1,390.- per delegate plus VAT
APIC Members EUR 1,490.- per delegate plus VAT
EU GMP Inspectorates EUR 795.- per delegate plus VAT

Option II: Day 2 and Day 3

Non-ECA Members EUR 1,590.- per delegate plus VAT
ECA Members EUR 1,390.- per delegate plus VAT
APIC Members EUR 1,490.- per delegate plus VAT
EU GMP Inspectorates EUR 795.- per delegate plus VAT

Option III: Day 1 – Day 3

Non-ECA Members EUR 1,990.- per delegate plus VAT
ECA Members EUR 1,790.- per delegate plus VAT
APIC Members EUR 1,890.- per delegate plus VAT
EU GMP Inspectorates EUR 995.- 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.

Students/Scientists for Poster Session

(contact Axel H. Schroeder at schroeder@concept-heidelberg.de)
Day 1 – Day 3 – EUR 500.- per delegate plus VAT (including conference participation)

Registration

Via the attached reservation form, by e-mail or by fax message. Or you register online at www.bio-conference.org.

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 "ECA-Bio" to receive the specially negotiated rate (single room € 105,00 per night, including breakfast) for the duration of your stay. Reservation should be made directly with the hotel not later than 18 May 2012. Early reservation is recommended.

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

Reservation Form (Please complete in full)

Bio Production Forum

Munich, Germany, 19 – 21 June 2012

- Option I – Day 1 and Day 2, 19/20 June 2012
 Option II – Day 2 and Day 3, 20/21 June 2012
 Option III – Day 1 – 3, 19-21 June 2012
 Poster Session – Day 1 – 3, 19-21 June 2012
 Yes, I also would like to participate in the site visit
 Mr Ms

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Title, first name, surname

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Department

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If you cannot attend the conference you have two options:

1. We are happy to welcome a substitute colleague at any time.
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 - until 2 weeks prior to the conference 10 %
 - until 1 weeks prior to the conference 50 %
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