



# The University of Heidelberg invites to

## Speakers:

**Dr Carl Anderson**  
*Duquesne University, USA*

**Ray W. Bolton**  
*AstraZeneca Engineering, UK*

**Jordan Cheyne**  
*Pfizer Ltd., UK*

**Dr Gerd Fischer**  
*sanofi-aventis, Germany*

**Dr James S. Fox**  
*GlaxoSmithKline, UK*

**Dr Thomas Fürst**  
*Schering AG, Germany*

**Prof Christina Graffner**  
*Swedish Medical Products  
Agency, Sweden*

**Dr Thorsten Herkert**  
*AstraZeneca, Germany*

**Dr Ajaz Hussain**  
*Sandoz Inc., USA*

**Ken J. Leiper**  
*Benson Associates, UK*

**Dr John O'Reilly**  
*Roche Ireland Ltd, Ireland*

**Dr David Radspinner**  
*Thermo, USA*

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

**Prof Carl Wassgren**  
*Purdue University, USA*

**Dr Chris Watts**  
*FDA, USA*

Co-sponsored by



# The Heidelberg PAT Conference 2006

Including a PAT Update  
from FDA by  
Dr Chris Watts, FDA

27 – 29 September 2006  
Heidelberg, Germany

## About the University of Heidelberg

The University of Heidelberg is one of the **top-ranking locations in the world of international science and scholarship**.



As Germany's oldest seat of higher learning it can look back on a tradition for which it is envied by many other universities, not only in Germany. But while its six-hundred-year history is a source of justified pride, it would be foolish indeed to

rest on the laurels of the past. Accordingly, the University is intent on playing an active role in shaping the future, both by **engaging in innovative research and by educating 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 subjects 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). NIRS is one of the most important analytical techniques within the framework of the Process Analytical Technology (PAT) initiative, a key element for improving drug safety and drug quality. In 2001, the American authority US FDA initiated a PAT programme, which has already been considered by EMEA, the European registration authority. **To this end, the IPMB defines itself as a NIRS Competence Center with the opportunity to enhance the knowledge for other 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 PAT Conference 2006

Dear Madam, dear Sir,

It is a great pleasure for me to invite you to the International PAT Conference 2006 in Heidelberg. After a first successful PAT Conference in January 2005, this is the second PAT Conference presented by the University of Heidelberg. It was developed to give you an update on how PAT tools and technologies may be used in the pharmaceutical industry.

Experts from the pharmaceutical industry, regulatory authorities (EU and FDA) and academia (including Duquesne University, USA) will present current issues, trends and applications, such as

- Design Space
- Data management
- PAT in API and drug product manufacturing
- Spectroscopic imaging
- Risk management.

This PAT Conference will be an excellent opportunity to get the latest information on different areas of development and supporting technologies currently being used.

Since **Process Understanding** is one of the key issues in Process Analytical Technology (PAT), we decided to include sessions focussing on **Basic Science and Understanding of Manufacturing Processes**.

It is also the aim of this extraordinary event to be a meeting place for interesting discussions. Here you can meet the important personalities from regulatory authorities as well as colleagues from the industry.

I would be glad to welcome you in Heidelberg on behalf of the Institute of Pharmacy and Molecular Biotechnology.



Dr Gabriele Reich  
IPMB, University of Heidelberg

# The Heidelberg PAT Conference 2006

27 - 29 September 2006, Heidelberg, Germany

## Regulatory Background and Objectives

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The Publication of the FDA's Guidance for Industry on Process Analytical Technology (PAT) in September 2004 put in place the principles, regulatory strategy, and clarity to remove any regulatory uncertainty limiting the application of innovative technology. The removal of this uncertainty was seen as essential to drive a consistent high product quality and to improve process efficiency through reduced process variability using science based and risk assessed approaches through

- continuous improvement rather than corrective actions,
- significantly improved process understanding,
- the application of appropriate measurement and control strategies.

