



Invitation to
The University of Heidelberg

Speakers:

Sander van den Ban
GSK, UK

Dr Lina Ertle
ANSM, France

Dr James Evans
Hospira Boulder, USA

Prof Brian Glennon
*UCD School of Chemical and
Bioprocess Engineering
University College Dublin,
Ireland*

Roland Guidat
Corning SAS, France

Dr Karthik Iyer
FDA, CDER, USA

Dr Conor McSweeney
Pfizer Global Supply, Ireland

Dr Gabriele Reich
*Faculty of Biological Sciences,
University of Heidelberg,
Germany*

Dr John O'Reilly
Roche Ireland

Prof Steve Wicks
*The School of Science, University
of Greenwich, Medway Campus,
UK*

Dr Janet Woodcock
CDER, FDA, USA

Dr Axel Zeitler
University of Cambridge, UK

QbD / PAT Conference 2013

16 - 17 October 2013
Heidelberg, Germany



Including a key-note presentation from
Dr Janet Woodcock, Director CDER, FDA
on the expectations for the next 25 years

Co-sponsored by



Key Topics:

- The pivotal Role of PAT / QbD
- Close the gap between Practice and Performance
- From API to Drug Product Manufacture
- Batch and Continuous Processes

The University of Heidelberg QbD / PAT Conference 2013

16 - 17 October 2013, Heidelberg, Germany

About the University of Heidelberg



The University of Heidelberg is one of the **top-ranked institutions of international science and scholarship**. Being Germany's oldest University with a six-hundred-years history, innovative research and modern teaching has always been the major focus. Accordingly, the university plays an active role in **education of the decision-makers of tomorrow**.



Institute of Pharmacy and Molecular Biotechnology (IPMB)

The Institute of Pharmacy and Molecular Biotechnology (IPMB) is part of the Faculty of Biological Sciences. The research activities of the IPMB cover a wide range of topics with strengths in drug discovery, drug delivery, molecular biology and biotechnology, bioinformatics and instrumental analysis. In the field of instrumental analysis, a broad range of techniques are used routinely. Major research activities are concerned with Near Infrared Spectroscopy (NIRS) and Chemical Imaging. Both techniques are among the most important analytical tools within the framework of the Process Analytical Technology (PAT) initiative, a key element for improved process understanding, drug quality and drug safety. **To this end, the IPMB defines itself as a PAT Competence Center with the opportunity to enhance the knowledge for many PAT technologies.** This makes the IPMB a partner for industry and authorities. In order to facilitate the knowledge transfer from university to industry, the IPMB collaborates with many national and international pharmaceutical companies. In addition, the IPMB has strong collaborative interactions with nearby research centers and provides extensive teaching and training to undergraduate, graduate and Ph.D. students.

Invitation to the QbD / PAT Conference 2013



Dear Sir or Madam,

After eight successful Conferences from 2005 to 2012 which tracked the evolution of PAT and QbD, we would like to invite you to participate in

The University of Heidelberg International QbD / PAT Conference 2013.

Once again, this event will provide a broad ranging platform for informative and interactive discussions with contributions by recognised experts from:

- industry
- regulatory authority
- academia

This year's programme will focus on the pivotal role PAT plays in delivering the levels of process understanding and process control necessary to enable efficient RTR testing in pharmaceutical batch manufacturing and successfully implement QbD and the new concepts of process validation, e.g. accelerate the transition from process design to continuous verification over the product lifecycle. Practical applications will be presented and potential hurdles will be discussed including regulatory expectations and technical approaches to drug product development and manufacture. In addition, the opportunities and challenges critical to continuous processing will be addressed.

This year's conference will provide an A to Z perspective of the pharmaceutical production process from API to formulated product. The performance of the pharmaceutical production cannot be improved significantly if you do not look at it holistically.

