Invitation to

The University of Heidelberg

Speakers:

Dr Jörg Gampfer
Baxter AG, Austria

Sven-Erik Hillver
Medical Products Agency, Sweden

Dipl.-Ing. (FH) Thorsten Herdling
Merck Serono, Germany

Dr Ajaz Hussain
Wockhardt, USA

Prof Dr Richard Lakerveld
University of Delft, NL

Dr Line Lundsberg
Lundsberg Consulting Ltd., UK

Julie Maréchal-Jamil
European Generic Medicines Association, Belgium

Prof Karl Molt
University of Duisburg-Essen, Germany

Prof Dr Fernando J. Muzzio
Rutgers University, USA

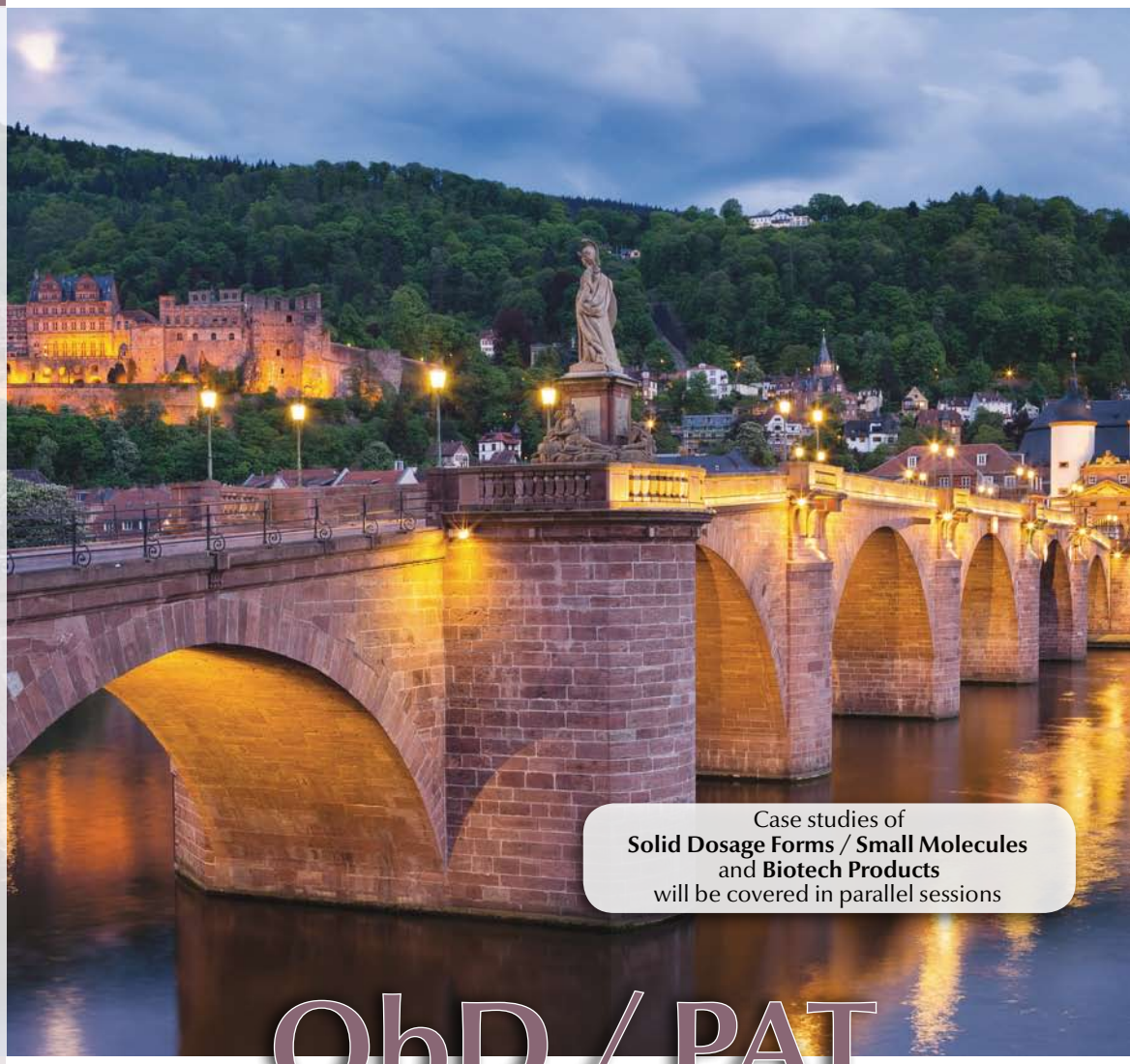
Dr Gabriele Reich
Faculty of Biological Sciences, University of Heidelberg

