ECA
European Compliance Academy

Regulatory Developments
New Methods
Practical Experiences

Two European Conferences

Endotoxin & Pyrogen Testing
and
Microbiology

Speakers of the European Endotoxin and Pyrogen Testing Conference:

MICK DAWSON
Cape Cod
SVEN M. DEUTSCHMANN
Roche
ANJA FRITSCH
Confarma France
ROBERT J. MELLO
CDER, FDA
WOLFGANG MUTTER
Hyglos
MAXIMILIAN SCHLICHT
Labor L+S AG
ANKE SCHULZ
Merck/Millipore
ROBERT SCHWARZ
Baxter AG
DR. ANDREAS WIESER
Max von Pettenkofer-Institut, LMU Munich
WALTER ZWISLER
Zwisler Laboratories

Speakers of the European Microbiology Conference:

CHRISTINA BACH
PEI, German Federal Institute for Vaccines and Biomedicines
BARBARA GERTEN
Merck
MARCEL GOVERDE
MGP Consulting
SYLVIE GUYOMARD DEVANLAY
ACM Pharma
LAURENT LEBLANC
BioMerieux
ROBERT J. MELLO
CDER, FDA
URSULA OBST
Karlsruhe Institute of Technology
SEBASTIEN RIBAULT
Merck/Millipore
TIM SANDLE
BPL
HERBERT SCHMIDT
WHO
ALEXANDRA STÄRK
Novartis Pharma Stein
NICOLA SWIFT
Charles River
RADHAKRISHNA TIRUMALAI
USP

European Endotoxin and Pyrogen Testing Conference
8 May 2012, Frankfurt, Germany

HIGHLIGHTS:
- FDA's View on Endotoxin/ Pyrogen testing
- ELISA-based testing method
- Methods of endotoxin reduction for primary packaging materials and their validation approach
- Masking of Endotoxins
- MAT - current developments
- Experiences with alternative pyrogen testing

European Microbiology Conference
9-10 May 2012, Frankfurt, Germany

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 Microbological Laboratory Manager". Please find details at www.gmp-certification.eu

Invitation
to the European Microbiology Conference 2012 in Combination with European Endotoxin & Pyrogen Testing Conference

Dear Colleague,

I would like to invite you to the European Microbiology Conference and Endotoxin and Pyrogen Testing Conference 2012 organised by the European Compliance Academy (ECA).
Since several years, ECA has been organising Conferences on the different topics of pharmaceutical microbiology. The European Microbiology Conference and the conferences on Endotoxin and Pyrogen testing became regularly events in the calendar of microbiologists all over Europe. In 2012, ECA offers the unique possibility to participate in 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 great pleasure for me if you could join us in Frankfurt.

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

European Endotoxin and Pyrogen Testing Conference

8 May 2012, Frankfurt/Main, Germany

Chaired by Dr Sven M. Deutschmann, Roche Diagnostics

Objectives

This Conference will inform you about current developments in Endotoxin and Pyrogen testing as well as the practical use of established test system like LAL for Endotoxin testing, especially for noteworthy specifics on testing of elastomeric stoppers.
Some topics:
- Regulatory requirements, especially FDA's view
- New available methods, e.g. ELISA-based
- Solutions for issues with masking
- Testing of packaging materials esp. elastomeric stoppers
- Application of MAT as alternative pyrogen testing method

Background

The LAL test is established in the last years as the preferred system for testing of Endotoxins, for in process control as well as for final release testing and was prescribed in the Pharmacopoeia. During the same period, the importance of alternative Pyrogen testing methods for the pharmaceutical industry increased considerably, because they provide an opportunity to reduce time and a possibility to close the gaps of the classic methods of rabbit testing and LAL. Some of the reasons are:
- The LAL test is generally complicated due to potential interferences and inhibitors.
- LAL reagent has to be harvested from Horseshoe Crabs. An environmental or an ecological disaster could extinguish the Limulus population.
- Contamination of biologicals by non-endotoxin pyrogens not detectable in LAL test is not unlikely.
- Animal experiments have to be reduced. Also the LAL test is not a true in vitro test.