The conference offers a broad range of highly interactive sessions with case studies and lectures where experts will share their knowledge and experiences in the following areas:

- The pivotal role of **PAT / QbD**
- Close the gap between **Practice** and **Performance**
- From **API** to **Drug Product Manufacture**
- **Batch** and **Continuous Processes**

It would be a great pleasure for me to welcome you in Heidelberg on behalf of the Institute of Pharmacy and Molecular Biotechnology.

A handwritten signature in blue ink, appearing to read 'G. Reich'.

Dr Gabriele Reich
IPMB, University of Heidelberg

Regulatory Background and Objectives

This year is the 10th anniversary of the publication of the draft PAT Guidance and coincidentally the 50th anniversary of the introduction of Good Manufacturing Practice.

Today after 10 years active involvement with PAT and QbD, all manufacturing sectors of the industry are still seen as failing to perform at levels commensurate with society's current expectation.

Plainly in spite of PAT and QbD current Good Manufacturing Practice is no longer capable of delivering Good Manufacturing Performance.

This conference will take a holistic overview of how the principles of PAT and QbD which have evolved in many application areas in the interim, could be extensively deployed to close the gap between Practice and Performance across the manufacturing spectrum from:

- API manufacture
- particle engineering
- formulated product manufacture
- setting meaningful specifications
- designing and implementing controllable processes

using continuous verification to consistently deliver:

- right first time performance
- high levels of equipment utilisation
- significant product lead time reduction

in both batch and continuous processes.

Regulatory agencies from Europe and the US will also outline developments in regulatory practice, which will speed the adoption and control of these evolving manufacturing developments.

Moderator

Dr Gabriele Reich, IPMB, University of Heidelberg

Social Event



After an intensive first conference day, all speakers and participants are invited to a dinner in the pleasant atmosphere of a traditional restaurant in Heidelberg. Here you will have the opportunity to establish new contacts, discuss technical matters in more detail, or just relax. Furthermore, you are invited to a guided tour of the historical city of Heidelberg. The participation in this tour will also be free of charge.

Conference Programme

► Session 1 Setting the Scene

■ Welcome by the University

Dr Gabriele Reich, IPMB, University of Heidelberg, Germany

■ If Quality by Design supported by Process Analytical Technology is the solution, what was the problem?

- Is it now time to rethink our understanding of pharmaceutical quality and how can it be achieved?
- If PAT is to play a role in support of Quality by Design principles, do we need to abandon current manufacturing technology and think differently about the way we manufacture?
- Is it now time to move to clinically relevant material specifications based on process performance rather than chemical attributes?
- Should the pharmaceutical industry business models and accounting processes change to pave the way for the modernisation of pharmaceutical manufacturing?
- Regulators have been very patient about the pharmaceutical industry's resistance to adopt QbD – are we seeing the beginning of the end?

Prof. Steve Wicks, University of Greenwich, UK

► Session 2 Process Understanding and Control of Active Pharmaceutical Ingredients (APIs)

■ Bridging the gap between Process Quality and Quality Control with PAT

- QC-PAT
- Virtual samples
- Sustainability
- Process Verification in real time

Dr John O'Reilly, Roche, Ireland

■ Case Study: Implementation of an In-process Mid-IR PAT System for the Safe Operation and Control of a Sodium Borohydride Reduction Reaction

- Extremely hazardous reaction
- Large scale
- Process Variations
- Seeing the chemistry

Dr John O'Reilly, Roche, Ireland

■ Engineering Particles – the key to Deliver better Drug Product

- Understanding processes to facilitate better process control
- Role of PAT in optimising Particle Engineering
- Matching API properties with Drug Product requirements
- Case studies to illustrate each point.

