Invitation to

The University of Heidelberg

Speakers:

DR ALI AFNAN
Step Change Pharma, USA, previously with FDA

PROF DR CARL ANDERSON
Duquesne University, USA

DR IAN CLEGG
Pfizer, UK

DR PAUL FRAKE
GSK, UK

DR RICCARDO LUIGETTI
European Medicines Agency (EMA), UK

INGRID MAES
PricewaterhouseCoopers, Belgium

DR GAWAYNE MAHBOUBIAN-JONES
Philipp Morris International, Switzerland

DR PETER POECHLAUER
DSM Pharma Chemicals, Austria

DR ALAIN PRALONG
ENABLE GmbH, Switzerland

PROF ROB PRICE
Bath University, UK

DR GABRIELE REICH
IPMB, University of Heidelberg, Germany

DAVE RUDD
GSK, UK

DR VIBHAKAR SHAH
CDER, FDA, USA

MARTIN WARMAN
Vertex Pharmaceuticals Inc., USA

With FDA and EMA Speaker!

QbD / PAT Conference 2011

Impact of FDA's new Process Validation Guidance on QbD and PAT

5 - 7 October 2011,
Heidelberg, Germany

Co-sponsored by

ECA
European Compliance Academy

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 2011

Dear Sir or Madam,

After six successful Conferences from 2005 to 2010 which tracked the evolution of QbD from PAT, we would like to invite you to participate in

The University of Heidelberg International QbD / PAT Conference 2011

which will specifically review QbD/PAT in the context of **FDA's recently issued Process Validation Guidance.**

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

- regulatory authorities (EMA and FDA)
- industry
- academia

While this year's programme will still focus on the pivotal role PAT plays in delivering the levels of process understanding and process control necessary to underpin Quality by Design it will do so in the context of **the new range of opportunities and challenges continuous verification offers for demonstrating on line compliance, from small to large molecules, over the product lifecycle and the additional value it can bring to manufacturing performance.**

The workshop content will provide all delegates with an broad range of highly interactive sessions where experts will share their experiences in the following areas:

- The Limitations of Batch Processing and the Benefits of Continuous Processing for APIs
- Particle Engineering - Bridging the Gap between API and Drug Product Manufacture
- Practical Challenges in the Application of QbD in Drug Product Manufacturing
- How Continuous Verification Impacts Design Space
- Biotechnology – The Manufacturing Challenge where the Process is the Product
- Creating Data Management Platforms which will support Process Control for Continuous Production, Improvement and Traceabillity

These developments are equally applicable to new, legacy and generic product development and manufacture and are holistically pivotal to achieving the significant step change in industry performance still being sought, as is the content of the complementary series of case studies/applications in the lecture programme.
It would be a great pleasure for me to welcome you in Heidelberg on behalf of the Institute of Pharmacy and Molecular Biotechnology.

Dr Gabriele Reich
IPMB, University of Heidelberg

The Heidelberg QbD / PAT Conference 2011

5 - 7 October 2011, Heidelberg, Germany

Regulatory Background and Objectives

Throughout the 90's Regulatory agencies, FDA in particular, became increasingly concerned that validated processes could fail to produce consistent product quality efficiently.

By the turn of the century industry and agencies had jointly recognised that the ability to meet society's ever increasing healthcare expectation would require a significant step change in the industry's performance.

The next seven years saw the delivery of the PAT Guidance, cGMP for the 21st Century, the Critical Path Initiative and latterly QbD, which described the basic "building blocks" to address the key challenges to:

- successfully shift from empirical to science based standards for manufacturing process performance and quality
- identify and adopt appropriate technologies which will deliver these objectives
- encourage and manage the necessary innovation without compromising current quality performance.

Yet in spite of efforts to drive the innovation industry performance over the last decade has, at best, "flat lined".

The major reason for this is that industry has undergone and is still undergoing dramatic change the scale of which few would have predicted.

As a result the far more efficient, agile, flexible pharmaceutical manufacturing environment capable of reliably producing high-quality drug products without extensive regulatory oversight is still some way off.

Not surprisingly business performance expectations based on traditional business models are becoming increasingly difficult to sustain.

Initially significantly improved alignment across research, development and manufacturing was seen as key to successful PAT/QbD performance outcomes, and it still is.

However it is now increasingly apparent that there needs to be much greater understanding and clarity of the interactions between and across regulatory guidances if the changes outlined in the critical path initiative are to be achieved.

