



EUROPEAN COMPLIANCE
ACADEMY

Speakers from Authorities:

DR ANN MARIE KAUKONEN
*EMA PDCO, National Agency for
Medicines, Finland*

DR MANSOOR A. KHAN
FDA

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

PROF GERT RAGNARSSON
Swedish Medical Products Agency

DR JEAN TEMECK
FDA

University Speakers:

PROF DR JÖRG BREITKREUTZ
University Düsseldorf

DR CATHERINE TULEU
University of London

Industry Speakers:

DR BERNHARD BÖHM
Boehringer Ingelheim

DR JÖRG BREITENBACH
Abbott

DR RANGO DIETRICH
PharmDev Innovations

DR THOMAS FÜRST
Boehringer Ingelheim

DR ROBERT HARRIS
Beyond Quality Ltd

DR JOSEF HOFER
exdra GmbH

DAVID HOLT
AstraZeneca

RODNEY HORDER
form. Abbott

JIM KERNAN
PharmaFlow

DR JÖRG LIPPERT
Bayer Technology Services

DR LINE LUNDSBERG-NIELSEN
NNE Pharmaplan

DR RAMESH PADAVALA
Novartis Pharma

BARBARA SPANGL-KAVSEK
Siemens

DR MICHEL ULMSCHNEIDER
F. Hoffmann - La Roche

DR WILLI WEBER
Sanofi-Aventis

DR GERD WÖHRLE
Abbott



Part I: Quality by Design
Part II: Paediatric Drugs

Good Development Practice Conference

18–19 May 2010, Vienna, Austria

Quality by Design & Efficiency in Pharmaceutical Development

HIGHLIGHTS:

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

19–20 May 2010, Vienna, Austria

Formulation Development & Manufacturing of Paediatric Drugs

HIGHLIGHTS:

- Authority and Industry Point of View
- Formulation Strategies
- Modelling
- How to find the right Formulation (Dosage Form, Taste and Dosing)
- How to develop and manufacture the Formulation
- Project Management

Book both conferences and save up to € 400,-!

Speakers of both conferences

DR BERNHARD BÖHM

Boehringer Ingelheim Pharma GmbH & Co KG, Germany

Project Leader R&D at the Boehringer Ingelheim site in Biberach, Germany

DR JÖRG BREITENBACH

Abbott GmbH & Co.KG, Germany

Senior Director and Head of SOLIQS, Abbot's global drug development business

PROF DR JÖRG BREITKREUTZ

University Düsseldorf, Germany

University Professor at the Heinrich-Heine-University, Düsseldorf, Institute of Pharmaceutics and Biopharmaceutics with a focus on paediatric formulations

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.

DR ROBERT HARRIS

Beyond Quality Ltd, U.K.

Pharmaceutical Development Consultant

DR JOSEF M. HOFER

Exdra GmbH, Germany

Managing Director of exdra GmbH and assistant lecturer for Regulatory Affairs at the University in Bonn

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

DR ANN MARIE KAUKONEN

National Agency for Medicines, Finland

Senior Researcher (Pharm. Assessor), PDCO member

JIM KERNAN

Pharmaflow Limited, Ireland

Joint Managing Director

DR MANSOOR A. KHAN

FDA Center for Drug Evaluation and Research, USA

Director Division of Product Quality Research

DR JÖRG LIPPERT

Bayer Technology Services GmbH, Germany

Head of Systems Biology

RICCARDO LUIGETTI, PHD

European Medicines Agency (EMA), U.K.

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

**Speakers of both conferences
(cont.)**

DR LINE LUNDSBERG-NIELSEN

NNE Pharmaplan, Danmark

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

PROF GERT RAGNARSSON

Swedish Medical Products Agency, Sweden

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

DR RAMESH PADAVALA

Novartis Pharma AG, Switzerland

External Affairs Pediatrics and member of Pediatric Group.

BARBARA SPANGL-KAVSEK

Siemens AG Austria

Teamlead Process Analytics , Corporate Technology Central Eastern Europe , Research & Technologies , Life Science Systems

DR JEAN TEMECK

FDA Office of Pediatric Therapeutics, USA

Director of Paediatric International Program

DR CATHERINE TULEU

School of Pharmacy, University of London, U.K.

