



Invitation to The University of Heidelberg

Speakers:

PROF DR CARL ANDERSON
Duquesne University, USA

DR JON CLARK
CDER, FDA, USA

IAN CLEGG
Pfizer, UK

DR PAUL FRAKE
GSK, UK

DR JEAN MARIE GOEFFROY
Takeda, USA

KEN J. LEIPER
Benson Associates, UK

DR RICCARDO LUIGETTI
*European Medicines Agency
(EMA), UK*

DR PETER POECHLAUER
DSM Pharma Chemicals, Austria

DR GABRIELE REICH
*IPMB, University of Heidelberg,
Germany*

DR ROBERT SCHNEPF
Merck KGaA, Germany

DR RICHARD STOREY
ASTRAZENECA, UK

MARTIN WARMAN
Vertex Pharmaceuticals Inc., USA

DR STEPHEN R. WICKS,
*Industrial Pharmacist, previously
with Pfizer Inc., UK*

DAVID WILSON
ASTRAZENECA, UK



With FDA and EMA Speaker!

QbD / PAT Conference 2010

29 September - 1 October 2010,
Heidelberg, Germany

Co-sponsored by



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 2010



Dear Madam, dear Sir,

After five successful PAT and QbD/PAT Conferences from 2005 to 2009, we would like to invite you to participate in

The University of Heidelberg International QbD / PAT Conference 2010

Once again, the aim of this event is to provide a platform for interesting and interactive discussions with:

- regulatory authority representatives (EMA and FDA)
- industry experts
- university colleagues

mutually committed to meet society's and regulator's growing expectations of the industry.

This year's the programme will again focus on the pivotal role **PAT plays in delivering the levels of process understanding and process control to underpin Quality by Design. It will also include a range of processing considerations proving increasingly important to ensure that Good Manufacturing Practice is actually more capable of delivering Good Manufacturing PERFORMANCE consistently.**

The workshop content will provide all delegates with highly interactive settings where experts from the pharmaceutical industry, regulatory authorities and international academia will share their experiences in the following areas:

- Process Understanding - Facilitating the Transition from Process Validation to Continuous Verification
- How Material Science can help bridge the gap between API and Drug Product Manufacture
- What's driving the transition from Batch to Continuous Processing
- Performance-Based Quality Specifications - Establishing a Science-Based Target for Pharmaceutical Manufacturing

These developments are equally applicable to new, legacy and generic product development and manufacture and pivotal to achieving the significant step change in industry performance being sought, as is the content of the complementary series of case studies 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.

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

Dr Gabriele Reich
IPMB, University of Heidelberg

The Heidelberg QbD / PAT Conference 2010

29 September - 1 October 2010, Heidelberg, Germany

Regulatory Background and Objectives

In many minds it was only at the turn of the century that both industry and regulatory agencies began to fully comprehend that the ability to meet society's ever increasing healthcare expectations would require a significant step change in the industry's performance.

Over the last 50 years clinical science, engineering science underpinning good manufacturing practice and the analytical science pivotal to the concept of validation are a few examples of complimentary scientific disciplines which deployed collectively have delivered significantly greater healthcare benefits currently enjoyed by society than they would have if used individually.

Convergence is not new. It has provided the multidisciplinary platforms of complementary sciences underpinning the development of pharmaceutical science for decades.

What has changed is the speed and breadth of development of these complementary sciences and the opportunities these changes offer to totally change the industry's business model.

However in spite of the PAT Guidance, cGMP for the 21st Century and the Critical Path Initiative and latterly QbD which described the "building blocks" to address the key challenges to:

- encourage and manage innovation while ensuring high quality
- identify and adopt appropriate technologies which will IMPROVE overall quality
- successfully shift from empirical to science based standards for manufacturing process quality

7 years later industry is still failing to sponsor the levels of innovation necessary to develop the desired more efficient, agile, flexible pharmaceutical manufacturing sector capable of reliably producing high-quality drug products without extensive regulatory oversight from both regulatory / industry perspectives.

What hasn't changed is industry / regulatory conservatism

As a direct result:

- manufacturers have been slow to adopt PAT/QbD
- the concept of design space is not clearly understood
- regulatory approaches have not evolved adequately

leading to high levels of regulatory uncertainty within the industry.