So there are still many significant issues to be addressed.

To these ends this year's conference theme will be based on Industry challenges and opportunities in the light of the recent Process Validation Guidance with particular reference to the transition to continuous verification in its application to:

- small and large molecules
- batch and continuous operations
- API, legacy and biotech manufacturing

With an **extensive Workshop programme** covering

1. The Limitations of Batch Processing and the Benefits of Continuous Processing for APIs
2. The pivotal role of particle engineering in improving process performance
3. Practical Challenges in the Application of QbD in Drug Product Manufacturing
4. How Continuous Verification Impacts on the Design Space
5. Biotechnology – The Manufacturing Challenge where the Process is the Product
6. Creating a Data Management Platform to Support Process Control for Continuous Production, Improvement and Traceability

Case Study Programme with topics covering

1. The Transition from Validation to Continuous Verification
2. Selecting Measurement & Control Options to Maximise Process Performance
3. Continuous Verification – Enabling Telescoped API Reactions at Multiple Scales
4. Control Engineering – Its Pivotal Role in Continuous Verification and Manufacturing Excellence
5. Novel Design to Define a Design Space in Powder Blending
6. The Compliance Revolution – The Impact on the Role of the QP and the Quality Function

and a **Regulatory Progress Insight**

7. QbD / PAT – The Benefits and Challenges – a European Overview
8. QbD / PAT – The Benefits and Challenges – an FDA Overview

The conference will also include a programme of short presentations from vendors providing equipment / support for PAT and QbD initiatives.

Moderator

Dr Gabriele Reich, *IPMB, University of Heidelberg*

Conference Programme

- **Welcome by the University**
  Dr Gabriele Reich, *IPMB, University of Heidelberg, Germany*

- **Pharma 2020: Supplying the Future**
  - Future trends in healthcare will revolutionise pharmaceutical supply chain and manufacturing
  - Timely access to various emerging technologies will increase the efficiency of the manufacturing and distribution functions
  - Collaboration between the parties involved in the healthcare provision will contribute to make the industry more efficient
  - Companies should develop different approaches for different product types and patient segments, learn to use their supply chains and manufacturing as a means of market differentiation and source of economic value, and recognise the role of information

  Ingrid Maes, PricewaterhouseCoopers, Belgium

- **The Transition from Validation to Continuous Verification**
  - Over 3 decades of practice has demonstrated amply that the 3 consecutive batch validation cannot give any assurance of quality
  - To achieve consistent quality, real time knowledge of process and product, combined with controlled loops are needed
  - Such a continuous verification system will not only deliver consistent quality, but can also facilitate meeting business efficiency and regulatory compliance objectives

  Dr Ali Afnan, Step Change Pharma, USA,
  Previously with FDA

WORKSHOP I

- **The Limitations of Batch Processing and the Benefits of Continuous Processing for APIs**
  This workshop will focus on weaknesses and strengths of batch and continuous process steps, and on options to combine batch and continuous steps. Using typical examples from small-scale synthesis labs, attendants learn to

  - recognize show stoppers in batch process scale-up
  - define continuous steps to remove batch plant limitations
  - translate batch recipes into flow recipes

  Dr Peter Poechlauer, DSM Pharma Chemicals, Austria

- **Case Study 1: Selecting Measurement & Control Options to Optimise Process Performance**
  - The benefits that will accrue from a successful implementation of the continuous verification approach to validation are totally dependent on the ability to understand, manage and control the product/process risk profile across the manufacturing process, over the product life cycle
  - This case study will review the key issues to be considered from the perspective of:
    – the range of variability the product can "tolerate"
    – the linkages between the complexity of the product and the risks resulting from the inputs and the process
    – selection of processes which are actually capable of interfacing with the most appropriate responsive measurement and control systems to monitor and manage variability

  Martin Warman, Vertex, Cambridge MA, USA

- **Case Study 2: Continuous Verification – Enabling Telescoped API Reactions at Multiple Scales**
  - Examples of using spectroscopy (Mid-IR and Raman) to profile reactions to manufacture API
  - Such an approach can provide continuous data on starting materials, products and intermediates
  - Data will be shown on chemical transformations and also on "work-up" operations and cover several orders of magnitude in physical scale