Senior Lecturer and Deputy Director of the Centre for Paediatric Pharmacy Research

DR MICHAEL ULMSCHNEIDER

F. Hoffmann - La Roche Ltd, Switzerland

PAT and Analytical Business Process Group

DR WILLI WEBER

Sanofi-Aventis Deutschland GmbH, Germany

R&D Metabolism and PK FFM

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 Part 1 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.

Participants of Part 2 of the conference (**Formulation Development & Manufacturing of Paediatric Drugs**) are invited for a dinner on Wednesday evening.

These are excellent opportunities to share your own views and experiences with colleagues from other companies in a relaxed and casual atmosphere.

Part 1: Quality by Design & Efficiency in Pharmaceutical Development

18–19 May 2010, Vienna, Austria

Objectives

During this part of the 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)** 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 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 WOEHRLE, *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

BARBARA SPANGL-KAVSEK, *Siemens AG*

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

DR MANSOOR A. KHAN, *FDA*

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*

Part 2: Formulation Development & Manufacturing of Paediatric Drugs

19–20 May 2010, Vienna, Austria

Objectives

Since December 2006, the Regulation (EC) No 1901/2006 on Medicinal Products for Paediatric Use (the '**Paediatric Regulation**') is effective and **mandatory for all pharmaceutical companies developing new products**.

At this part of the Conference, **all relevant aspects of paediatric formulation development and manufacturing** will be addressed. Questions like suitable dosage forms, acceptable daily intake, taste masking, dosing accuracy, manufacturability and compliance issues will be discussed in various case studies.

The development of paediatric formulations requires specific knowledge and skills combined with dedicated pre-clinical work and the flexibility to introduce new and sophisticated dosage forms to both development and production.

Background

The Regulation has been dramatically changing the development of medicinal products in Europe. So far only few medicinal products have had a specific approval for paediatric use. Off-label-use was and still is widely spread. The aim of the regulation is to improve the provision of secure suitable medicinal products for children from the age of 0 to 17. On the other hand, the implementation of the requirements will drive **complexity and investments** for the pharmaceutical industry; **new development strategies, new formulations** and more resources are needed. The overall approach and understanding of pharmaceutical development will change. The phar-

pharmaceutical industry needs to integrate all the paediatric aspects in the complete development process and has to assess the paediatric use for both products in early and late development and already authorised products.

Data needs to be generated for Marketing Authorisation of all new products since July 26, 2008 and new indications, pharmaceutical dosage forms and routes of admission since January 26, 2009. In many cases, pharmaceutical industry needs to develop new paediatric formulations. Hence, a sound paediatric development strategy is needed, addressing and considering various challenges.

Target Group

This ECA Conference addresses Research & Development functions, Project Managers as well as EU Regulators and Inspectors. Executives in general management positions will be able to better understand the issues and implications of the new requirements.

Programme

Quality Expectations and Issues for Paediatric Medicines

- Quality expectations from a regulatory point of view
- PIPs
- MAAs

DR ANN MARIE KAUKONEN, *EMA PDCO*

The FDA Point of View on Paediatrics

- US Pediatric Legislation and its implementation
- International collaborations
- Outlook

DR JEAN TEMECK, *FDA Office of Pediatric Therapeutics*

The FDA:NIH Collaboration

- Pediatric formulations: Some physicochemical and pharmacokinetic considerations in FDA:NIH Collaboration

DR MANSOOR A. KHAN, *FDA Center for Drug Evaluation and Research*

Consequences for the Industry

- Experience from a company perspective
- Internal Implementation
- Approach to Paediatric Drug Development

DR RAMESH PADAVALA, *Novartis*

Potential Strategies for formulating Medicines for Children

- Issues, challenges and potential strategies
- Case studies from recent experience

DR ROBERT HARRIS, *Beyond Quality Ltd.*

PBPK Modelling

- PBPK modelling and how to use it
- How to understand substances
- Pooling and dosing
- Standard procedures and reports
- Study design