Prof Brian Glennon, University College Dublin, Ireland

► Session 3 Process Understanding and Control for Finished Dosage Forms

■ Applied Process Understanding in Drug Product Development: a Combined Pharmaceutical Science, Materials Science and Chemical Engineering Approach

- Understanding structure-performance relationship of formulation, excipients and process, is a key element in quality by design (QbD) and assurance of product quality
- Structure- performance relationships support identification of critical attributes of excipient and formulation in product design in support of right level of assurance for product quality
- A combined modelling approach for formulation structure & excipient functionality is provided to demonstrate its use in data driven systematic development
- Used to demonstrate the link to measurement, control and monitoring of critical aspects of the formulation and manufacturing process to ensure security of supply of quality product to patient

Sander van den Ban, GSK, UK

■ The relative Strengths and Weaknesses of Spectroscopy across the Spectrum

- From MHz to EHz: dielectric spectroscopy to X-ray fluorescence
- Special focus on vibration spectroscopy: THz-TDS, FT-IR, Raman and NIR
- What information can be extracted from different spectra
- Pick the right tool for your PAT application
- Know the limits of the techniques

Dr Axel Zeitler, University of Cambridge, UK

■ Designing and Implementing Controllable Processes – Novel Approaches to be named

■ Case Study: The Use of Applied Modelling Approaches to Improve Product Performance in Design and in Setting Meaningful Specifications

- In the early (development) phase of a product the emphasis is in understanding product performance, and the impact of process and excipients
- Understanding impact of variability on product will dramatically change from early phase design and development to the products' commercial supply phase
- Modelling can be used to set meaningful, relevant specifications for the product including estimates of anticipated variability
- The success of the design phase is linked to how well anticipated variability will match actual introduced variability in the commercial supply of the product
- Examples are given of how materials science and process modelling can be used in design and understanding variability to set meaningful specifications

Sander van den Ban, GSK, UK

■ Case Study: Understanding and Control of a Tablet Coating Process

- Appropriate PAT tools to gain in-depth coating process understanding
- Challenges of coating process monitoring
- Design and performance of a multivariate NIR method for real-time monitoring of an industrial pan coating process: simultaneous determination of two CQAs, e.g. coating growth and tablet moisture content
- Limitations of PLS calibration modelling in coating process control
- Novel approach for direct coating thickness determination from real-time NIR spectral data: efficient and selective calibration without the need to reference samples
- Statistical evaluation of NIR chemical images to assess inter- and intra-tablet coating variability

Dr Gabriele Reich, IPMB, University of Heidelberg, Germany

► Session 4 Real Time Release

■ Case Study: The Manufacturing Benefits of Real Time Release

- RTR Activity in Pfizer
- Case Study of RTR project
- Overview of Regulatory Queries and the different expectations
- Return on Investment

Conor McSweeney, Pfizer Global Supply, Ireland

► Session 5 Continuous Manufacturing

■ Case Study: Continuous API Manufacture

- Why you can go faster from lab to API production through "Advanced-Flow™ Reactor"
- Quality by design with continuous flow reactor (Proven Acceptable Range of parameters)
- On line effective Process Analytical Technology
- cGMP / Cleaning procedure in a continuous flow reactor

Roland Guidat, Corning, France

■ Case Study: Integrated Continuous Manufacturing of Pharmaceuticals

- How integrated CM offers a paradigm shift in pharma manufacturing
- The rationale, opportunities and challenges for CM
- The global perspective
- Case study of first of its kind end to end manufacturing plant

Dr James Evans, Hospira Boulder, USA

► Session 6 Regulatory Perspectives

■ The Role and Relationship of CGMP Statistics with Pharmaceutical Quality

- Recent enforcement action examples
- CGMP statistical references
- Bioequivalence
- Use of Consensus Standards for Pharmaceutical Manufacturing quality

Dr Karthik Iyer FDA /CDER
(via video conference)

■ NIRS; PAT, RTR testing - EU Experience and Regulatory Perspective

- NIRS used in pharmaceutical industry for qualitative and quantitative analysis
- Often associated to Process Analytical Technology and Real Time Release
- The variety of applications represent challenge for both regulators and applicants
- Consequently there is no standard approach: applicants should clearly define:
 - the scope
 - justify all assumptions and claims
 - provide supportive and comprehensive data in tabulated format

Dr Lina Ertle, ANSM, France

■ What to expect in the next 25 years of medicine?