PAT is increasingly being globally recognised as a powerful knowledge engine capable of facilitating those objectives, but as a regulatory guidance document it is atypical – it's non prescriptive! It specifies what should be done and why but not HOW!

The current question and challenge is whether the industry has the strategies to **benefit** from PAT by transferring it to an **effective "Design for Manufacture"**.

As a direct result the industry and regulatory agencies are now actively engaged in a range of forums e.g. **ICH** and **ASTM** to rapidly put in place consensus documents describing HOW the objectives described in the Guidance can be addressed.

This PAT conference will give you an excellent current overview of

- regulatory, industry and academia perspectives from Europe and the US,
- the science that is available to support some of the common pharmaceutical processes,
- the status of a broad range of applications and supporting technologies being pursued to further improve industry performance facilitated by the PAT initiative,
- how these applications individually and collectively impact Design for Manufacture through the integration of:
  - process knowledge
  - measurement
  - control
  - engineering
  - Information Technology

and will enable the transformation of **Design for Manufacture philosophy into reality**.

## Moderator

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**Dr Gabriele Reich**

## Conference Programme 27 - 29 September 2006

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### ■ Welcome by the University

**Dr Gabriele Reich, Faculty of Biological Science, University of Heidelberg**

### ■ PAT – An FDA-Update

**Dr Chris Watts, FDA, CDER, OPS, USA**

### ■ Quality by Design and Bioequivalence / Bioavailability Assessment

**Dr Ajaz Hussain, Sandoz Inc., USA**

- Pharmaceutical equivalence
- Bioequivalence and therapeutic equivalence
- Relation to Quality by Design

### ■ PAT from an European Perspective

**Prof Christina Graffner, Swedish Medical Products Agency, Sweden**

- Product Development
- Real Time quality assurance
- Understanding and its possible implications on post approval variations

### ■ Cost Benefits by PAT?

**Ken J. Leiper, Benson Associates, UK**

- What are the compelling business drivers for implementing PAT?
- How can they be:
  - Quantified
  - Achieved?
  - Sustained?

### ■ Current Research and Resources for Understanding Drying of Pharmaceutical Materials

**Dr Carl Anderson, Duquesne University, USA**

- Important considerations for drying of pharmaceutical materials
- Review of available literature regarding drying of pharmaceutical materials
- Current investigations into monitoring of drying

### ■ Current Research and Resources for Understanding Blending of Pharmaceutical Materials

**Dr Carl Anderson, Duquesne University, USA**

- Review of available literature regarding blending of pharmaceutical materials
- Review of current researchers in the field of pharmaceutical blending
- Description of tools used to understand the blending process
- Current investigations into understanding in-bin blending by NIR hyperspectral imaging
- Tools for assessing the blending process

- **The Science and Engineering of Tablet Coating**  
**Prof Carl Wassgren, Purdue University, USA**

  - Literature review concerning tablet coating
  - Tools for investigating tablet coating dynamics
  - Current investigations into inter- and intra-tablet coating variability
  
- **Risk Analysis as the Basis for Implementing a PAT Strategy**  
**Dr Thorsten Herkert, AstraZeneca, Germany**

  - ICH Q9 “Quality Risk Management”
  - Significance of Risk Management in a PAT system
  - Methodology of a failure mode and effect analysis
  - Team skills needed for a successful Risk Management
  - Risk Management and mitigation
  
- **General Considerations of Sampling in a PAT Environment**  
**Dr Carl Anderson, Duquesne University, USA**
  
- **Utilising Near-Infra Red Microscopy and Complimentary Tools for Mechanistic Understanding of Pharmaceutical Manufacturing**  
**Jordan Cheyne, Pfizer Ltd., UK**

  - Near-Infra Red microscopy for analysing solid dosage forms to understand the interactions of materials within tablets/capsules and blends and to correlate this with product performance
  - Technique, advantages and limitations to Pharmaceutical applications
  - Other analytical techniques for true Root Cause identification – complimenting and building a complex picture of interaction between materials in a product
  
- **Data Management Challenges in a PAT Environment**  
**Ray W. Bolton, AstraZeneca Engineering, UK**

  - In the context of global process research, development and operations:
    - What is a PAT environment?
    - Which PAT technology components can be shared between these organizations?
    - Why setting policies and standards for building PAT data management infrastructure is critical?
    - What are the benefits of establishing a global PAT data management infrastructure?
  