Specifications are still based on empirical compendial standards rather than science based on specific process and product need.

Concurrently the Pharmaceutical industry has undergone and is still undergoing dramatic change the scale of which few would have predicted.

Business performance expectations applying traditional business models are becoming increasingly difficult to sustain.

The changes outlined by the critical path initiative previously seen as optional will soon become an imperative.

The Pharmaceutical sciences will not only have to evolve more rapidly but become far more convergent than ever before.

From these perspectives

PAT and QbD are not mutually exclusive they are complementary.

Against this background this years conference will again have a significant interactive workshop content focusing on the respective roles PAT and QbD will play redressing the issues outlined above with an emphasis on convergence.

The first two workshops will focus on:

- Process Understanding - Facilitating the Transition between Process Validation and Continuous Verification
- Material Science - How Can Material Science Bridge the Gap Between API and Drug Product Manufacture?

As product, process, scientific understanding and risk management changes over time the concept of QbD being dynamic will also raise additional significant challenges critical to achieving the desired state which are the subjects of the remaining workshops :

- The Transition from Batch to Continuous Processing – An Overview of the Respective Sampling, Measurement and Control Issues
- Performance-Based Quality Specifications - Establishing a Science-Based Target for Pharmaceutical Manufacturing

The conference programme will also include presentations on a range of complimentary topics from academia, industry, and regulatory agencies covering:

- **Technology**
- **Experimental Design**
- **Manufacturing Unit operations: Batch Processing; Continuous API and Solid Dosage manufacture**
- **Biotechnology**
- **Regulatory perspectives from Europe and USA**

This programme will also include 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*

■ Key Note – ‘Pharmaceutical Industry Sustainability – Why the Pharmaceutical Sciences have to Evolve’

- Multinational drug companies are adjusting to life in a segment of the business cycle without blockbuster revenues needed to sustain organisations that have evolved to a size and complexity that is dependent on them
- Business models are now changing to create revenues from new sources and the industrial pharmaceutical sciences teams must evolve to serve the needs of the new business paradigms
- Drug industry economics will be discussed and the emerging drivers for industrial change considered
- Ways in which the pharmaceutical sciences could change to adapt to this new environment and succeed will be proposed

Dr Stephen R. Wicks, *Canterbury, Kent, UK*

■ Confidence – Critical for Batch Release

- This presentation will discuss approaches to address this confidence issue by detailed data analysis of a Hydrochlorothiazide surveillance case study from the perspective of:
 - Statistical analysis
 - Regulatory requirements
- and review the potential impact of the outcomes on industry

Dr Jon Clark, *CDER, FDA, USA*

WORKSHOP I

■ Process Understanding

■ Facilitating the Transition between Process Validation and Continuous Verification

Traditional process validation addressed only basic aspects of quality assurance; that is, the quality of only the validation batches was assured and the quality of subsequent batches was inferred. Modern concepts of process validation or better yet continuous verification assure that all batches produced are fit for purpose. This workshop will investigate the requirements of continuous verification and provide the tools such as multivariate experimental design and process monitoring to achieve the desired state for product quality. Principles that will be addressed include:

- Application of Experimental Design
- Science-based Approaches
- Capitalizing on Quality by Design
- Leveraging Product and Process Understanding
- Applying Risk Management for Quality
- Realizing & Utilizing Continuous Improvement

Dr Jean Marie Geoffroy, *Takeda Global Research and Development, USA*

WORKSHOP II

■ Material Science

■ How Can Material Science Bridge the Gap Between API and Drug Product Manufacture?

Today there is an increasing awareness that physical attributes of API's and excipients are as important as their chemical attributes in the manufacture of solid dosage forms.

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 development of “physical functional guidelines”
- The opportunities for manufacturing to control physical properties and even produce “designer” materials to limit the need for physical processing

Dr Richard Storey, *Astra Zeneca, Macclesfield, UK*

Dr David Wilson, *Astra Zeneca, Macclesfield, UK*

■ Impact of Material Properties on Blending Outcomes

- Real-time characterization of multicomponent powder blending
- Understanding the implication of physical material characteristics on powder blend kinetics
- Critical sources of blending variability
- Appropriate PAT tools and metrics for blending endpoint determination and assessment of blend homogeneity

