Invitation to

The University of Heidelberg

Authority Speakers:

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

Dr Øyvind Holte
Norwegian Medicines Agency

Speakers from Industry and University:

Sander van den Ban
GSK, UK

Fiona Clarke
Pfizer Ltd., UK

Dr Ajaz Hussain
Insight, Advice & Solutions, LLC, USA

Dr Peter McDonnell
Sanofi, France

Dr Peter Poechlauer
DSM, Austria

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

Justin Pritchard
Vertex, USA

Key Topics:

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

Co-sponsored by

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ACADEMY

The University of Heidelberg QbD / PAT Conference 2014

15 - 16 October 2014, Heidelberg, Germany

About the University of Heidelberg

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

Institute of Pharmacy and Molecular Biotechnology (IPMB)

The Institute of Pharmacy and Molecular Biotechnology (IPMB) is part of the Faculty of Biological Sciences. The research activities of the IPMB cover a wide range of topics with strengths in drug discovery, drug delivery, molecular biology and biotechnology, bioinformatics and instrumental analysis. In the field of instrumental analysis, a broad range of techniques are used routinely. Major research activities are concerned with Near Infrared Spectroscopy (NIRS) and Chemical Imaging. Both techniques are among the most important analytical tools within the framework of the Process Analytical Technology (PAT) initiative, a key element for improved process understanding, drug quality and drug safety. **To this end, the IPMB defines itself as a PAT Competence Center with the opportunity to enhance the know-ledge 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 2014

Dear Sir or Madam,

After 9 successful Conferences from 2005 to 2013 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 2014.

Once again, this year's event will provide a broad ranging platform for informative and interactive discussions with contributions by recognised experts from industry and regulatory authorities.

This year's programme will review the pivotal role PAT plays in delivering the levels of process understanding and process control necessary to replace conventional approaches to validation with continuous verification over the product lifecycle enabling further rapid adoption of Real Time Release (RTR) in pharmaceutical batch and continuous manufacturing.

Practical applications will be presented and potential hurdles discussed relating to technical approaches to drug product development, manufacture and regulatory expectations.

In addition, the opportunities and challenges critical to continuous processing will be addressed.

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

- Regulation
- PAT
- QbD
- R&D
- Manufacturing
- Small Molecules and Large Molecules
- Life Cycle Management

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

Regulatory Background and Objectives

Today, in an increasingly challenging financial environment, all manufacturing sectors of the pharmaceutical industry are still seen as failing to perform at levels commensurate with societys expectation of other sectors, after 10 years active involvement with PAT and QbD.

The application of Good Manufacturing Practice is still incapable of delivering Good Manufacturing Performance .

This conference will take a holistic overview of how the principles of PAT evolving in R&D and manufacturing are increasingly being used to redress this situation by:

- the introduction and extension of materials science
- setting meaningful process and product specifications

in

- API manufacture
- formulated product manufacture

using continuous verification to consistently deliver:

- right first time performance
- high levels of equipment utilization
- real time release
- significant product lead time reduction

which through the design and implementation of controllable processes should increasingly close the gap between Practice and Performance in both batch and continuous processes.

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

Moderator

Dr Gabriele Reich,
IPMB, University of Heidelberg

Conference Programme

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

REGULATORY

- **PAT / QbD – Reflections on the first 10 Years**
  - 10 years ago regulatory uncertainty and 'don't use or don't tell' approach to adaption of new analytical and process control technology
  - PAT Guidance – a different; unusual guidance. Some 'loved it' some didn't – why?
  - PAT Team Approach to facilitate innovation and continual improvement – what can we learn from this experience?
  - Current state of PAT & QbD implementation and regulatory challenges in the US and globally
  - Current FDA efforts and how the PAT Guidance/ Team approach can inform these efforts
  - Going forward – ensuring data integrity and continued process verification – how to be prepared?