Dr Jens Schewitz
Merck KGaA, Germany

Dr Mark Smith
Pfizer Global Supply, Ireland

Dr Ron Taticek
Genentech, USA

Dr Gert Thurau
Merck & Co. Inc., USA



Case studies of
Solid Dosage Forms / Small Molecules
and **Biotech Products**
will be covered in parallel sessions

QbD / PAT Conference 2012

26 - 27 September 2012, Heidelberg, Germany

Key Sessions:

- Real-time Release / Batch Manufacturing
- QbD Implementation / Practical Approaches
- Future Perspectives of QbD / Regulatory and Industrial Challenges
- QbD for Generics
- Continuous Manufacturing

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 2012

Dear Sir or Madam,

After seven successful Conferences from 2005 to 2011 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 2012.

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 generic drug product development and manufacture. In addition, the opportunities and challenges critical to continuous processing will be addressed.

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

- How to file and deploy a RTRT method: regulatory and industrial experiences
- Selection of PAT tools and impact on batch release decisions
- Practical approaches to QbD implementation in solid dosage form development and manufacture
- QbD for Biotech products
- Implications of NIR method development, implementation, maintenance and transfer in view of the new EMA Draft guideline on NIR Spectroscopy
- QbD for generic drugs: Regulatory and industrial challenges
- Impact of material properties and PAT instrumentation on continuous manufacturing

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 2012

26-27 September 2012, Heidelberg, Germany

Regulatory Background and Objectives

By the turn of the century the pharmaceutical industry and the regulatory 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. Significantly improved alignment across research, development and manufacturing was seen as key to successful performance outcomes as outlined in the PAT Guidance, cGMP for the 21st Century, the Critical Path and latterly QbD.

In spite of the opportunities to develop more flexible regulatory approaches to manage innovation, the pharmaceutical industry has been slow to adopt PAT/QbD. As a result, the shift from empirical compendial to science based standards necessary to enable both pharmaceutical manufacturing performance and product quality has not been fully accomplished yet. Gaps that need to be filled are a common understanding of the regulatory expectations and the use of pragmatic approaches to implement the design space concept and facilitate continual improvement over the product lifecycle.

To these ends, this year's conference themes comprise industry challenges and opportunities of PAT-based RTR testing and QbD implementation with a specific focus on practical applications including filing of submissions.

The conference programme is divided into 5 key sessions covering the following topics:

1. Real-time Release / Batch Manufacturing
2. QbD Implementation / Practical Approaches
3. Future Perspectives of QbD / Regulatory and Industrial Challenges
4. QbD for Generics
5. Continuous Manufacturing

Recognised experts from industry, academia, regulatory authority and the European Generic Medicines Association will attend and share their practical experience, their views and their specific knowledge in these fields.

To facilitate the discussion on specific approaches of QbD to small and large molecules, participants will have the opportunity to decide between two parallel sessions with case studies on QbD implementation for

- solid dosage forms
- biotech products

The goal is to provide all participants with a highly interactive platform to learn about technical progress, regulatory and business implications of PAT/QbD.