Dr Gabriele Reich, *IPMB, University of Heidelberg, Germany*

■ Process Design Considerations to Specifically Mitigate Risk During Product Manufacturing

- Under QbD, process design starts with intended product performance typically described and documented in a Target Product Profile (TPP):
 - The TPP should include, not only the intended patient performance, but also an indication of ‘acceptability’ around this performance; i.e. a “measure” of the acceptable variability in the end product
 - Instead of focusing process design simply on ‘specification’, we focus on determining, managing and therefore mitigating the risk of variability in patient product performance as an alternate science based framework for process development, e.g.: a process to make a high dose, immediate release solid dosage form will not have the risks and constraints of a low/micro dose, complex, or controlled release solid dosage form
 - Therefore the process design requirements will change to match the “Target Product Profile”.
- This presentation will provide examples of case studies which highlight the importance of identifying and working to reduce these product risk factors during process development

Martin Warman, *Vertex Pharmaceuticals Inc., Cambridge, MA, USA*

WORKSHOP III

■ The Transition from Batch to Continuous Processing

The goal of PAT is to enhance understanding and control of manufacturing processes and hence PAT has a direct relationship to QbD. Quality should be built-in by design.

To achieve significant manufacturing performance improvements measurement strategies have to reflect the specificity and selectivity defined by process needs within a time envelope capable of impacting on process performance.

This differs significantly with today's end product testing regimes where the measurements specified seldom relate with process performance requirements, and are carried out in time frames incapable of monitoring, controlling, or optimising process outcomes.

Understanding the relationship between the sample(s), the measurement(s) and process requirements to deliver the desired product is therefore essential to achieve QbD

This workshop will examine such measurement, monitoring and control requirements holistically, in the context of.

- API manufacturing
- Drug product manufacturing

and the relative benefits of operating in batch and continuous mode.

Ian Clegg, Pfizer, UK

WORKSHOP IV

■ Performance-Based Quality Specifications - Establishing a Science-Based Target for Pharmaceutical Manufacturing

This workshop will focus on linking the clinical needs of patients with critical quality parameters measured during manufacturing and includes:

- Establishing connections between manufacturing quality and clinical performance
- Developing a risk-based simulation platform to explore the impact of manufacturing quality
- A comparison of the manufacturing capabilities to therapeutic requirements as a prelude to quality by design
- A discussion of the necessity of multivariate specifications for pharmaceutical products

Prof Dr Carl Anderson, Duquesne University, USA

Ken Leiper, Benson Associates, UK

■ Case Study: Imaging – Understanding Material Distribution in the Matrix

- NIR chemical imaging (NIRCI) to bridge the gap between formulation / process development, manufacturing and product performance
- Data analysis to extract essential information from NIRCI
- Statistical evaluation of NIR chemical images: a novel approach for the assessment of sample homogeneity
- Exploring powder blend variability and API / excipient distribution patterns in solid dosage forms

Dr Gabriele Reich, IPMB, University of Heidelberg, Germany

■ Case Study: From Batch to Continuous: a “Quality by Design” Approach to Handle Hazardous Materials in API Manufacture

- Challenges of pharmaceutical contract manufacture
- Safe use of hazardous materials
- Quality
- Continuous vs batch manufacture
- Success factors of implementation

Dr Peter Poehlauer, DSM Pharma Chemicals

■ Case Study: Practical Challenges in the Application of a Quality by -Design Approach using PAT

- Design for Manufacture
- Real Time Assurance
- Release
- Near Infrared
- Analytical Methods

Dr Paul Frake, GSK, UK

■ Case Study: Continuous Processing - Making New Standards in Manufacturing Excellence Possible using Experimental Design

Dr Frank Roche, GSK (invited)

■ Practical Applications of QbD for an Injectable: Formulation Development and Manufacturing of Biotech Products

- General Overview on EFPIA mock documents on injectables
- Illustration of application the QbD workflow to an injectable
- Establishing a TPP, Identification of CQAs, Risk Assessment, Process
- Characterization, Control Strategy
- Regulatory Implications

Dr Robert Schnepf, Merck KGaA, Germany

■ QbD / PAT – Future EU Perspective

- Quality by Design Implementation
- EMA PAT Team
- Variations Regulation
- Quality Guidelines
- EU GMP
- Scientific Advice