  Dr Ajaz Hussain, Insight Advice & Solutions LLC, USA

REGULATORY

- **Analytical Methods and Sampling in the New Manufacturing Paradigm – a Regulatory Perspective**
  - Demonstrating end-product quality by on-line (PAT) measurements
  - Ph.Eur. 2.9.47: Uniformity of dosage units using large sample sizes
  - Analytics based on libraries/ calibration models: pitfalls and opportunities
  - Real time release testing: general considerations

  Dr Øyvind Holte, Norwegian Medicines Agency/ EDQM PAT working party/ EMA PAT team

APPLICATION

- **Continuous Manufacturing of Small Molecule APIs**
  - **Process Understanding and Process Control:** „understanding" a process means having a science-based process model (as opposed to a phenomenological description) and using this model to "control" the process both to keep it within the design space and to allow for continuous improvement
  - **Regulatory Aspects:** covers items such as definition of batch / lot etc., but also how to take the step from a control strategy based on analysis of batches to a control strategy for manufacturing processes consisting of a mix of batch and continuous steps
  - **Business Aspect:**
    - fields of activities where the changeover to continuous manufacturing has proven to be profitable
    - drivers to select a continuous manufacturing option
    - key success factors in implementing a continuous process

  Dr Peter Poechlauer, DSM

PROCESS UNDERSTANDING

- **Case Study 1:**
  The Evolution of Material Sciences as a Key Contributor to Determining the Critical Attributes of Active Pharmaceutical Ingredients (APIs)
  - Understanding the key material science methodologies deployed to fully understand active pharmaceutical ingredients from the molecular to bulk powder attributes
  - Case studies will be shared where these methods have enabled understanding of the critical attributes of an API which influence its subsequent behaviour in the final drug product

  Fiona Clarke, Pfizer Ltd., UK

PROCESS UNDERSTANDING

- **Case Study 2:**
  The Impact of Material Science in Increasing Understanding of Drug Product Performance and Manufacturability
  - Overview of the suite of material characterisation tools which can be utilised to evaluate a range of drug product platforms (incl. solid oral dose and aseptic)
  - Providing real examples of where through the understanding of material physical attributes it is possible to drive to full understanding of product performance.

  Fiona Clarke, Pfizer Ltd., UK

APPLICATION

- **Case Study 3**
  Quality by Design in Action:
  Improving Product Quality by the Transformational Use of Process Understanding in Design, Development, and Commercial Supply
  - Use of combined modelling approach in a systematic development of product & process for an oral solid dose product
  - Product quality is a direct function of formulation, excipients, and the process of manufacture
  - The manufacturing process must repeatedly deliver required product to the "performance" specification
  - Process measurement, control and monitoring are critical aspects to provide a sustainable supply of product to patient.

  Sander van den Ban, GSK, UK

APPLICATION

- **Case Study 4**
  Understanding Process Dynamics: the Route to Continuous Improvement
  Dr Peter McDonnell, Sanofi, France

APPLICATION

- **Case Study 5**
  The application of PAT to complex molecules synthesis
  Dr Peter McDonnell, Sanofi, Fance

PROCESS UNDERSTANDING

- **Bioequivalence – Still a Quality Achilles Heel?**
  - Pharmaceutical equivalence & Bioequivalence: a quick historical perspective
  - What has worked and what needs to be improved: Complex physical attributes, approval of complex generic and new drugs
  - Waiver of bioequivalence – based on in vitro characterization. A case example: In vitro dissolution
  - Bioequivalence considerations during continual improvement and post-approval changes
  - Specifications for critical physical attributes and bioavailability/bioequivalence: key considerations

  Dr Ajaz Hussain, Insight Advice & Solutions LLC, USA

PROCESS UNDERSTANDING

- **PAT in Action: a Lifecycle Approach to Applied Process Understanding**
  - A Lifecycle Approach to Applied Process Understanding to set meaningful process and product specifications combining:
    - Pharmaceutical science
    - Materials science
    - Chemical process engineering science
    - Measurement science

  Sander van den Ban, GSK, UK

REGULATORY

- **Compliance Enforcement Action Items**
  - Update on recent FDA Warning Letter, Untitled Letter, 483 notice of observations, and correspondences related to acceptance criteria
  - These examples cover expectations and issues related to Current Good Manufacturing Practices (CFR 210,211) and use of statistics

  Karthik Iyer FDA/CDER
  (via video conference)

APPLICATION

- **Case Study 6**
  The Development and Implementation of a Continuous Drug Product Manufacturing Process – The Process, Control, Regulatory and Cultural Change
  - From a vision to a qualified system
  - Integrating the systems and the people
  - Developing process knowledge in continuous manufacturing
  - Building an analytical organization to support continuous processing

