



EUROPEAN COMPLIANCE  
ACADEMY

### Conference Chairman

**DR RANGO DIETRICH**  
*PharmDev Innovations*

### Speakers

#### From Authorities:

**DR RICCARDO LUIGETTI**  
*European Medicines Agency (EMA),  
U.K.*

**PROF GERT RAGNARSSON**  
*Swedish Medical Products Agency*

#### From Industry:

**DR THOMAS FÜRST**  
*Boehringer Ingelheim*

**DAVID HOLT**  
*AstraZeneca*

**RODNEY HORDER**  
*form. Abbott*

**DR LINE LUNDSBERG-NIELSEN**  
*NNE Pharmaplan*

**INGRID MAES**  
*PricewaterhouseCoopers*

**DR MICHEL ULMSCHNEIDER**  
*F. Hoffmann - La Roche*

**DR GERD WÖHRLE**  
*Abbott*

# Quality by Design & Efficiency in Pharma- ceutical Development

**Vienna, Austria**  
**18 – 19 May 2010**

### HIGHLIGHTS:

- Authority and Industry Point of View
- Challenges and Possibilities
- Different Tools
- Case Studies – Success Stories
- CMC Documentation

Book Conference „Formulation Development & Manufacturing of  
Paediatric Drugs“ from 19-20 May 2010 as well and and save up to € 400,-!

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# Quality by Design & Efficiency in Pharmaceutical Development

18-19 May 2010, Vienna, Austria

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## Objectives

During this conference, **representatives from authorities** as well as specialists from the pharmaceutical industry share their **expert knowledge** on how Quality by Design can be implemented in Pharmaceutical Development. Hear about best practices from **early development up to process transfer** and learn how **Quality by Design (QbD)** and can be realised.

## Background

In the development of new pharmaceutical products, it is a need to design and establish sound and appropriate products and processes. New aspects like **ICH Q8, PAT and Quality by Design** need to be considered and the developed medical product has to be to be producible and get a fast approval.

Overall, **Quality by Design** has to be seen as an overarching paradigm and an interdisciplinary system from development to production. It is a systematic approach emphasising enhanced product and process understanding. Ideally, QbD already starts in the early design phase of a drug product where both patient needs and process design should be kept in mind. During the following and ongoing design of process and product, it is important to constantly determine critical quality attributes and to understand how process parameters affect these attributes.

Besides this, **knowledge and process transfer** have to be well organised and managed, in parallel with a sound **development work**. Both are important pre-requisites to **enter the market as soon as possible**.

## Target Group

This conference is designed for all specialists, engineers, managers and executives from Pharmaceutical and Technology Development, from the respective Quality Assurance but also from Quality Control departments. It is also addressed to CROs and members of the EU and national inspectorates and authorities.

## Programme

### Chairman

**DR RANGO DIETRICH**, *PharmDev Innovations*

### Quality Overview – 21st Century Pharmaceutical Development

- Evolution of Quality
- The Pharmaceutical Quality System
- Expectations from ICH Q10 and the enablers

**DR RODNEY HORDER**, *Consultant, formerly Vice President Quality Assurance, Abbott*

### Challenges and Possibilities from the Authority Point of View

- Preferred state in Product Development & Manufacturing
- Potential win-win options
- Possibilities for faster reviews and approvals

**PROF GERT RAGNARSSON**, *Swedish Medical Products Agency*

### Quality by Design: A Pharmaceutical Developer's View

- What is Quality by Design?
- Applying QbD principles in product and process development
- How ICH Q8 supports a more efficient transfer from pharmaceutical development to commercial production along with increased global regulatory flexibility

**DR RANGO DIETRICH**, *PharmDev Innovations*

### Analytical Tools to facilitate Formulation Studies and Development

- Utilizing liquid model systems to support rapid formulation development of solid solutions for poorly water-soluble drugs
  - Predicting stability of solid solutions during formulation development
  - Optimizing analytical development to support early-phase development projects
- DR GERD WOHRLE**, *Abbott*

### Near-IR, Chemometrics, and analytical Applications to support QbD

- Essentials of NIR
  - Use of MVDA
  - Example applications
  - Chemical imaging
- DR MICHEL ULMSCHNEIDER**, *F. Hoffmann - La Roche*

### Case Studies on QbD from Process Development to Manufacturing

- PAT and QbD tools integration across the entire product and process lifecycle
  - Combination with real-time environments and time-based information management systems
  - Future relationship with the regulatory authorities
  - How to define the proper business case
- INGRID MAES**, *PricewaterhouseCoopers*

### Case Studies of utilizing real time Release within QbD Development

- Exemplify the value and benefits of real-time release to both industry and regulators
  - How is real-time release positioned within a QbD development and submission?
  - Examples are provided through actual case studies
- DAVID HOLT**, *AstraZeneca*

### Case Study on successful QbD Implementation

- QbD for a combinational product
  - Lessons learned
- DR LINE LUNDSBERG-NIELSEN**, *NNE Pharmaplan*

### The EMA PAT Team: Experiences, Expectations and Outlook

- Role of the EMA PAT Team
  - QbD regulatory tools
  - Implementation of QbD: the EU perspective
- RICCARDO LUIGETTI PHD**, *EMA*

### The FDA Point of View on Quality by Design

- Evolution and interactivity of respective FDA guidances
  - PAT, Design, Quality by Design and their interaction
  - Experiences from the Agency's point of view
- FDA SPEAKER INVITED**

### Integration of ICH Q8, Q9, Q10 Elements and PAT into CMC Documentation

- FMEA for the selection of critical steps and variables
  - DoE for Analytics, Pharmaceutical Development and Manufacturing
  - The use of 6 sigma tools and ideas
- DR THOMAS FÜRST**, *Boehringer Ingelheim*

## Speakers

### **DR RANGO DIETRICH**

*PharmDev Innovations GmbH, Germany*

Contract Qualified Person and Managing Director of PharmDev Innovations GmbH, a fast growing provider of innovative service concepts to pharmaceutical industry focussed on gaining speed in development and efficiency in processes.