Dr. Riccardo Luigetti, EMA, UK

■ QbD / PAT – Future FDA Perspective

- This presentation will review:
 - How the Quality by Design initiative is shaping the future of FDA
 - The pivotal contribution Process Analytical Technology makes to QbD
 - How to maximise the impact of the data generated by a PAT solution

Dr Jon Clark, CDER, FDA, USA

Speakers



PROF DR CARL ANDERSON,
Duquesne University, Pittsburgh, PA, USA

Carl Anderson is an assistant professor of pharmaceutical sciences in the Mylan School of Pharmacy and Graduate School of pharmaceutical sciences. He joined the pharmaceutical Hoechst-Marion-Roussell in 1995 and worked there until 2002. At Duquesne University he leads a research group investigating industrial pharmaceutical applications of analytical technology, pharmaceutical applications of chemical imaging, and best practices in risk-based manufacturing. He is currently a member of ASTM E.55 Pharmaceutical Application of PAT.



DR JON CLARK, *CDER, FDA, USA*

Jon Clark, Ph.D. is Associate Director for Policy Development and GMP, Office of Pharmaceutical Science, Centre for Drug Evaluation and Research, FDA.



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 Process Engineering Manager at the GSK Global Manufacturing Services site Ware, Hertfordshire.



DR JEAN MARIE GEOFFROY, *Takeda, USA*

Jean-Marie Geoffroy, PhD is Senior Fellow for Takeda Pharmaceuticals Inc. His 20 years of technical experience includes process analytical technology, formulation development and marketed product support, focusing on technology transfer, process validation, and process optimization. He is currently a member of ASTM's E55 Executive Committee, AAPS, and ISPE. Prior to Takeda, he has worked at TAP Pharmaceuticals, Abbott Laboratories, Marion Merrell Dow Pharmaceuticals and CIMA Labs.



KEN J. LEIPER, *CChem., MRSC, Benson Associates, UK*

K. J. Leiper is an independent consultant in Pharmaceutical Quality Systems, Analytical Science, and Process Analytical Technology with 37 years experience in a range of senior management positions with Glaxo/Wellcome Manufacturing. Ken Leiper is chair of ASTM Pharmaceutical Application of Process Analytical Technology Committee E55.01.



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.



DR PETER POEHLAUER, *DSM Pharma Chemicals, Linz, Austria*

Peter Poechlauer received his PhD in organic chemistry from Innsbruck University in 1986. In 1990 he joined Chemie Linz, later OMV, as a synthetic chemist. Since 1996 he worked with DSM as scientist, project leader and competence manager. From 2003 to 2007 he headed a department of process technology. Since 2007 Peter Poechlauer has been working as principal scientist with a focus on process intensification and micro reactor technology.



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.



DR ROBERT SCHNEPF, *Merck KGaA, Darmstadt, Germany*

Dr Robert Schnepf studied Chemistry at the University of Essen, Germany and received his Ph.D in 2001 at the University of Bochum. He worked as Senior Scientist for Graffinity AG and Complex Biosystems (Ascendis Pharma). He started at Merck KGaA as Lab head Formulation Development in 2005, became leader of the Formulation Development for large molecules in Darmstadt in 2007 and since 2010 he leads a development team for the development and manufacturing of biological APIs and biopharmaceutical products. Robert Schnepf is a member of the EFPIA Working Group for Mock Submissions.



DR RICHARD STOREY, *ASTRAZENECA, Macclesfield, UK*

Following his PhD in crystallisation at Bradford University, Richard Storey worked in the supercritical fluid crystallisation SME "Bradford Particle Design". He moved to Pfizer in Sandwich, UK to the Materials Science group in 1998. Richard moved to AstraZeneca in 2003 to manage the solid state group, and more recently, one of the Early Development groups. Since 2007 has been working as an Associate Principal Scientist in the area of formulation and process understanding with a specific focus on enabled formulations and lyophilisation.



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.



DR STEPHEN R. WICKS, *Industrial Pharmacist, previously with Pfizer Inc., Canterbury, Kent, UK*

Steve Wicks is an independent pharmaceutical scientist. He spent 25 years with Pfizer Inc. rising to become a Vice President of Worldwide Pharmaceutical Sciences in the Pfizer Global R&D division and a member of the Pfizer UK Group Ltd board of directors. He is a visiting professor of pharmaceutical science at the Universities of Greenwich and Bath, an honorary Fellow of the University of London's School of Pharmacy and a Fellow of the Royal Pharmaceutical Society of Great Britain. Steve has held academic positions at the University of Bath and Liverpool John Moores University and industrial positions with GSK and Abbott.