  Justin Pritchard, Vertex, USA

REGULATORY

- **CGMP Statistics – Process Capability Enforcement Actions**
  - Process Capability
  - Use of consensus standards
  - Example of a Warning Letter related to use of process capability

  Karthik Iyer FDA /CDER
  (via video conference)

APPLICATION

- **Case Study 7**
  Moving PAT from "Nice to Have" to a Reliable Measure of Product Quality
  - Committing to Real Time Release testing and in-process controls using process analysis technology
  - Material planning to enable PAT implementation from day 1
  - Lessons learned from developing chemometric models
  - Delivering results: Building confidence with data and protocol driven activities

  Justin Pritchard, Vertex, USA

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.

Speakers

Sander van den Ban
GSK, UK
Sander van den Ban is a technical director in GlaxoSmithKline and worked in the Pharmaceutical Industry for over 10 years in various positions as Chemical Process Engineer in Research and Development, Engineering Technology and Capital Management, Process Design and Development and Solid Dose Centre of Excellence. In his current role as a Product Lead in the Oral Solid Dose Centre of Excellence he is accountable for the technical transfer and introduction of well understood reliable manufacturing processes for tablet dosage forms into manufacturing with particular focus on QbD and interaction with US, European and International regulatory agencies.

Fiona Clarke
Pfizer Ltd., UK
Fiona Clarke is currently Director of Material Characterisation within Pfizer's Global Supply organisation. Under her leadership this group has grown over the past 15 years from one focused on the deconstruction of tablet matrices for problem solving to the group which today provides advanced understanding of material attributes and their impact to final product performance across all business units. She has a BSc (Hons) in Forensic and Analytical Chemistry from the University of Strathclyde and a PhD in Pharmaceutical Analysis from the London School of Pharmacy.

Dr Øyvind Holte
Norwegian Medicines Agency
Øyvind Holte is a scientific officer at the Norwegian Medicines Agency. His main activities are the assessment of applications for new drug products and variations to existing products, mainly chemical drug products. He is a member of the EDQM PAT working party, and was involved in the elaboration of the recently published Ph.Eur. chapter 2.9.47 'Uniformity of dosage units using large sample sizes'. He is a member of the EMA PAT team. The PAT team provides general regulatory guidance in relation to PAT/QbD and specific guidance to applicants.

Dr Ajaz Hussain
Insight, Advice & Solutions, LLC, USA
Dr Ajaz Hussain's career at US FDA spanned 10 years; from 2000-2005 he served as the Deputy Director of the Office of Pharmaceutical Science (OPS) in the Center for Drug Evaluation and Research (CDER), FDA and held a "peer reviewed" Senior Biomedical Research position in the US Government Service. Ajaz is now a management consultant for life science sector. During his industrial career he has built teams to develop and launch several fist-in class complex generic and biosimilar products, contributed to advancing plant based vaccines and development of evidence necessary to demonstrate tobacco harm reduction.

Speakers

Dr Peter McDonnell
Sanofi, France
Peter graduated with a PhD in physical organic chemistry in 1985 and has been working in the Pharma industry since then, primarily in development, but also in medicinal chemistry. Since joining Genzyme (now Sanofi) 20 years ago, he has worked across many platforms including API (small molecule, biologics, polymers) and dosage forms. He has recently accepted the position of Global Innovation Strategy and External partnership Manager for the Development function of Sanofi based in Paris.

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

Dr Peter Poechlauer, DSM, Austria
Peter Poechlauer received a PhD in organic chemistry from Innsbruck University in 1986. 2 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. Since 2014 he has been responsible for Innovation Management.

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.

Justin Pritchard, Vertex, USA
Justin Pritchard is a Scientist in Process Analytical Technology at Vertex Pharmaceuticals Incorporated. Justin has been responsible for the development, implementation, and validation of PAT methods for continuous manufacturing. His background in spectroscopy, solid state analysis and traditional separations science provides broad analytical experience for his current role as a PAT practitioner. Justin also currently serves on the Steering Committee for PPAR (Pharmaceutical Process Analytical Roundtable).