Moderator

Dr Gabriele Reich, *IPMB, University of Heidelberg*

Conference Programme

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

➤ Session 1
Real-time Release / Batch Manufacturing

- **Real Time Release Testing from an EU Regulatory Perspective**
  - RTRT and Control Strategy
  - Importation from third country
  - Submission Requirements
  - Parametric Release and Sterility
  - Assessors and GMP Inspectors
  - Regulatory Experience

  Sven-Erik Hillver, Swedish Medicines Agency, Sweden

- **Challenge and Opportunities of Large Sample Sizes for Batch Release Decisions**
  - The advances through PAT allow new approaches to deploying test methods, including the ability to take larger amounts of data without extra resources
  - This is desirable from the perspective of QbD, process understanding and the new concepts for process validations
  - However there are potential hurdles due to historic approaches on how to make batch release decisions which could discourage use of PAT for content uniformity testing and release

  Dr Gert Thurau, MSD, USA

- **PAT Tools for Real Time Release**
  - Raw materials release
  - On-line blend analysis
  - Automated tablet core analysis

  Dr Mark Smith, Pfizer Global Supply, Ireland

- **Industry Experiences in Launching, Managing and Transferring a RTRT method globally 2006 - today**
  - Detailed description of a real-life example for a complete RTRT process and 6 years of experience
  - Aspects of NIR method development, implementation and life-cycle maintenance both within the original site and two subsequent transfer sites will be discussed
  - How to file and deploy a NIR RTRT method, including so-called "parallel testing" and a proven approach to use the reference method
  - Customer requirements from production and quality units on management of NIR methods, potential conflicts with evolving regulatory positions and how this could determine the future of PAT in the pharmaceutical industry

  Dr Gert Thurau, MSD, USA

➤ Parallel Session 2
QbD Implementation / Practical Approaches

Please choose one parallel session according to your interest.

Solid Dosage Forms

- **Case Study I:**
  A QbD Approach Across Multiple Process Steps
  - Assessment of the functional relationship between CPPs and CQAs across multiple process steps
  - Mechanistic analysis of functional relationships to enhance process understanding
  - Holistic process optimization (e.g. granulation / tabletting)
  - Overall design space setting including variables of different process steps
  - Control space setting considering economical aspects
  - Feed-forward control to improve process performance and product quality in an economic manner

  Dr Gabriele Reich, University of Heidelberg

- **Case Study II: A PAT Study of a Fluidbed Granulation Process: from Risk Analysis to the Routine Process Scale up and QbD Principles**
  - Fluid bed granulation in the solids production is a key process step for the quality of the finished product
  - Measurement of quality attributes and combination with critical process parameters by multivariate data analysis, DoE and QbD gives a better understanding of the process, the possibility to control the process and to minimise variations
  - Results of these investigations facilitate scaling up granulation processes

  Dipl.-Ing. Thorsten, Herdling, Merck KGaA, Darmstadt

Biotech Products

- **Implementation of a Systematic QbD Methodology in a Biopharmaceutical Environment**
  - Using a common risk approach strategy for legacy and development products
  - Implementation of a platform approach by utilizing appropriate risk management software systems
  - Application of advances statistical methodology (MVDA) and experimental planning (DoE) for establishing appropriate process knowledge and control.

  Dr Jörg Gampfer, Baxter, Vienna

- **QbD Case Study: Global Implementation of QbD for a Biologic Product**

  Overview of lessons learned from approval of new biologic product developed using QbD elements. Topics included:
  - Justification of Critical Quality Attributes and their acceptable ranges
  - Identifying Critical Process Parameters and Design Space
  - Justification of Control System and Process Monitoring Program
  - Lifecycle Management
  - Documentation of QbD elements in the dossier
  - Lessons learned are based on Health Authority feedback in the major markets.

  Dr Ron Taticek, Genentech, a member of Roche Group, USA

➤ Session 3
Future Perspectives of QbD – Regulatory and Industrial Challenges

- **QbD and PAT - an Analysis of the Current Situation**
  - Review of the current state of the Initiatives
  - Perspective on how regulatory uncertainty could be reduced in the implementation of Quality by Design
  - Arguments starting with the SUPAC guidelines, how prior knowledge was used within these, and then how best to justify prior knowledge in the context of design space
  - Two historical case examples utilized to illustrate the relevance of the proposed arguments

  Ajaz Hussain, Wockhardt, USA

- **The EMA Guideline Draft on the Use of Near Infrared Spectroscopy (NIRs) – a Review**
  - Content of the guide in the form of Ishikawa diagrams
  - Practically and theoretically relevant aspects and implications of developing and applying NIR methods
  - Maintenance and cost of NIR methods