DR DAVID WILSON, *ASTRAZENECA, Macclesfield, UK*

Dr David Wilson studied Chemical Engineering at Imperial College, London, before being employed as a Senior Scientist at AstraZeneca. Since 2006 David has been involved in the characterisation and processing of pharmaceutical products with experience of wet granulation, melt extrusion, emulsion and vial filling.

Supplier Support for QbD and PAT

Selected Suppliers are invited to present their latest systems and products in short presentations.

Short Presentations (as of 10 September 2010)

Business Process Management Supporting QbD Process Development and Lifecycle Management

Jochen König, *IDS Scheer AG, Germany*

Transmission Raman for Robust Content Uniformity Analysis

Dr Darren Andrews, *Cobalt Light Systems, UK*

Design considerations and best practices, for the implementation of a fluorescence spectrophotometer in laboratory and plant Pharma PAT

Colin Dye, *Expo Technologies, UK*

PAT challenges in fermentation at Roche Diagnostics GmbH, Penzberg. A case study: evaluation of inline process analyzers within fermentation process development

Francois Kjell, *Siemens, Belgium*

Calibration Transfer from a Laboratory NIR Spectrometer to an at-line System for Physical Properties and API Content Determination of Tablets

Nutsima Schnell, *Büchi Labortechnik AG, Switzerland*

SAM-Spec® sensor: the Swiss-knife for PAT. Example of Application: Simultaneous Prediction of API concentration, Particle Size Distribution and Homogeneity on Drug Layering Process.

Fabien Chauchard, *Indatech, France*

A Streamlined, Science-Based Program for Successfully Implementing On-line TOC Analyzers for Real-Time Release Testing of Pharmaceutical Water

Alexis Sorokovsky, *GE Power & Water, France*

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.

Heidelberg – Optimal Accessibility via Frankfurt Airport

As one of the most beautiful cities in Europe, Heidelberg is at first sight an interesting venue – but is it also easily accessible? The answer is: Yes! The connection to Frankfurt Airport is convenient and fast. Next to London, Frankfurt Airport offers the **most frequent air connections in Europe**. It takes only about 45 minutes to get from Frankfurt to Heidelberg.

- Lufthansa Shuttle Bus: You can take this bus also if you do not fly by Lufthansa. It leaves for Heidelberg approximately once an hour.
- The TLS Airport Shuttle Service Frankfurt can be booked directly at the Marriott Hotel : Germany's most experienced Airport Shuttle-Service TLS brings you promptly and reliably from the airport to your hotel. This shuttle service can be ordered directly in the reservation form of the Marriott Hotel.
- Train: You can get on the train at the Airport Station. A train leaves up to three times per hour and usually takes less than an hour to get you to Heidelberg.

Conference Exhibition

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.

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

Dates

Wednesday, 29 September 2010, 09:00 – 18:30 h
(Registration and coffee 08:00 – 09:00 h)

Thursday, 30 September 2010, 08:30 – 18:30 h

Friday, 1 October 2010, 08:30 – 15:30 h

Venue

MARRIOTT Hotel
Vangerowstraße 16
69115 Heidelberg, Germany
Phone ++49 (0) 62 21 - 90 80
Fax ++49 (0) 62 21 - 908 608

Fees

Conference
Non-ECA Members EUR 1,990.- per delegate plus VAT
ECA Members EUR 1,791.- per delegate plus VAT
APIC Members EUR 1,890.- per delegate plus VAT
(does not include ECA Membership)
EU GMP Inspectorates EUR 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 "PAT Conference 2010" to receive the specially negotiated rate for the duration of your stay. Reservation should be made directly with the hotel not later than 17 August 2010. Early reservation is recommended.

Conference language

The official conference language will be English.

Organisation and Contact

CONCEPT HEIDELBERG
P.O. Box 10 17 64
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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 Heidelberg QbD / PAT Conference 2010
29 September - 1 October 2010, Heidelberg, Germany

Mr Ms

Title, first name, surname

Company

Department

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)!