Conference Exhibition - Supplier Support for QbD and PAT

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

- to get to know systems from various manufacturers,
- to personally meet with potentially interesting suppliers

and

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

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

Welcome to Heidelberg

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

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

Heidelberg – Optimal Accessibility via Frankfurt
Airport Shuttle Service PCS
http://www.pcs-hd.de/
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TLS Airport Shuttle Service Heidelberg
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Phone +49 (0)6221 77 00 77,
info@tls-heidelberg.de

Lufthansa Bus Airport Shuttle
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Tel. +49 (0)6152 – 97 69 099,
info@frankfurt-airport-shuttles.de

Train
You can get on the train directly at the airport. Trains leave up to two times per hour and it takes less than one hour to get to Heidelberg. www.bahn.de

What are The ECA Foundation and the ECA Academy?

The European Compliance Academy Foundation (ECA Foundation) is an independent professional organisation chaired by a Scientific Advisory Board with members from the pharmaceutical industry and regulatory authorities. The ECA Foundation's goal is to 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. The ECA Academy offers professional basic and advanced education (training) programmes. All services offered by the ECA Academy and with regard to ECA Academy Memberships are solely managed by Concept Heidelberg (a leading European training and information services provider). The ECA Foundation is conceptual sponsor of the ECA Academy.

How Do You Become a Member of ECA?

By participating in one of the ECA Academy Conferences or Courses you will automatically become a ECA Academy Individual Member for two years - free of charge. More information about ECA Academy can be obtained on the Website http://www.gmp-compliance.org

What Are the Benefits of ECA?

During the membership, you enjoy a € 200,- discount on the regular participation fee of any European Conference or Course presented by the ECA Academy. In addition you will receive the GMP Guideline Manager Software with a large number of guidelines, e.g. EC Directives, FDA Guidelines, ICH Guidelines.

Lufthansa
Official Airline

Special Offer with Lufthansa – Discounted Travel for QbD/PAT Conference 2014 Attendees
As an ECA course or conference attendee, you will **receive up to 20% discounted travel fares** (according to availability). And as Lufthansa German Airlines offers a comprehensive global route network linking major cities around the world you will most likely be able to benefit from these special prices and conditions.
And this is how it works: Once you registered for a course or conference you will receive a link together with your registration confirmation.
Opening that link will take you to the Mobility Partner Program website where you can enter a code in the "Access to Event Booking" area you will also receive. This will take you into an online booking platform* that will automatically calculate the discount offered or provide you with an even better offer if another promotional fare is available.

We look forward to welcoming at one of our next events – and we already wish you a pleasant flight!

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

Easy Registration

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

Reservation Form:
+ 49 6221 84 44 34

e-mail:
info@concept-heidelberg.de

Internet:
www.pat-conference.org

Date

Wednesday, 15 October 2014, 09:00 – 18:30 h
(Registration and coffee 08:00 – 09:00 h)
Thursday, 16 October 2014, 08:30 – 16:00 h

Venue

Heidelberg Marriott Hotel
Vangerowstraße 16
69115 Heidelberg, Germany
Phone +49(0)6221 908 0
Fax +49(0)6221 908 660

Fees (per delegate plus VAT)

ECA Members € 1,690
APIC Members € 1,790
Non-ECA Members € 1,890
EU GMP Inspectorates € 945
The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on both days and all refreshments.
VAT is reclaimable.

Conference language

The official conference language will be English.

Accommodation

CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form when you have registered for the event. Please use this form for your room reservation to receive the specially negotiated room rate for the duration of your stay. Reservation should be made directly with the hotel. Early reservation is recommended.

Organisation and Contact

CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg, Germany
Phone +49 (0) 62 21/84 44-0
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For questions regarding content:
Dr Günter Brendelberger (Operations Director)
at +49 (0) 62 21 / 84 44 40 or per e-mail at
brendelberger@concept-heidelberg.de)

For questions regarding reservation, hotel, organisation etc.:
Ms Marion Weidemaier (Organisation Manager)
at +49 (0) 62 21 / 84 44 46 or per e-mail at
weidemaier@concept-heidelberg.de.

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

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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 University of Heidelberg QbD / PAT Conference 2014
15 - 16 October 2014, 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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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).

Privacy Policy: By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at http://www.gmp-compliance.org/eca_privacy.html). I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.

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