### **DR THOMAS FÜRST**

*Boehringer Ingelheim Pharma GmbH & Co. KG, Germany*

Senior Scientist at the Development Unit of Boehringer Ingelheim, responsible for the scientific quality of submissions and the QOS.

### **DAVID HOLT**

*AstraZeneca, U.K.*

Senior Project Scientist, Analytical Development

### **DR RODNEY L HORDER B PHARM, PHD, MRPHARMS**

*Consultant, U.K.*

Formerly Divisional Vice President, Quality Centre of Excellence Europe, Abbott Quality & Regulatory

### **RICCARDO LUIGETTI PHD**

*EMA, U.K.*

Scientific Administrator at EMA's CHMP/CVMP Quality Working Party (QWP) and member of the EMA PAT Team.

### **DR LINE LUNDSBERG-NIELSEN**

*NNE Pharmaplan, Danmark*

Senior QbD & PAT Consultant at NNE Pharmaplan A/S and Owner, Lundsberg Consulting

### **INGRID MAES**

*PricewaterhouseCoopers, Belgium*

Director Pharma & Life Sciences

### **PROF GERT RAGNARSSON**

*Swedish Medical Products Agency, Sweden*

Scientific Director, Pharmaceuticals & Biotechnology, member of management group. Appointed Professor at MPA in May 2007

### **DR MICHAEL ULMSCHNEIDER**

*F. Hoffmann - La Roche Ltd, Switzerland*

PAT and Analytical Business Process Group

### **DR GERD WOEHRLE**

*Abbott GmbH & Co. KG, Germany*

Group Leader Analytical Development of SOLIQS, the global drug delivery business of Abbott

## Social Event




Participants of the Conference **Quality by Design & Efficiency in Pharmaceutical Development** are cordially invited to a guided sight-seeing tour of Vienna and dinner on Tuesday evening.

This is an excellent opportunity to share your own views and experiences with colleagues from other companies in a relaxed and casual atmosphere.

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|--------------------------------------|--|
| <b>Date</b>                          | Tuesday, 18 May 2010, 09.00 h – 18.00 h (Registration and coffee 08.30 h – 09.00 h)<br>Wednesday, 19 May 2010, 08.30 h – 12.30 h   |
| <b>Conference Fees</b>               | EU GMP Inspectorates EUR 745.- per delegate plus VAT<br>ECA Members EUR 1.340.- per delegate plus VAT<br>APIC Members EUR 1.415.- per delegate plus VAT<br>Non-ECA Members EUR 1.490.- per delegate plus VAT<br>The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on second day and all refreshments. VAT is reclaimable.  |
| <b>Would you like to save money?</b> | If you book the conference „Quality by Design & Efficiency in Pharmaceutical Development“ <b>TOGETHER WITH</b> the conference „Formulation Development & Manufacturing of Paediatric Drugs“ from 19-20 May 2010, the <b>fee for <u>each</u> conference reduces</b> as follows:<br>EU GMP Inspectorates EUR 645.- per delegate plus VAT<br>ECA Members EUR 1.160.- per delegate plus VAT<br>APIC Members EUR 1.245.- per delegate plus VAT<br>Non-ECA Members EUR 1.290.- per delegate plus VAT<br>The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first and second day, lunch on all days and all refreshments. VAT is reclaimable. |
| <b>Venue</b>                         | Renaissance Wien Hotel<br>Linke Wienzeile/Ullmannstr. 71<br>1150 Vienna<br>Austria<br>Tel.: +43 1 89 102<br>Fax: +43 1 89 102 300  |
| <b>Accommodation</b>                 | 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 “ECA 6273” to receive the specially negotiated rate for the duration of your stay. Reservation should be made directly with the hotel not later than 19 April 2010. Early reservation is recommended.   |
| <b>Conference language</b>           | The official conference language will be English.  |

## 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.gmp-compliance.org**

### Organisation

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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

### Contacts

**For questions regarding content:**  
Mr Wolfgang Schmitt (Operations Director) at +49-62 21 / 84 44 39, or per e-mail at w.schmitt@concept-heidelberg.de.  
**For questions regarding reservation, hotel, organisation etc.:**  
Ms Susanne Ludwig (Organisation Manager) at +49-62 21 / 84 44 44, or per e-mail at ludwig@concept-heidelberg.de.

### About CONCEPT HEIDELBERG

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.

### 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.

### How Do You Become a Member of ECA?

By participating in one of the European Compliance Conferences or Courses, you will automatically become a member of ECA for two years - free of charge. More information about ECA can be obtained on the Website **www.gmp-compliance.org**.

### What Are the Benefits of ECA?

During the membership, you enjoy a 10 % discount on the regular participation fee of any European Conference organised by ECA in co-operation with CONCEPT HEIDELBERG. A CD ROM with a large number of guidelines, e.g. EC Directives, FDA Guidelines, ICH Guidelines, will be forwarded to you when you are using your membership for a conference registration.

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

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P.O. Box 10 17 64  
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Reservation Form (Please complete in full)

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**Quality by Design & Efficiency in Pharmaceutical Development**  
18-19 May 2010, Vienna, Austria

Mr  Ms

Title, first name, surname

Company

Department

**Important: Please indicate your company's VAT ID Number**

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 week 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)!