



EUROPEAN COMPLIANCE
ACADEMY

Speakers

From Authorities:

DR ANN MARIE KAUKONEN
*EMA PDCO, National Agency for
Medicines, Finland*
DR MANSOOR A. KHAN
FDA
DR JEAN TEMECK
FDA

From Universities:

PROF DR JÖRG BREITKREUTZ
University Düsseldorf
DR CATHERINE TULEU
University of London

From Industry:

DR BERNHARD BÖHM
Boehringer Ingelheim
DR JÖRG BREITENBACH
Abbott
DR ROBERT HARRIS
Beyond Quality Ltd
DR JOSEF HOFER
exdra GmbH
JIM KERNAN
PharmaFlow
DR JÖRG LIPPERT
Bayer Technology Services
DR RAMESH PADAVALA
Novartis Pharma
DR WILLI WEBER
Sanofi-Aventis

Formulation Development & Manufacturing of Paediatric Drugs

Vienna, Austria
19 – 20 May 2010

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 Conference „Quality by Design & Efficiency in Pharmaceutical
Development“ from 18-19 May 2010 as well and and save up to € 400,-!

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 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 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 Collaborations

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**
- Suitable formulations
 - Selections of excipients
 - The academic and clinical approach
- DR CATHERINE TULEU, University of London**
- Manufacturability of Paediatric Formulations**
- Various dosage forms
 - Individual dosage forms or one size fits all
 - How these decisions fit with adult development
- DR JÖRG BREITENBACH, Abbott**
- Outsourcing of Development and Manufacturing Activities**
- Case Study: Project management, development, manufacturing and supply chain of a paediatric oncology product for O4CP.
- JIM KERNAN, Pharmaflow**
- Experiences of a paediatric CRO**
- How a paediatric CRO can help
 - Examples for successful development
- DR JOSEF HOFER, exdra**

Speakers

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 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

DR ANN MARIE KAUKONEN

National Agency for Medicines, Finland

Senior Researcher (Pharm. Assessor), PDCO member

DR MANSOOR A. KHAN

FDA Center for Drug Evaluation and Research, USA

Director Division of Product Quality Research

JIM KERNAN

Pharmaflow Limited, Ireland

Joint Managing Director

DR JÖRG LIPPERT

Bayer Technology Services GmbH, Germany

Head of Systems Biology

DR RAMESH PADAVALA

Novartis Pharma AG, Switzerland

External Affairs Pediatrics and member of Pediatric Group.

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 WILLI WEBER

Sanofi-Aventis Deutschland GmbH, Germany

R&D Metabolism and PK FFM

Social Event

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

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

**Date**

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

Conference Fees

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.

Would you like to save money?

If you book the conference „Formulation Development & Manufacturing of Paediatric Drugs“ **TOGETHER WITH** the conference „Quality by Design & Efficiency in Pharmaceutical Development“ from 18-19 May 2010, 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.

Venue

Renaissance Wien Hotel
Linke Wienzeile/Ullmannstr. 71
1150 Vienna
Austria
Tel.: +43 1 89 102
Fax: +43 1 89 102 300

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 “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.

Conference language

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



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Organisation

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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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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

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 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)!