This lecture is closing with a question and answer session

Dr Janet Woodcock, Director for Drug Evaluation and Research (CDER), FDA, USA
(via video conference)

Speakers



Sander van den Ban, GSK, UK

Sander van den Ban is a Product Lead in Global Manufacturing & Supply for GlaxoSmithKline. He has worked in the Pharmaceutical Industry for over 10 years in various positions as Chemical Process Engineer in Research and Development, Engineering Technology and Capital Management, and Process Design and Development. He has been a Product Lead in the Oral Solid Dose Centre of Excellence since 2009 and accountable for the transfer and introduction of well understood reliable manufacturing processes for tablet dosage forms from R&D into manufacturing with particular focus on QbD and interaction with US, European and International regulatory agencies.



Dr Lina Ertle, ANSM, France

Dr Lina Ertle is head of quality assessment unit at the French Agency. She holds a doctorate in Pharmacy (1990) and a master in Pharmaceutical Technologies (1991) from the University of Montpellier (France). From 1991 to 2002, she held management positions in QC and QA for Solvay Pharmaceuticals and MSD laboratories. In 2003, she joined the department of inspection at the French Agency and was promoted to head of quality assessment unit in February 2010. She has been extensively involved in the EMA PAT team and in the EDQM PAT team and is member of EMA QWP. She actively contributes and lead discussions through EU on the guidelines and chapters concerning implementation of PAT and ICH Q8, 9 and 10 in pharmaceutical industry.



Dr James Evans, Hospira Boulder, CO, USA

Dr Evans has extensive experience in API pharmaceutical manufacturing and R&D for both MNC's and biotech companies and is currently Director of MS&T at Hospira, leading the development of an API manufacturing CoE. Previously he was Associate Director at the Novartis-MIT Center for Continuous Manufacturing responsible for delivering the first of its kind, bench scale, Integrated Continuous Manufacturing platform that can be utilized as a model and learning tool for transforming the pharmaceutical manufacturing paradigm. Dr Evans received his PhD in Chemical and Process Engineering from Herriot Watt University and an MS in Instrumentation and Analytical Chemistry from UMIST.



Prof. Brian Glennon, UCD School of Chemical and Bioprocess Engineering, University College Dublin, Ireland

Brian Glennon is Professor of Chemical Engineering at the School of Chemical & Bioprocess Engineering, University College Dublin. His main research interest is in Pharmaceutical Process Engineering. He is also Director and Co-Founder of APC Ltd, a Pharmaceutical Process Engineering company delivering process engineering solutions and technologies to the international pharmaceutical industry.



Roland Guidat, Corning SAS, Samois sur Seine, France

Roland Guidat is Chief Reactor Engineer at Corning Advanced Flow reactors since 2007. He has more than 35 years' experience in the chemical industry, both in production plant and as supplier of equipment. He was Head of Manufacturing department at ICI (specialities Chemicals), and worked in production, Engineering and maintenance at Solvay and Hoechst. He was also Technical manager in a pump manufacturer, managing director of a reactor and exchanger company, founder and managing director of a company dedicated to design and Marketing of large welded plate heat exchangers (several thousands of m² in one piece).

Speakers



Dr Karthik Iyer, FDA, CDER, USA
(via video conference)

Karthik Iyer (ASQ CSSBB, CQE) works as a senior policy advisor in FDA/CDER/OC/OMPQ. His main responsibilities are to support both CDER and ORA with respect to CGMP manufacturing statistics (sampling, statistical process control, process validation, use of statistical consensus standards). His prior experiences include refining, chemical, and consumer products industries with an emphasis on manufacturing statistics. He has a BS in Chemical Engineering from the University of Illinois, an MBA from the University of Iowa, and a MS in Biosciences Regulatory Affairs from Johns Hopkins University respectively.