Target Audience

This Conference is addressed to all persons from
- pharmaceutical manufacturers
- biopharmaceutical companies
- contract laboratories
- tissue establishments

who are involved in Endotoxin and Pyrogen testing

European Endotoxin and Pyrogen Testing Conference

8 May 2012, Frankfurt/Main, Germany

Programme

FDA's View on Endotoxin/Pyrogen Testing

- Endotoxin assay information to include within the CMC portion of CDER Regulatory filings
- Endotoxin Limits – Pediatric Considerations
- Retirement of FDA's 1987/1991 LAL Guidance and issuance of the new Pyrogen and Endotoxin Testing Q&A Guidance document

DR ROBERT J. MELLO, CDER, FDA

Compliant Bacterial Endotoxin Testing in a post-FDA Guideline World

- Topics that were addressed in the withdrawn FDA guidance documents on endotoxin testing, but are not in the pharmacopoeial bacterial endotoxins test (BET) chapters.
- The use of control standard endotoxin
- Batch sampling and the numbers of units to test
- Retesting
- Medical device issues and others.
- Alternate sources of information on these matters

MICK DAWSON, CAPE COD

New testing method – based on ELISA

- Technology of the method
- Elimination of matrix effects
- Application spectrum

DR WOLFGANG MUTTER, HYGLOS

Case Study: Experiences with EndoLISA

DR ANDREAS WIESER, MAX VON PETTENKOFER-INSTITUT, LMU MUNICH

Case Study – different methods of endotoxin reduction for primary packaging materials and their validation approach

- Requirements for primary packaging materials
- Methods for endotoxin reduction
- Validation approach for a cleaning process
- Validation approach for a depyrogenation process

ROBERT SCHWARZ, BAXTER AG

Masking of Endotoxins

- Masking Effects of Complex Formulations
- Routine Testing of Protein Solutions
- Development of Analytical Strategies: "Hard Spike"- Recovery Studies

DR MAXIMLIAN SCHLICHT, L+S

Short presentation: MAT scientific background

- MAT's history
- Mechanism of action
- Possibilities and pitfalls

DR CHRISTINA BACHE, PAUL-EHRLICH-INSTITUT

The PyroDetect System: The Human(e) Alternative in Pyrogen Testing

- Principle of the Monocyte-Activation Test using cryoblood to induce Interleukin-1 response
- Quality criteria and usage of pooled human whole blood
- Accordance with EP requirements

ANKE SCHULZ, MERCK

MAT Experiences using the Monocyte Activation Test

- Comparison of methods
- Implementation
- Pitfalls and points to consider

DR WALTER ZWISLER, ZWISLER LABORATORIES

Optimized MAT using the monocytic cell line MonoMac6

- Validation of the MAT based on the MonoMac6 cell line
- Real-life experience
- MonoMac6 in direct incubation with medical devices

DR ANJA FRITSCH, CONFARMA

European Microbiology Conference

9-10 May 2012, Frankfurt/Main, Germany

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 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 the participants will have ample opportunity to discuss with speakers and other participants about specific issues.

Background

The role of pharmaceutical microbiology gets 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

- Pharmaceutical 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

Programme

Module 1: Current Regulatory Developments

Chaired by Dr Sven M. Deutschmann, Roche Diagnostics

Current Activities of USP in Microbiology and Sterility Assurance

- New Proposals on Sterilization Methods
- Revised chapter on Control and Monitoring of Aseptic Processing Environments
- New Proposal on Bioburden Control in Non-sterile Product Manufacturing

RADHAKRISHNA TIRUMALAI, PH.D., US PHARMACOPEIAL CONVENTION

Japanese Pharmacopoeia – the not harmonised microbiological chapters

- Changes in JP 16 published 2011
- Media-Fill Test
- Water testing
- Mycoplasma testing

BARBARA GERTEN, MERCK MILLIPORE

New WHO Guideline

- The WHO Prequalification Programme
- WHO Good practices for pharmaceutical microbiological laboratories
- Other WHO guidance for quality control laboratories

HERBERT SCHMIDT, WHO

Issues in FDA/CDER Microbiology Product Quality Reviews

- Objectionable Organisms in non-sterile oral drug products (B. cepacia issues)
- Microbial Limits testing
- Hold times for sterile reconstituted/diluted drug products
- Rapid Microbiology Methods

DR ROBERT J. MELLO, CDER, FDA

Module 2: Current Development in Microbiological Methods

Chaired by Dr Marcel Goverde, MGP

Mycoplasma PCR - Agencies Acceptance and Expectations
DR SVEN DEUTSCHMANN, ROCHE DIAGNOSTICS

Stressed Microorganisms
- Stress and fitness
- VBNC and dormancy
- Stress and biofilms
- How can we find and fight?

PROF. URSULA OBST, KIT

Use of Disposable materials and instruments to avoid Microbial contamination in Pharma Processes
- Why disposable in Biotech manufacturing?
- Disposable vs Stainless Steel approach
- Zero microbial risk using disposables?