- **Statistical Techniques for PAT**  
**Dr Thomas Fürst, Schering AG, Germany**

  - Overview over the tools of the trade
  - Design of Experiments
  - Multivariate Data Analysis
  - Applications
  - Software packages
  
- **PAT at Roche Ireland Limited, A Holistic Approach**  
**Dr John O’Reilly, Roche Ireland Ltd, Ireland**

  - PAT is an integral part of API manufacturing at Roche Ireland
  - Near infrared technology employed in in-line process analysis since 1994
  - Continuous in-line monitoring has led to significant process improvements and financial rewards
  - Successes and disappointments encountered during the evolutionary period
  - Great acceptance of PAT where analysis has led to clear benefits (manufacturing, laboratory, engineering teams)
  
- **Beyond Process Analysis – Lessons Learned from a Holistic Approach to PAT**  
**Dr David Radspinner, Thermo, USA**

  - Integrating Risk Management into your PAT Program
  - Patient Focused PAT efforts
  - User Requirements – Who is the User?
  - Regulatory Communication – who and what
  - Outsourcing vs. in-house capabilities
  
- **Enabling the Development of Manufacturing Science by Expediting Product Transfer to Manufacturing**  
**Dr James S. Fox, GlaxoSmithKline, UK**

  - Range and scope of challenges which have to be addressed to successfully transform design for manufacture from a concept to reality:
    - Industry reluctance to undertake significant post licence variations as an obstacle for developing manufacturing science
    - Regulatory stimulus, framework and manufacturing opportunity to improve on today’s product quality and process efficiency standards across a product’s life cycle
    - Significant technical and cultural challenges
  
- **Principles and Practices of Process Design in a PAT Environment**  
**Dr Gerd Fischer, sanofi-aventis, Germany**

  - Discussion of the ASTM Standard Practice on PAT Process Design: risk assessment and mitigation, continuous improvement, process fitness for purpose, intrinsic performance assessments, manufacturing strategy, data collection and formal experimental design, multivariate tools, process analyzers, process control
  - How products and manufacturing processes should be designed using science- and risk-based strategies to manage variation
  - How Process Design, Process Understanding, and Quality Risk Management are linked
  - How Process Understanding can form the basis to adjust the level of regulatory oversight

## ■ Integrating PAT Equipment with Process Automation and Control Systems

Ray W. Bolton, AstraZeneca Engineering, UK

- What is the problem? – Issues and difficulties arising from current practice
- OPC standard used throughout the global process automation industry as a possible solution?
- Examples of tactical developments to provide standard OPC interfaces for critical PAT applications

- Benefits of adopting an industry standard solution for real time interfacing to control systems
- Can a generic OPC interface to PAT equipment be defined?

## ■ Design Space: A Pragmatic Perspective

Dr Ajaz Hussain, Sandoz Inc., USA

- Evolution of Design Space concept
- Make your own PAC
- From SUPAC & BACPAC

## ■ A Regulatory Perspective of a PAT Driven Future

Dr Chris Watts, FDA, CDER, OPS, USA

## ■ PAT – Training Needs and Resources

Ken J. Leiper, Benson Associates, UK

- Changes in work practice inevitably requires skill base reappraisal
- What skill changes might be required to effectively implement PAT?
- How will the new skill portfolio be:
  - Defined?
  - Developed?
  - Delivered?
  - Sustained?

## 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, go deeper into technical matters, 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.

## 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**. From Frankfurt it takes only about 45 minutes to get to Heidelberg.