  Prof Karl Molt, University Duisburg-Essen, Germany

- **Strategies for Linear and Nonlinear Calibrations in Instrumental Analysis taking into account applicable Standards**
  - Calibrations with linear functions
  - Application of non-linear second-order calibration functions
  - Limits of Detection and Quantification for linear and non-linear cases

  Prof Karl Molt, University Duisburg-Essen, Germany

- **Analytical Risk Mitigation for Raw Materials: A Concept for Sourcing in the Emerging Markets**
  - An increasing number of raw materials are purchased in emerging markets
  - New concept on analytical risk mitigation for raw materials by combining the results of routine testing (e.g. NIR-S, HPLC, HPLC-MS, Optical microscopy) and multivariate data analysis
  - Principles of ICH Q8,9 and 10 are combined in this new approach by using aspects of risk analysis and QbD principles for analytical methods
  - Due to this mathematical approach an easy fingerprint of the raw materials can be generated and variances in the material quality and shifts of the process will be visible

  Dr Jens Schewitz, Merck KGaA, Darmstadt

➤ Session 4
QbD for Generics

- **Quality by Design for Generics - Regulatory Challenges in EU**
  - Results from an EGA/ISPE Workshop with practical case studies
    - The Business Case for QbD
    - Technical Elements of QbD - Addressing Q8 /Q9 /Q11
    - Regulatory and Compliance Impact on QbD
  - What is needed from industry point of view to support QbD submissions in Europe
  - Differences between EU and US FDA approach

  Julie Maréchal-Jamil, European Generic Medicines Association

- **Making Implementation of Quality by Design in the Generic Industry a Successful Business Advantage**
  - Practical implementation of QbD
  - Roadmap for QbD
  - Application of Quality Risk Management
  - Design of Experiment
  - PAT
  - Continual Improvement
  - Process Validation
  - Challenges
  - Success
  - Business drivers

  Dr Line Lundsberg-Nielsen, Lundsberg Consulting Ltd.

➤ Session 5
Continuous Manufacturing

- **Addressing Material Properties in the Design of a Direct Compression Continuous Manufacturing System**
  - A number of material properties of pure ingredients and blends are critical to the performance of continuous manufacturing processes for solid dose pharmaceutical products, including, especially:
    - Powder cohesion
    - Electrostatics
    - Agglomeration
    - Segregation tendencies
    - Blend hydrophobicity
    - Shear sensitivity
  - Review of the methods for measuring these material properties and assessing their impact on the process and the product

  Prof Dr Fernando Muzzio, Rutgers University, USA

- **PAT Instrumentation for Continuous Manufacturing**
  - NIR
  - FBRM
  - Dynamic sampling
  - Contributing mass
  - Real-time Release

  Dr Mark Smith, Pfizer Global Supply, Ireland

- **Case Study: The Application of a Plant-wide Control Strategy for a Continuous Pharmaceutical Process at the Novartis-MIT Center for Continuous Manufacturing**
  - Continuous pharmaceutical manufacturing
  - Quality by design
  - Plant-wide control
  - Pilot plant
  - Integration
  - PAT
  - Process modelling
  - Parametric sensitivities
  - Critical quality attributes
  - Critical process parameters
  - Feedback control

  Prof Dr Richard Lakerveld, University of Delft, NL

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 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
weidemaier@concept-heidelberg.de.

Already registered Exhibitors:

- **Bruker Optic GmbH,** Ettlingen, Germany
- **Thermo Electron Karlsruhe GmbH,** Karlsruhe, Germany
- **Sentronic GmbH,** Dresden, Germany
- **Open Text Software GmbH,** Grosbrunn, Germany (www.opentext.de/qbdpat)

Speakers

Dr Jörg Gampfer
Baxter AG, Vienna, Austria
Jörg Gampfer obtained his degree in chemistry and PhD in the field of molecular biology / immunology. Senior scientist in a start-up company for vaccine development. Joining Baxter in 2005, heading a department for Product & Process Design. Since 2011 Six Sigma Master Black Belt consulting routine production in plasma fractionation and recombinant product manufacturing sites. Supporting developmental products in the early and late stage development and leading the operational part of the global QbD initiative.