Dr Conor McSweeney, Pfizer Global Supply, Ireland

Conor McSweeney graduated from University College Cork (UCC) in 1998 with a PhD in Analytical chemistry having previously completed an Honours Chemistry Degree from UCC in 1994. He worked in the Loughbeg API plant in Ireland as an Analytical Chemistry Specialist from 1998 -2001 and he then moved to the Loughbeg Drug product plant and took up the role as Chemistry laboratory Co-ordinator. Conor started working with Process Analytical Sciences Group in 2006 as a Senior Scientist and was promoted to Manager-PAT project in 2008.



Dr Gabriele Reich, Faculty of Biological Sciences, University of Heidelberg, Germany

Gabriele Reich is Senior Lecturer for Pharmaceutical Technology and Biopharmaceutics at the Institute of Pharmacy and Molecular Biotechnology (IPMB), Faculty of Biological Sciences, University of Heidelberg and Research Group Leader at IPMB / Department of Pharmaceutical Technology and Biopharmaceutics.



Dr John O'Reilly, Manufacturing Science & Technology, Clarecastle, Roche Ireland

Joined Roche/Syntex at Clarecastle in 1981 as a process development chemist. Worked as analytical development chemist on a wide variety of products for large, medium and small scale production including materials for clinical trials. Began implementing PAT solutions in 1985. Currently involved in all aspects of analytical technology transfer, analytical development and innovation. A Core member of the Process Analytical Technology team at Roche focussed on the development and implementation of sustainable PAT systems at Clarecastle and in the wider Roche manufacturing community.



Prof Steve Wicks, The School of Science, University of Greenwich, Medway Campus, Kent, UK

Steve is Professor of Pharmaceutical Sciences in the School of Science. Prior to this he spent 25 years with Pfizer Inc. rising to become a Vice President of Science and Technology in the Pfizer Global Research and Development division and a member of the Pfizer UK Group Ltd Board of Directors. Currently, Steve co-leads the Medway Pharmaceutical Sciences Centre (Director of Research and Enterprise) that provides executive education in Quality by Design and Quality Risk management. Scientific programmes include: flow chemistry, complex drug-cyclodextrin interactions, pharmaceutical materials science and veterinary formulation science.



Dr Janet Woodcock, CDER, FDA, USA
(via video conference)

Janet Woodcock is the director of the Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration (FDA), USA. Dr. Woodcock has led many of FDA's drug initiatives. She introduced the concept of risk management in 2000 as a new approach to drug safety. Since 2002, she has led the "Pharmaceutical Quality for the 21st Century Initiative," FDA's highly successful effort to modernize drug manufacturing and its regulation. In 2004, she introduced FDA's "Critical Path" Initiative, which is designed to move medical discoveries from the laboratory to consumers more efficiently. Most recently, Dr. Woodcock launched the "Safety First" and "Safe Use" initiatives designed to improve drug safety management within and outside FDA, respectively.



Dr Axel Zeitler, University of Cambridge, UK

Dr Axel Zeitler is a University Lecturer at the Department of Chemical Engineering and Biotechnology, University of Cambridge where he leads the Terahertz Applications Group. He is a Fellow and Tutor at Gonville & Caius College where he was a Research Fellow prior to his current appointment. In addition to his university position he holds a College Lectureship in Chemical Engineering as well as in Chemistry. Dr Zeitler completed his PhD at the School of Pharmacy, University of Otago, New Zealand following his undergraduate degree at the University of Würzburg, Germany. He has held research positions at the Cavendish Laboratory, University of Cambridge, UK and TeraView Ltd., also in Cambridge, UK.

Conference Exhibition - Supplier Support for QbD and PAT

During the two conference days, leading suppliers of PAT-related equipment are invited to exhibit their products in a presentation room, allowing participants

- to get to know systems from various manufacturers,
 - to personally meet with potentially interesting suppliers
- and
- to learn more about the performance of the latest equipment.