DR SEBASTIEN RIBAULT, MERCK MILLIPORE

Objectionable Microorganisms
- What is an objectionable microorganism?
- How do we find them?
- How do we handle them?

DR MARCEL GOVERDE, MGP CONSULTING

Evaluation of the impact of commonly used clean room disinfectants in an agar culture medium
LAURENT LEBLANC, BIOMERIEUX

Evaluation of the interference of biocides on the performances of neutralizing culture media for Environmental Monitoring (EM) in Pharmaceutical Industries
- EM sampling program for ultra-clean pharmaceutical environment relies on the performance of culture media:
  - Nutritive properties
  - Efficient neutralizing properties
- Methodology to evaluate the growth and neutralizing performances of contact plates culture media with neutralizers
  - Study of biocides toxicity in agar plates
  - "Worst-Case" Disinfectant neutralization study
  - Global performance score for growth promotion and neutralization to 3 neutralizing culture media.
  - Comparison of global performance score of each neutralizing culture media.

DR SYLVIE GUYOMARD DEVANLAY, ACM PHARMA

Microbiological storage period for reconstituted sterile, unpreserved drug products prior to patient administration
- FDA requirement of a product specific, risk based approach
- Test procedure
- Results on variety of products
- Conclusion for patient leaflet

ALEXANDRA STÄRK, NOVARTIS PHARMA

Replacement of Gram staining with PTS
- LAL based assay
- Technical and scientific background
- Implementation
- Practical experiences

NICOLA SWIFT, CHARLES RIVER

Speakers of both Conferences

DR CHRISTINA BACHE , PAUL-EHRLICH-INSTITUTE, GERMANY
Dr Bache studied Biology in Mainz, Germany. Since 2005, she is employed at the Paul Ehrlich Institute, the German Federal Institute for Vaccines and Biomedicines in the Divison Microbial Safety. She has made research on different alternative tests in nationally granted projects.

MICHAEL E. DAWSON, PH.D., RAC, ASSOCIATES OF CAPE COD, INC.
Dr Dawson is Director of Regulatory Affairs at Associates of Cape Cod, Inc. (ACC). Responsibilities include world-wide compliance of ACC's products. He has broad experience in manufacture and application of endotoxin testing reagents, instrumentation and of software. He was educated in the United Kingdom, receiving a Bachelor's degree from the University of Wales and a doctorate from the University of Southampton. He is a member of the Parenteral Drug Association and the Regulatory Affairs Professionals Society and holds regulatory affairs certification (RAC) for the United States.

DR SVEN M. DEUTSCHMANN, ROCHE DIAGNOSTICS GMBH, GERMANY
Sven Deutschmann studied biology at the University of Braunschweig where he obtained his PhD in cell culture technology. In 1995 he joined Boehringer Mannheim GmbH, now Roche Diagnostics GmbH, as Manager QC. Since 2001 he is Director of the Microbiology QC Department.

DR ANJA FRITSCH, CONFARMA FRANCE
Anja Fritsch studied biochemistry and gained her PhD in 2004. After a post-doc period at the University of Freiburg, she joined Confarma in 2011 as Chief Scientific Officer. Her main field of interest is the development of cell-based assay systems for the analysis of variety of biological reactions.

BARBARA GERTEN, MERCK KGAA, DARMSTADT, GERMANY
After her studies in microbiology and biochemistry, Barbara Gerten was employed in different companies responsible for QC and R+D. Since 2008 she is head of the laboratory RTU Media / Validation at Merck KGaA. She is a member in several national and international bodies of microbiological topics in ISO and CEN.

DR MARCEL GOVERDE, MGP CONSULTING, SWITZERLAND
Mr Goverde studied biology at the University of Basel, where he gained his PhD in 2001. From 2002-2010 he led the QC-Labs for non-sterile product testing, growth promotion, container closure testing, environmental monitoring and preservative effectiveness testing at F. Hoffmann-La Roche Ltd. From 2010-2011 he worked as a QC expert for microbiology at Novartis Pharma at the chemical department. Since 2003 he is the Swiss delegate in the EDQM group for modern microbiological methods. In 2011 he set up his own company for consulting, training and project management.