  Dr Ian Clegg, Pfizer, UK

WORKSHOP II

- **Particle Engineering**
  In the manufacture of solid dosage forms there is an increasing awareness that physical attributes of APIs and excipients are as important as their chemical attributes. This workshop will provide a detailed insight into:

  - Physical factors impacting API and excipient variability
  - How such material properties actually adversely affect processes and product performance
  - The impact of materials science assessment on process understanding and design space
  - The opportunities for manufacturing to control physical properties and even produce "designer" materials to limit the need for physical processing
  - The need to develop "physical functional" guidelines

  Prof Robert Price, University of Bath, UK

- **Case Study 3: Control Engineering – Its pivotal Role in Continuous Verification and Manufacturing Excellence**
  - Over the last 30 years, pharma has developed paradigms for process 'control' which are not delivering the step change in performance sought by industry and regulators
  - Other industry sectors have different approaches to control which are reviewed
  - The central role of the PAT and Process Validation Guidances in demonstrating the urgent need for true control of processes is examined
  - Goals for new pharmaceutical processes following these Guidances are suggested

  Dr Gawayne Mahboubian-Jones, Philipp Morris International, Switzerland

WORKSHOP III

- **Practical Challenges in the Application of QbD in Drug Product Manufacturing**

  This workshop will consider how the traditional approach to oral solid dosage form manufacture as used for legacy products can be exploited as a platform for improving process understanding to explore opportunities to incorporate Quality by Design which impact on significantly improving:

  - Selection of most appropriate measurement technology
  - Real time assurance
  - Process/product performance
  - Design for manufacture

  Dr Paul Frake, GSK, UK

WORKSHOP IV

- **How Continuous Verification Impacts Design Space**

  Process understanding is the key to pharmaceutical quality. As such, tools that enhance process understanding have a direct impact on the operating space for a pharmaceutical process. With the current outstanding analytical capabilities for continuous process verification, the relationships between process understanding, quality by design, design space, and raw materials for secondary manufacturing are very important. This workshop will explore the flexibility that continuous verification brings to a design space along with the necessity of regular review and updates of models necessary to maintain it. While process understanding is the key to pharmaceutical quality, continuous verification is pivotal to its delivery.

  Prof Dr Carl Anderson, Duquesne University, USA

WORKSHOP V

- **Biotechnology – The Manufacturing Challenge where the Process is the Product**

  Dr Alain Pralong, ENABLE, Switzerland

- **Case Study 4: Novel Approach to Establish the Design Space of Homogeneity for Endpoint Determination of Powder Blend Processes**
  - Qualitative assessment of blend homogeneity according to QbD principles
  - Principal Component Scores Distance Analysis (PC-SDA) of NIR spectral data to build a design space for blending process trajectories
  - Endpoint determination based on a solid statistical rationale
  - Real-time application to monitor powder blend processes and report blend homogeneity in QbD filings

  Dr Gabriele Reich, IPMB, University of Heidelberg, Germany

WORKSHOP VI

- **Creating a Data Management Platform to Support Process Control for Continuous Production, Improvement and Traceability**

  Real time process control or continuous manufacturing have not been regularly implemented in the pharmaceutical industry. Indeed, even the API manufacturing is more often batch-wise than continuous. The drivers creating a milieu for change include the regulators demand for knowledge, process understanding and control. Moving away from a data-rich, but knowledge poor environment challenges common working practices which cannot be satisfied with the current tools at our disposal; namely a batch record that reports adherence to standard operating practices. The need for process control and continuous verification demands a versatile, compliant, knowledge generating data platform which facilitates real time control and quality assurance.

  This workshop will explore and address the needs, the drivers and the necessary data flow across several domains to achieve a functioning compliant system supporting continuous manufacturing.

  Dr Ali Afnan, Step Change Pharma, USA, previously with FDA

- **Case Study 5: The Compliance Revolution – The Impact on the Role of the Qualified Person and the Quality Function**
  - The introduction of 'Quality by Design' concepts into pharmaceutical development and manufacture has resulted in significant ramifications for the quality organisation
  - The presentation will highlight a number of these areas and will attempt to provide guidance to help those involved in quality decisions and processes to keep pace with the changing environment.