Sven-Erik Hillver
Medical Products Agency, Sweden
Sven-Erik Hillver has worked with the Medical Products Agency in Sweden for more than 20 years as a quality assessor and hold position as Senior Expert within the Department of Pharmacy and Biotechnology. He represents the MPA in the Quality Working Party at the EMA and did act as Rapporteur for the revised guideline on Real Time Release Testing that was published by EMA in April.

Dipl.-Ing. (FH) Thorsten Herdling
Merck Serono, Darmstadt, Germany
Thorsten Herdling studied Chemical Technologies at the University of Applied Science in Darmstadt until 2000. After 3 years in a company for automation and sensor technologies, he has been working in Pharma Analytics at Merck KGaA Darmstadt focusing on qualification and validation of computerized systems. In 2008 Thorsten Herdling joined the laboratory for Process Analytical Technology (PAT) and since 2010 he heads the laboratory for Process Analytical Technology (PAT) at Merck Serono Darmstadt.

Dr Ajaz Hussain
Wockhardt Ltd., USA
Dr Ajaz S. Hussain began his career in teaching, first at the Ohio Northern University and then at the University of Cincinnati. He then moved to FDA and rising thought the ranks he reached the position of Deputy Director Office of Pharmaceutical Science (1995- 2004). His most recognizable contribution at FDA were the establishment of Biopharmaceutical Classification Guidance, championing the PAT and Pharmaceutical Quality for the 21st Century Initiative and serving as the FDA's lead for quality at ICH and facilitating progress of ICH Q8, Q9 and Q10. He then moved to Sandoz as VP & Global Head for Biopharmaceutical (2004 -2007) and to Philip Morris International (PMI) in Neuchatel, Switzerland. He is now returning home in USA and to the pharmaceutical sector as the Chief Scientific Officer & President Biotechnology at Wockhardt, Ltd.

Prof Dr Richard Lakerveld
University of Delft, NL
Richard Lakerveld obtained his Ph.D. degree in chemical engineering from Delft University of Technology in 2010 and has worked for the past two years as Postdoctoral Associate at the Massachusetts Institute of Technology within the Novartis-MIT Center for Continuous Manufacturing. Currently, Richard is an Assistant Professor at Delft University of Technology.

Dr Line Lundsberg
Lundsberg Consulting Ltd, U.K.
Line Lundsberg is a QbD & PAT Senior Specialist and holds a Ph.D in NIR spectroscopy. She has many years of experience within the pharmaceutical Industry in implementing QbD and PAT in both Development and Manufacturing for Innovator Companies but have the last years been involved in training and consulting the Generic Industry on how to implement and apply the QbD principles from a practical point of view. She is a well-respected speaker at international conferences and is co-author of the Good Practice Guide on Product Realization using Quality by Design, published by ISPE.

Julie Maréchal-Jamil
European Generic Medicines Association, Brussels, Belgium
Since 2007, Julie has joined the regulatory and scientific affairs team of the European Generic medicines Association (EGA) Secretariat, with responsibilities in the areas of Quality, Compliance, Environment, Health & Safety as well as Bioequivalence. Her work consists in the internal coordination of Working Groups activities and external liaison with policy makers, EU institutions, Medicines Agencies, International organisations as well industry and professional associations.

Prof Karl Molt
University of Duisburg-Essen, Germany
Karl Molt is Professor for Instrumental Analysis at the University of Duisburg-Essen, Germany. His main working areas are: IR/NIR spectroscopy for process and quality control, Chemometrics for evaluation of spectrometric data, statistics for quality assurance.

Prof Dr Fernando J. Muzzio
Rutgers University, USA
Fernando Muzzio received his PhD in 1991 on mixing theory, from Univ. of Massachusetts and was appointed as Professor II, Chemical and Biochemical Engineering, at Rutgers University, USA. He is Director of the Engineering Research Center on Structured Organic Particulate Systems and a voting member of the FDA committee on Pharmaceutical Sciences and Clinical Pharmacology.