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

LAURENT LEBLANC, BIOMERIEUX, FRANCE

DR ROBERT J. MELLO, CDER, FDA, USA
Dr Mello is a senior microbiology reviewer within the New Drug Microbiology Staff, Office of Pharmaceutical Science, CDER, FDA. He earned a B.S. in Biology from Providence College and a Ph.D. in Biochemistry from the Johns Hopkins University School of Medicine. Dr. Mello, joined FDA in 2005. He is a member of the FDA team that produced the recent FDA Guidance for Industry on Pyrogen and Endotoxins Testing: Questions and Answers, and is also a member of the Agency's Pyrogenicity Working Group assessing alternative methods of pyrogen testing.

DR WOLFGANG MUTTER, HYGLOS GMBH, GERMANY
Wolfgang Mutter studied Biology at the University Tübingen.. he was employed in different positions at Boehringer Mannheim/Roche Diagnostics from 1998 to 2004. Until 2008 he was member of the executive board of Profos AG. Since 2009 he hold he is CEO of Hyglos GmbH.

PROF DR URSULA OBST, MICROBIOLOGIST, GERMANY
Head of Department Microbiology of Natural and Technical Interfaces, Institute of Functional Interfaces, Karlsruhe Institute of Technology. She studied Biology at Ruperto Carola, Heidelberg. From 1977- 78 she was head at DGF Stoess, Eberbach, followed by positions as scientific officer, Head of Water Quality Dept. and Managing Director at Municipal Waterworks of Mainz. In 2001 she joined KIT and since 2007 she is Deputy Director of the institute and professor at Karlsruhe University.

Speakers (cont'd)

DR SÉBASTIEN RIBAULT, PHD, DIRECTOR BIOPRODUCTION & DEVELOPMENT, BIOPHARM PROCESS SOLUTION, MERCK MILLIPORE, MARTILLAC, FRANCE
Dr Ribault received his Microbiology Engineer degree in 1997 from the Engineer School of Luminy, Marseille, France and his PhD in Molecular and Cellular Biology in 2001 from the University of Strasbourg. Previously to his current position, he was Head of the Predevelopment – Technology – Collaboration Biomonitoring R&D group and Head of the Applied Biology Group in Merck Millipore, Molsheim.

TIM SANDLE, BIO PRODUCTS LABORATORY, UK
Tim Sandle has over twenty years experience of working in the pharmaceutical industry. Tim has worked both as a parasitologist and microbiologist. Tim has extensive experience of cleanrooms, water testing, endotoxin analysis, microbial identifications, sterility testing, aseptic filling and risk assessment. In addition Tim has published over seventy articles and book chapters on the subject of pharmaceutical microbiology.

DR MAXIMILIAN SCHLICHT, LABOR L+S AG, BAD BOCKLET, GERMANY
After a postdoctoral research at the well-respected lab of Prof. Hillen, Erlangen, he joined Bio-Rad in 2007 and worked as a key account manager in Germany. Since 2010 he is employed at Labor L+S AG as head of department for testing of bacterial endotoxins and molecular biological assays.

DR HERBERT SCHMIDT, WHO, SWITZERLAND
Dr Herbert Schmidt is a pharmacist and earned his PhD in 1997 in analytical chemistry at the University of Münster / Germany. Between 1997 and 2007 he worked for two German Official Medicine Control Laboratories in the quality control and quality assurance of medicines. During the years 2007 - 2010 he gained experience as an inspector in a GxP Inspectorate, Düsseldorf, Germany. Since 2010 Dr Herbert Schmidt has been working for WHO in the Programme Quality Assurance and Safety: Medicines.

ANKE SCHULZ, MERCK/MILLIPORE, GERMANY
Anke Schulz worked as a Technical Assistant in the pharmaceutical field prior to her study of Nutrition with the focus on Marketing and Sales in Food Industry. In 2008 she joined the Biotest AG (today Merck Millipore). In 2009 Anke became the international Product Manager for pyrogen testing. This position includes the technical support of the PyroDetect System based on the Monocyte-Activation Test (MAT).

ROBERT SCHWARZ, BAXTER AG, VIENNA
After his apprenticeship as medical/technical analyst Robert Schwarz joined at IMCL / Labor Hernals, Vienna. From 2001 to 2005 he stays as coordinator of environmental monitoring at Baxter, Vienna. Since 2005 he is validation specialist for equipment qualification. He is responsible for the validation of the room disinfection systems.

ALEXANDRA STÄRK, NOVARTIS PHARMA STEIN, SWITZERLAND
After studying Hygiene Technology at the Technical University of Albstadt-Sigmaringen, Alexandra Stärk has worked since 1995 at Novartis Pharma AG in Basel/Stein. She is currently responsible for the microbiological QA and QC. She plays a key role in rapid microbiology and in microbiology for sterile production.