DR JÖRG LIPPERT, *Bayer Technology Services*

Project Management in paediatric Development

- Global paediatric development strategy
- The need for a parallel development
- How to fit paediatric development into the overall development landscape
- Capacity and timeline aspects: what to think about?
- When to start what: being ready for submission vs. minimizing risk
- Patent / exclusivity aspects

DR BERNHARD BÖHM, *Boehringer Ingelheim*

How to find and develop the right Dose

- Juvenile population and the adequate dose
- Things to consider

DR WILLI WEBER, *Sanofi-Aventis*

Taste and Taste Masking

- Influence on the final taste of the formulation
- Taste masking
- Taste assessment

PROF JÖRG BREITKREUZ, *University Düsseldorf*

Finding the right Formulation	<ul style="list-style-type: none"> ■ Suitable formulations ■ Selections of excipients ■ The academic and clinical approach <p>DR CATHERINE TULEU, <i>University of London</i></p>
Manufacturability of Paediatric Formulations	<ul style="list-style-type: none"> ■ Various dosage forms ■ Individual dosage forms or one size fits all ■ How these decisions fit with adult development <p>DR JÖRG BREITENBACH, <i>Abbott</i></p>
Outsourcing of Development and Manufacturing Activities	<ul style="list-style-type: none"> ■ Case Study: Project management, development, manufacturing and supply chain of a paediatric oncology product for O4CP. <p>JIM KERNAN, <i>Pharmaflow</i></p>
Experiences of a paediatric CRO	<ul style="list-style-type: none"> ■ How a paediatric CRO can help ■ Examples for successful development <p>DR JOSEF HOFER, <i>exdra</i></p>
Dates	
Conference “Quality by Design & Efficiency in Pharmaceutical Development”	<p>Tuesday, 18 May 2010, 09.00 h – 18.00 h (Registration and coffee 08.30 h – 09.00 h) Wednesday, 19 May 2010, 08.30 h – 12.30 h</p>
Conference Fees	<p>EU GMP Inspectorates EUR 745.- per delegate plus VAT ECA Members EUR 1.340.- per delegate plus VAT APIC Members EUR 1.415.- per delegate plus VAT Non-ECA Members EUR 1.490.- 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.</p>
Conference “Formulation Development & Manufacturing of Paediatric Drugs”	<p>Wednesday, 19 May 2010, 14.15 h – 18.30 h (Registration and coffee 13.45 h – 14.15 h) Thursday, 20 May 2010, 8.30 h – 16.30 h</p>
Conference Fees	<p>EU GMP Inspectorates EUR 745.- per delegate plus VAT ECA Members EUR 1.340.- per delegate plus VAT APIC Members EUR 1.415.- per delegate plus VAT Non-ECA Members EUR 1.490.- 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 second day and all refreshments. VAT is reclaimable.</p>
Would you like to save money?	<p>If you book the conference „Quality by Design & Efficiency in Pharmaceutical Development“ TOGETHER WITH the conference „Formulation Development & Manufacturing of Paediatric Drugs“, the fee for each conference reduces as follows: EU GMP Inspectorates EUR 645.- per delegate plus VAT ECA Members EUR 1.160.- per delegate plus VAT APIC Members EUR 1.245.- per delegate plus VAT Non-ECA Members EUR 1.290.- per delegate plus VAT 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.</p>
Venue of both conferences	<p>Renaissance Wien Hotel Linke Wienzeile/Ullmannstr. 71 1150 Vienna, Austria Phone +43 1 89 102, Fax +43 1 89 102 300</p>
Accommodation	<p>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.</p>
Conference language	<p>The official conference language will be English.</p>

Easy Registration



Reservation Form:
CONCEPT HEIDELBERG
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Organisation

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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.

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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

Formulation Development & Manufacturing of Paediatric Drugs
19-20 May 2010, Vienna, Austria

Mr Ms

Title, first name, surname

Company

Department

Important: Please indicate your company's VAT ID Number

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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)!