Please contact Ms Marion Weidemaier for further information on the opportunity to exhibit at the conference: Phone +49(0)62 21-84 44 46
Fax +49(0)62 21-84 44 34
E-Mail: weidemaier@concept-heidelberg.de.



Welcome to Heidelberg

Heidelberg is known for its world-famous Castle and the picturesque Old Town in breathtakingly beautiful surroundings. The city also stands for **Germany's oldest university and modern research facilities**, for historic streets and a lively university atmosphere as well as for total relaxation and beautiful walks, plus stimulating international conferences and festivals.



Fly to Frankfurt and stay in Heidelberg - one of the most beautiful cities in Europe

Heidelberg – Optimal Accessibility via Frankfurt

Airport Shuttle Service: PCS & HLS
Phone: +49 (0)6221 – 164 664
Fax +49 (0)6221 – 183 094
pcs@pcs-hd.de / www.pcs-hd.de
approx. 70 € one way (as of January 2012)

Lufthansa Airport Shuttle
Booking and fares:
Phone +49 (0)6152 – 97690-99,
Fax +49 (0)6152 – 97690-21,
info@frankfurt-airport-shuttles.de,
<http://www.transcontinental-group.com/en/frankfurt-airport-shuttles>

Train:
You can get on the train directly at the Airport. Trains leave up to two times per hour and it takes less than an hour to get to Heidelberg (cost: approx. 25€). <http://www.bahn.de>

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.

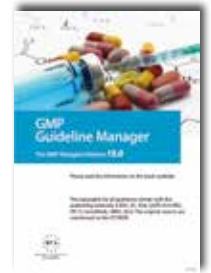
What Are the Benefits of ECA?

First benefit:

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

Second benefit:

The GMP Guideline Manager Software with a large number of guidelines, e.g. EU Directives, FDA Guidelines, ICH Guidelines, will be forwarded to you when you are using your membership for a conference registration.



How Do You Become a 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. 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 <http://www.gmp-compliance.org>.



Special Offer with Lufthansa – Discounted Travel for QbD/PAT Conference 2013 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!

*Please note: You may have to enable pop-ups on the Mobility Partner Program website – otherwise the booking platform window will not open.

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.pat-conference.org

Date

Wednesday, 16 October 2013, 09:00 – 18:30 h
(Registration and coffee 08:00 – 09:00 h)
Thursday, 17 October 2013, 08:30 – 16:30 h

Venue

Crowne Plaza Hotel Heidelberg
Kurfürstenanlage 1
69115 Heidelberg
Germany
Phone +49(0) 62 21 – 917 – 0
Fax +49(0) 62 21 – 917 – 100



Fees

ECA Members € 1,690.- per delegate plus VAT
APIC Members € 1,790.- per delegate plus VAT
Non-ECA Members € 1,890.- per delegate plus VAT
EU GMP Inspectorates € 945.- 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.

Conference language

The official conference language will be English.

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 room rate for the duration of your stay. Reservation should be made directly with the hotel. Early reservation is recommended.

Organisation and Contact

CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg, Germany
Phone +49 (0) 62 21/84 44-0
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For questions regarding content:

Dr Günter Brendelberger (Operations Director)
at +49 (0) 62 21 / 84 44 40 or per e-mail at
brendelberger@concept-heidelberg.de

For questions regarding reservation, hotel, organisation etc.:

Ms Marion Weidemaier (Organisation Manager)
at +49 (0) 62 21 / 84 44 46 or per e-mail at
weidemaier@concept-heidelberg.de

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

CONCEPT HEIDELBERG
Postfach 10 17 64
Fax 06221/84 44 34

D-69007 Heidelberg

Reservation Form (Please complete in full)

The University of Heidelberg QbD / PAT Conference 2013

16 - 17 October 2013, Heidelberg, Germany

Mr Ms

Title, first name, surname

Company

Department

Important: Please indicate your company's VAT ID Number **Purchase Order Number, 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). (As of January 2012)