NICOLA LOUISE SWIFT BSC MSB CBIOL, CHARLES RIVER ENDOTOXIN AND MICROBIAL DETECTION DIVISION
Nicola studied at the University of Liverpool and holds a 2:1 BsC (Hons)Microbiology. After that she held different microbiological positions in North West Water Laboratories, and Liverpool Pharmacy Practice National Health Service and in QC of Baxter Healthcare. 2003 she joined Charles River as Technical Sales Manager, looking after customer accounts in England, Wales and Northern Ireland. Providing expertise in Endotoxin Analysis including product validation, all aspects of testing and also Rapid Microbiology (Gram ID).

RADHAKRISHNA TIRUMALAI, PH.D., USP, ROCKVILLE, MD, USA.
Dr Tirumalai has been at the USP since 2003 and is currently a Principal Scientific Liaison in General Chapters / Science and Standards. He is the Staff Liaison to the USP Expert Committees on Microbiology, and Toxicology. He represents USP on PDA expert task forces and committees related to Microbiology and Sterility Assurance and on AAMI expert Working groups related to Microbiology, Sterility Assurance and Biocompatibility. He holds a Ph.D. degree in Biochemistry.

Social Event

As a delegate of the European Microbiology Conference or of both the European Endotoxin and Pyrogen Testing Conference and the European Microbiology Conference you are cordially invited to a social event on 9 May 2012. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

Easy Registration

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

Reservation Form:
+ 49 6221 84 44 34

e-mail:
info@concept-heidelberg.de

Internet:
www.microbiology-conference.org
www.gmp-compliance.org

Dates

European Endotoxin and Pyrogen Testing Conference
Tuesday 08 May 2012 09.00 – 18.00 h
(Registration and coffee 08.30 - 09.00 h)

European Microbiology Conference
Wednesday, 09 May 2012, 09.00 – 17.30 h
(Registration and coffee 08.30 - 09.00 h)
Thursday, 10 May 2012, 08.30 – 16.30h

Venue

WELCOME HOTEL FRANKFURT
Leonardo-da-Vinci-Allee 2
60486 Frankfurt/Main, Germany
Phone +49 (0)69 770 670 0
Fax +49 (0)69 770 670 444

Fees per delegate, + VAT

European Endotoxin and Pyrogen Testing Conference
ECA Members EUR 790.-
APIC Members EUR 840.-*
Non-ECA Members EUR 890.-
EU GMP Inspectorates EUR 445.-

European Microbiology Conference
ECA Members EUR 1,590.-
APIC Members EUR 1,690.-*
Non-ECA Members EUR 1,790.-
EU GMP Inspectorates EUR 895.-

European Endotoxin and Pyrogen Testing Conference TOGETHER with the European Microbiology Conference
ECA Members EUR 2,080.-
APIC Members EUR 2,180,-*
Non-ECA Members EUR 2,280.-
EU GMP Inspectorates EUR 1,140.-

The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the 9 May 2012, lunch on all three days and all refreshments during the conferences. VAT is reclaimable.

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" to receive the specially negotiated rate (single room € 108,- per night, incl. breakfast) for the duration of your stay. Reservation should be made directly with the hotel not later than 10 April 2012. Early reservation is recommended.

*does not include ECA Membership

Registration

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

Conference Language

The official conference language will be English.

Organisation and Contact

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
info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content:
Axel Schroeder (Operations Director) at +49-62 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 +49-62 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

☐ **European Endotoxin and Pyrogen Testing Conference**
8 May 2012, Frankfurt/Main, Germany

☐ **European Microbiology Conference**
9-10 May 2012, Frankfurt/Main, Germany

☐ **European Endotoxin and Pyrogen Testing Conference AND European Microbiology Conference**
8-10 May 2012, Frankfurt/Main, Germany

☐ Mr ☐ Ms

Title, first name, surname

Company Department

Important: Please indicate your company's VAT ID Number **Purchase Order No. if applicable**

Street / P.O. Box

City Zip Code

Country

Phone / Fax

E-Mail (Please fill in)

General terms and conditions
If you cannot attend the conference you have two options:
1. We are happy to welcome a substitute colleague at any time.
2. If you have to cancel entirely we must charge the following processing fees: Cancellation
- until 2 weeks prior to the conference 10 %,
- until 1 weeks prior to the conference 50 %
- within 1 week prior to the conference 100 %.

CONCEPT HEIDELBERG reserves the right to change the materials, instructors, or speakers without notice or to cancel an event. If the event must be cancelled, registrants will be notified as soon as 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.
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)!

wa/vers1/15122011