- Lufthansa Shuttle Bus: Even if you do not fly, you can take this bus. It leaves Frankfurt Airport approximately once an hour.
- TLS Airport Shuttle Service Frankfurt: Germany's most experienced Airport Shuttle-Service TLS brings you promptly and reliably from the airport to your 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 to Heidelberg.

## Welcome to Heidelberg



Heidelberg stands for the world-famous Castle and a picturesque Old Town in breathtakingly beautiful surroundings. It stands both for **Germany's oldest university and modern research facilities**. For historic streets and a lively university atmosphere. For total relaxation and beautiful walks, plus stimulating international conferences and festivals.

## Conference Exhibition



Leading suppliers of PAT-related equipment and services are invited to exhibit their products in a presentation room during the three conference days.

## Speakers

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### Dr Carl Anderson

*Duquesne University, Pittsburgh, PA, USA*

Dr. Carl Anderson is an assistant professor of pharmaceutical sciences. His group is focussed on pharmaceutical applications of analytical technology and chemical imaging.

### Ray W. Bolton

*Technology Group, AstraZeneca Engineering, Macclesfield, UK*

Ray Bolton has worked in ICI, Zeneca and AstraZeneca for thirty years. The last six years have been spent designing and building process analytical technology infrastructure for use in development and manufacturing with a special emphasis on integrating PAT technology into process equipment control systems and data management systems.

### Jordan Cheyne

*Process Analytical Support Group, Pfizer Ltd., Sandwich, UK*

Jordan Cheyne is a Scientist within the Root Cause Analysis team of PASG. His role is global support to manufacturing sites for troubleshooting of production issues.

### Dr Gerd Fischer

*sanofi-aventis, Frankfurt, Germany*

Dr. Gerd Fischer is head of the Technical Quality and Compliance Expertise group in Corporate Quality and Compliance. He is responsible for site support incl. training and standard-setting activities.

### Dr James S. Fox

*GlaxoSmithKline, UK*

### Dr Thomas Fürst

*Schering AG, Berlin, Germany*

Dr Fürst joined Schering in 1987, working in a production facility for oral dosage forms. Later he joined the analytical development department. His responsibilities were method development and validation of analytical methods. Since Feb. 2006 Dr. Fürst is head of the Pharmaceutical Development Services group of Schering Berlin.

### Prof Christina Graffner

*Scientific Director of Pharmaceuticals and Biotechnology, Swedish Medical Products Agency, Uppsala, Sweden*

Christina Graffner is Expert of the ad hoc EU-PAT group of EMEA's scientific committees CHMP and CVMP and Alternate member of the European Pharmacopoeia Commission, chairwoman of its expert group 12 (galenical products) including the ad hoc group Inhalanda and its expert group Standard Terms.

### Dr Thorsten Herkert

*AstraZeneca, Plankstadt, Germany*

Dr Thorsten Herkert joined AZ in 2001 working on the implementation of NIR in the Plankstadt facility. Since this time he is involved in equipment qualification, method development and validation and the development of a RTR Strategy in AZ. Later he joined the quality assurance department. Since 2005 he is the responsible QP for tablet and API production in Plankstadt.

### Dr Ajaz Hussain

*Sandoz Inc., USA*

Global Head for Biopharmaceutical Development and Vice President. Prior to joining Sandoz he led the FDA Initiatives on Biopharmaceutics Classification System, PAT and CGMP's for the 21st Century. He is also a Professor at Universities of Purdue & Michigan.

### 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 John O'Reilly

*Roche Ireland Ltd., Clarecastle, Ireland*

Dr. John O'Reilly has been working in the pharmaceutical industry for the last twenty five years. He started work as an R&D Chemist with Syntex Ireland in 1981 which later became Roche Ireland in 1994. John currently divides his time in supporting the on-going integration of the process analytical systems into the core company structures, in the development and implementation of new PAT applications and in the transfer of analytics for new products

### Dr David Radspinner

*PAT Business Development Director, Thermo, Madison, USA*

Dr. Radspinner leads Thermo's development of solutions for pharmaceutical process enhancement through modern analysis and control. Dr. Radspinner formerly led the drug product PAT initiative within Aventis Pharmaceuticals.