  Dave Rudd, GSK, UK

REGULATORY PERSPECTIVE

- **QbD / PAT – The Benefits and Challenges – A European Overview**
  - Quality by Design Implementation
  - QbD EU regulators view
  - Scientific dialogue
  - EMA PAT Team
  - Variations Regulation

  Dr Riccardo Luigetti, EMA, UK

- **QbD / PAT / CPV– The 21st Century Opportunity**

  Dr. Vibhakar Shah, Consumer Safety Officer / Senior Policy Advisor, Office of Manufacturing and Product Quality, Division of Good Manufacturing Practice Assessment, CDER, FDA, USA
  (via video conference)

Speakers

DR ALI AFNAN, *Step Change Pharma, USA*
Dr Ali M. Afnan, is the president of Step Change Pharma, Inc. which offers a range of consultancy services targeting the development and delivery of Pharmaceutical Manufacturing Excellence. Dr Afnan was recruited in May 2003 by CDER, FDA to join the Agency's PAT and Drug Product Quality initiatives. He was a member of the PAT steering team and a co-author of the PAT Guidance. He had also been a member of the core team responsible for drafting, and finalizing, the most recent Guidance from FDA on Process Validation. Dr Afnan has received several FDA and CDER level awards. He left the FDA in March 2010.

PROF DR CARL ANDERSON,
Duquesne University, Pittsburgh, PA, USA
Dr Anderson received his Ph.D. in chemistry from the University of Texas at Austin. His work experience in improving pharmaceutical manufacturing includes 7 years at Aventis Pharmaceuticals and 9 years as a professor at Duquesne University in the Graduate School of Pharmaceutical Sciences.

DR IAN CLEGG, *Pfizer, Sandwich, UK*
Ian is Associate Research Fellow for PAT at Pfizer Worldwide R&D in the UK. He has extensive experience of applying PAT measurement technologies to a range of manufacturing processes. He has a PhD in Measurement science and is a regular presenter on the subject of PAT.

DR PAUL FRAKE, *GSK, Ware, Hertfordshire, UK*
Paul Frake has worked for GSK (including former versions) for

over 20 years, in both Pharmaceutical Development, R&D, and more recently in the Global Manufacturing Services organisation. He is currently the Technical Services Lead at the Global Manufacturing and Supply site at Ware, Hertfordshire.

DR RICCARDO LUIGETTI
European Medicines Agency (EMA), London, UK
Riccardo Luigetti currently works as Senior Scientific Administrator at the European Medicines Agency (EMA), where he is responsible for the co-ordination of the scientific secretariat of the Quality Working Party (QWP) and the Process Analytical Technology (PAT) Team. He is a PhD organic chemist as background qualification. Before joining EMA he has worked at University carrying out research work and as quality assessor and GMP inspector for the Italian regulatory agency.

INGRID MAES, *PricewaterhouseCoopers, Belgium*
Ingrid Maes holds a master's degree of Engineering Sciences in Chemistry & Biotechnology (Brussels University). Ingrid has 23 years' experience in the pharma, biotech and life sciences industry. Her key activity areas are: future visions, R&D and manufacturing, innovation & technology management, strategy and regulatory compliance.

DR GAWAYNE MAHBOUBIAN-JONES
Philipp Morris International, Neuchatel, Switzerland
Gawayne Mahboubian-Jones currently works for Philip Morris International as Manager – QbD. His primary responsibilities in this role are the implementation of QbD and PAT. Prior to joining PMI earlier this year, he worked for 7 years for Optimal Industrial Automation, providing PAT solutions to a wide range of pharmaceutical companies. He has trained the FDA PAT inspectors on control aspects of PAT, spoken for the FDA on the subjects of PAT and QbD, and has worked extensively with ASTM E55 to create international standards to support the application of PAT.

DR PETER POECHLAUER
DSM Pharma Chemicals, Linz, Austria
Peter Poechlauer received a PhD in organic chemistry from Innsbruck University in 1986. Two years of post-doc studies at Munich University in the Laboratories of Prof. Rolf Huisgen followed. Both activities were dedicated to the elucidation of organic reaction pathways. In 1990 he joined Chemie Linz, later OMV, as a synthetic chemist. Since 1996 he has worked with DSM as scientist, project leader and competence manager. 2003 – 2007 he headed a department of process technology. Since 2007 he has worked as principal scientist with a focus on process intensification and micro reactor technology.