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 Group Leader at IPMB / Department of Pharmaceutical Technology and Biopharmaceutics.

Dr Jens Schewitz
Merck KGaA Darmstadt, Germany
Jens Schewitz has been working within Merck since 1999. His current position is Associate Director Quality Operations Pharma Production Darmstadt (Microbiology, special analytics, validation support, process analytical technology) He is running a PAT Project for the implementation of a Real time release in the solid production Darmstadt. Associate member of the board in the working group AK PAT of the GDCh. Nominated expert of Merck KGaA in the EFPIA working group on Near Infra Red Spectroscopy by the pharmaceutical industry.

Dr Mark Smith
Pfizer Global Supply, Ringaskiddy, Ireland
Dr Mark Smith graduated from Strathclyde University with a degree in Forensic and Analytical Chemistry before accepting a position with Abbott Laboratories as part of a team that established the company's global NIR initiative. After three years he took up a PhD at The School of Pharmacy in London investigating multivariate calibration modelling and transfer in NIR spectroscopy for pharmaceutical applications. Mark joined Pfizer seven years ago and currently holds the position of Senior Manager in the Process Analytical Sciences Group with global responsibilities for the implementation of PAT in the Primacy Care Oncology operating unit to support Pfizer Global Supply. He is a key contributor to Pfizer's RTRT strategy and involved in a number of new manufacturing and testing paradigms within the company, including continuous processing.

Speakers

Dr Gert Thurau
Merck & Co., Inc., West Point, PA, USA
Dr Gert Thurau is leading the central Process Analytical Technology (PAT) group at Merck which supports chemical, formulation and biopharmaceutical processes across the product life cycle. As a member of the team that developed and filed Merck's first real-time release testing product he is one of the initiators of Merck's Quality by Design Realization team. He is a member of the scientific board of IFPAC and serves as the industry co-chair for IFPAC 2012.

Dr Ronald Taticek, *Genentech, Inc., USA, a Member of the Roche Group*
Dr Taticek is the interim Head of Biologics Product Quality Management and Head of the Commercial Product Quality Stewards Group in Pharma Technical Quality at Roche. He has more than 18 years of experience working in biotechnology at Genentech, Bayer and the Biotech Research Institute (Montreal, Canada). He has held positions of increasing responsibility in Process Development, Manufacturing, Technical Regulatory and now Quality. Most recently, he led the QbD implementation effort for large molecules at Genentech. That effort included participating in the FDA QbD Pilot Program and interactions with EMA and Health Canada on QbD. In his current role, Ron is focused on lifecycle management of Roche's biologic products.

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.

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.

Lufthansa
Official Airline

Special Offer with Lufthansa – Discounted Travel for QbD/ PAT Conference 2012 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 – other-wise 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, 26 September 2012, 09:00 – 18:30 h
(Registration and coffee 08:00 – 09:00 h)
Thursday, 27 September 2012, 08:30 – 16:30 h

Venue

Heidelberg Marriott Hotel
Vangerowstr. 16
69115 Heidelberg, Germany
Phone + 49 (0) 6221 908 0
Fax + 49 (0) 6221 908 698

Fees

ECA Members € 1,590.- per delegate plus VAT
APIC Members € 1,690.- per delegate plus VAT
(does not include ECA Membership)
Non-ECA Members € 1,790.- per delegate plus VAT
EU GMP Inspectorates € 895.- 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 or be sure to mention "QbD/PAT Conference 2012" to receive the specially negotiated room rate (single room € 135,- per night incl. breakfast) for the duration of your stay. Reservation should be made directly with the hotel not later than 15 August 2012. 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
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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Postfach 10 17 64
Fax 06221/84 44 34

D-69007 Heidelberg

Reservation Form (Please complete in full)

The Heidelberg QbD / PAT Conference 2012
26-27 September 2012, Heidelberg, Germany

Please tick **ONE** group for parallel session 2:
☐ Solid Dosage Forms
☐ Biotech Products

☐ 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 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). (As of January 2012)

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