### Dr Gabriele Reich

*Faculty of Biological Sciences, University of Heidelberg, Germany*

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

### Prof Carl Wassgren

*Purdue University, West Lafayette, IN, USA*

Dr. Wassgren is an associate professor of mechanical engineering and also holds a courtesy appointment in industrial and physical pharmacy. His research focuses on modeling the dynamics of particulate systems.

### Dr Chris Watts

*FDA Process Analytical Technology Team, Office of Pharmaceutical Science, Center for Drug Evaluation and Research (CDER), FDA, Rockville, USA*

Chris is the Team Leader for Standards and Technology in the Office of Pharmaceutical Science at the FDA's Center for Drug Evaluation and Research. His current responsibilities include developing Agency policy and training programs, managing standards efforts, and collaborating in research ventures with industry and academia. Prior to joining the FDA, his industrial experience involved product and process development, as well as the scale-up and manufacture of inhalation and oral drug products. He received his B.S. in Biomedical Engineering from Boston University and Ph.D. in Pharmaceutics from The University of Tennessee.

## Date

Wednesday, 27 September 2006, 09:00 – 18:00 h  
(Registration and coffee 08:30 – 09:00 h)  
Thursday, 28 September 2006, 08:30 – 18:00 h  
Friday, 29 September 2006, 08:30 – 16:00 h

## Venue

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

## Fees

Non-ECA Members € 1.990,- per delegate plus VAT  
ECA Members € 1.791,- 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 all three days and all refreshments. VAT is reclaimable.

## Accommodation

CONCEPT has reserved a limited number of rooms in the Marriott Hotel. Reservation should be made directly with the hotel not later than 15 August 2006. You will receive a room reservation form when you have registered for the course. Please use this form for your room reservation or be sure to mention CONCEPT to receive the specially negotiated rate for the duration of your stay. Early reservation is recommended.

## Registration

Via the attached reservation form, by e-mail or by fax message. Or you register online at [www.pat-conference.org](http://www.pat-conference.org)

## Conference language

The official conference language will be English.

## Co-sponsor: The European Compliance Academy (ECA)

The European Compliance Academy is an independent educational organisation chaired by a Scientific Board with members from 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.

## Organised by CONCEPT HEIDELBERG

CONCEPT HEIDELBERG  
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Dr Günter Brendelberger (Phone +49 (0) 62 21 / 84 44 40, e-mail: [brendelberger@concept-heidelberg.de](mailto:brendelberger@concept-heidelberg.de)), the responsible project manager, will help you with any technical questions as regards content.

Marion Weidemaier (Phone +49 (0) 62 21 / 84 44 46, e-mail: [weidemaier@concept-heidelberg.de](mailto:weidemaier@concept-heidelberg.de)), the responsible organisation manager, will help you with any questions concerning reservation, hotel, etc.

Founded in 1978, CONCEPT HEIDELBERG is the leading organiser of seminars on pharmaceutical production, quality control, quality assurance and GMP in Europe. This year more than 240 events will be organised by CONCEPT HEIDELBERG. ECA has entrusted CONCEPT HEIDELBERG with the organisation of its events.

## Refunds / Cancellations

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 % of the registration fee.
- until 1 week prior to the conference 50 % of the registration fee.
- within 1 week prior to the conference 100 % of the registration fee.

CONCEPT 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 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. You are not entitled to participate in the conference until we have received your payment (receipt of payment will not be confirmed)!

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  
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D-69007 Heidelberg

Reservation Form (Please complete in full)

**The Heidelberg PAT Conference 2006**  
27 – 29 September 2006, Heidelberg, Germany

Mr       Ms

\_\_\_\_\_  
Title, first name, surname

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