DR ALAIN PRALONG, *ENABLE GmbH, Switzerland*
Alain Pralong worked from 2000 to 2004 on manufacturing Adenovaccine clinical trial material at Schering-Plough. Following a move to Roche in 2004, where he managed their transfer of Avastin process manufacturing from Genentech. From 2007 to 2008, he worked at Merck-Serono in the manufacturing of hormones used in treatment of infertility. Since 2008, Alain has been Vice President at Crucell where he led the Global Process Development Department working on various monoclonal antibodies and vaccines until the take over of Crucell by Johnson & Johnson in 2011. Alain works now as consultant for Pharma-Consulting ENABLE GmbH.

PROF ROB PRICE, *Bath University, UK*
Professor Robert Price leads the pharmaceutical surface science research group at the University of Bath, UK. Prof. Price and his team design and optimise formulations for drug delivery systems, working closely with the pharmaceutical industry in the search for the optimal physicochemical characteristics of new drug candidates for development.

DR GABRIELE REICH
Faculty of Biological Sciences, University of Heidelberg,
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 Scientist at IPMB / Department of Pharmaceutical Technology and Pharmacology.

DAVE RUDD, *GSK, Ware, UK*
David is responsible for Product Quality and the quality aspects of New Product Introduction within GlaxoSmithKline Manufacturing. Based in Ware in the UK, David has more than 30 years experience in pharmaceutical R&D and Manufacturing and has been intimately involved in the development of much of the existing regulatory guidance which covers 'Quality by Design' philosophy.

DR VIBHAKAR SHAH, *CDER, FDA, USA*
Consumer Safety Officer / Senior Policy Advisor, Office of Manufacturing and Product Quality, Division of Good Manufacturing Practice Assessment.

MARTIN WARMAN
Vertex Pharmaceuticals Inc., Cambridge, MA, USA
Martin is currently a Scientific Fellow with responsibility for PAT at Vertex Pharmaceuticals. Previously he ran a successful consultancy company supporting the development and implementation of PAT within the pharmaceutical industry. He has over 15 years relevant experience in the field having in the past led the PAT Development Team as part of the Process Analytical Support Group (PASG) within Pfizer Global Manufacturing; during which time he gained experience in developing and implementing a wide variety of PAT solutions, from spectroscopic, through chromatographic and including acoustic.

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.

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.

Conference Exhibition - Supplier Support for QbD and PAT

During the three 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 supplier

and

- to learn more about the performance of the latest equipment.

Please contact 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, weidemaier@concept-heidelberg.de.

Short Presentations (as of 29 August 2011)

- **Reactive Spectrometers for Field Based Material Analysis**
  Hans-Joachim Schmidt,
  analyticaon Instruments, Germany
- **Continuous Processing and 100% NIR Inspection in Pharmaceutical Processes**
  Dr. Sven Borchert,
  Uhlmann VisioTec GmbH, Germany

Lufthansa
Official Airline

Special Offer with Lufthansa – Discounted Travel for QbD/PAT Conference 2011 Attendees

Lufthansa German Airlines offers a comprehensive global route network linking Frankfurt, Stuttgart with major cities around the world. As the Official Airline to this event, Lufthansa offers special prices and conditions to all attendees.

To make your reservation, please click on the link you will receive with your registration confirmation and enter the access code **DEZUPP** in the "Access to Event Booking" area. 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.

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 lufthansa.mobility@dlh.de by quoting the access code as an event reference.

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. EC 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.

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, 5 October 2011, 09:00 – 18:30 h
(Registration and coffee 08:00 – 09:00 h)
Thursday, 6 October 2011, 08:30 – 18:30 h
Friday, 7 October 2011, 08:30 – 15:30 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 € 1,790.- per delegate plus VAT
APIC Members € 1,890.- per delegate plus VAT
(does not include ECA Membership)
Non-ECA Members € 1,990.- per delegate plus VAT
EU GMP Inspectorates € 995.- per delegate plus VAT

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 "QbD/PAT Conference 2011" to receive the specially negotiated room rate (€ 139,- incl. breakfast) for the duration of your stay. Reservation should be made directly with the hotel not later than 7 September 2011. Early reservation is recommended.

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
E-mail: info@concept-heidelberg.de
www.concept-heidelberg.de

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:

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

D-69007 Heidelberg

Reservation Form (Please complete in full)

The Heidelberg QbD / PAT Conference 2011
5 - 7 October 2011, Heidelberg, Germany

☐ Mr ☐ Ms

Title, first name, surname

Company

Department

Important: Please indicate your company's VAT ID Number **Purchase Order Number, if applicable**

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City Zip Code

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Phone / Fax

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

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