Formulating better medicines for children
Meeting the needs of the children

21st to 22nd September 2011
Strasbourg, France

Course No. 6386

Updated programme

3rd conference of the
European Paediatric Formulation Initiative EuPFI

A conference organised by
the International Association for Pharmaceutical Technology
in partnership with
the European Paediatric Formulation Initiative

EuPFI

Keynote Speakers

Susanne Keitel, PhD
Director of the European Directorate for the Quality of Medicines & HealthCare (EDQM), France

Mansoor A. Khan, PhD
Director of Division of Product Quality Research, CDER, FDA, USA

Diana Van Riet-Nales, PharmD
Quality Working Party, EMA, UK and RIVM, The Netherlands

Tom Sam, PhD, MBM, FFIP
Director Pharmaceutical CMC, Global Quality Merck Sharp & Dohme, The Netherlands
Science & Technology Officer, FIP’s Industrial Pharmacy Section

Soap box sessions – Poster session – Exhibition
Formulating better medicines: New insights and innovations

Wednesday, 21st September 2011  10.00-18.00 h

**Set-up and poster mounting**

**Welcome and Introduction**
Catherine Tuleu, PhD, Chair of EuPFI
The School of Pharmacy, University of London, London, United Kingdom
Prof. Jörg Breitkreutz, PhD
Heinrich-Heine-University Düsseldorf, Düsseldorf, Germany

The EMA Perspective: Case studies from the PDCO Formulations Group (chemicals & biologicals)
Caroline Le Barbier, PhD
Scientific Administrator, Quality Sector, Chemicals, European Medicine Agency (EMA), United Kingdom
Isabel Esteve, PharmD
Scientific Administrator, Quality Sector, Biologicals, European Medicine Agency (EMA), United Kingdom

Industry case studies: Exploring a risk management approach towards developing the optimal paediatric formulation-applying quality by design and multi-criteria decision making
Tom Sam, PhD, MBM, FFIP
Director Pharmaceutical CMC, Global Quality Merck Sharp & Dohme, IP President / Science & Technology Officer, FIP's Industrial Pharmacy Section, United Kingdom

EMA Guideline on pharmaceutical development of medicines for paediatric use
Diana Van Riet-Nales, PharmD
Coordinator regulatory affairs, Chemical Pharmaceutical Assessment (CFB) at the Dutch National Institute for Public Health and the Environment (RIVM) and Vice-Chair of the EMA / CHMP's Quality Working Party, The Netherlands

WHO guideline development of paediatric medicines: points to consider in pharmaceutical development
Professor Emeritus Henning Kristensen, PhD, DSc., D.hc
Department of Pharmaceutics, Faculty of Pharmaceutical Sciences, University of Copenhagen and WHO representative

**Question and Answer session**

**Soap box session 1**
Moderation:
Catherine Tuleu, PhD
Prof. Jörg Breitkreutz, PhD

Lunch, exhibition and poster presentations

**Focus Session: Extemporaneous preparations**
Chairs:
Terry Ernest, PhD
Principal scientist, GlaxoSmithKline, United Kingdom

Extemporaneous compounding in Europe
Maria Carvalho, PhD
School of Pharmacy, University of London, United Kingdom

International initiatives on extemporaneous dispensing (WHO, Commonwealth Pharmacy Association)
Prof. Anthony J. Nunn
NIHR Medicines for Children Research Network and Liverpool John Moores University, United Kingdom

Discussion

**Focus Session: Taste masking and Taste assessment**
Chair:
Catherine Tuleu, PhD, Chair of EuPFI
The School of Pharmacy, University of London, London, United Kingdom

Assessing taste without using humans: Rat Brief Exposure Aversion model and electronic tongue
David Clapham, BPharm MRPharmS
GlaxoSmithKline, United Kingdom

Palatability assessment: an industrial perspective
Gesine Winzenburg, PhD
Novartis Pharma AG, Switzerland

Discussion

Afternoon break and exhibition

**Focus Session: Administration Devices**
Chair:
Jenny Walsh, PhD
AstraZeneca, United Kingdom

Regulatory aspects of devices
Herbert Wachtel, PhD
Boehringer Ingelheim Pharma GmbH & Co. KG, Germany

Development of child-appropriate devices
Dominik Erhard, PhD
Raumedic, Germany

Discussion

End of scientific programme

Wine tasting sponsored by INRESA and networking dinner
Thursday 22nd September 2011  08.30-15.00 h

Introduction day 2

FDA: Contribution to developing paediatric formulations and transatlantic collaboration
Mansoor Khan, R.Ph., PhD
Director, Division of Product Quality Research, FDA/CDER/OPS/OTR, United States

Paediatric Formulations: The "A" in ADME"
Susan Abdel-Rahman PharmD, PhD
Professor of Pediatrics and Pharmacy, University of Missouri-Kansas City School of Medicine, United States

Focus Session: Age-appropriate formulations
Chair:
Richard Kendall, PhD
MSD, United Kingdom

Off-patent Oral Oncology Drugs for Kids (O3K FP7-project): from bedside to PUMA
Dr Angelo Paci, PharmD, PhD
Institut de Cancérologie Gustave Roussy, France

Current administration practices and preferred formulations of children’s medicines in Tanzania
Dr Lisa V. Adams, M.D.
Dartmouth Medical School, United States

Discussion

Coffee break, exhibition and poster presentations

Soap box session 2
Moderation:
Catherine Tuleu, PhD
Prof. Jörg Breitkreutz, PhD

Lunch, exhibition and poster presentations

Quality of ingredients in paediatric medicines
Susanne Keitel, PhD
Director of the European Directorate for the Quality of Medicines & HealthCare (EDQM), France

Focus Session: Excipients
Chair:
Prof. Jörg Breitkreutz, PhD
Heinrich-Heine-University Düsseldorf, Düsseldorf, Germany

Excipient toxicokinetics
Karel Allegaert, PhD
Leuven University, Belgium

Update on the STEP (Safety and Toxicity of Excipient for Paediatrics) Database
Smita Salunke, MPharm
EuPFI, United Kingdom
Barbara Brandys
NIH Library, United States

Discussion

General Discussion

Closing of conference
Soap Box Presentations

Soap box session 1 – Wednesday, 21st September 2011

To Drink, Chew, or Swallow: Paediatric Dosage Forms and Rites of Passage
Wiet Stephan et. al., McNeil Consumer Healthcare, Neuss, Germany

In vitro performance of a dry powder inhaler using mouth-throat models of 4-5-year-old children
Below, Antje et. al., Heinrich-Heine University, Institute of Pharmaceutics and Biopharmaceutics, Düsseldorf, Germany

Orodispersible Minitablets as a child-appropriate dosage form with enalapril maleate: Avoiding the problems of extemporaneous formulations?
Hermes, Martin et. al., Heinrich-Heine University, Institute of Pharmaceutics and Biopharmaceutics, Düsseldorf, Germany

Selecting the food matrix with the highest masking power for delivering recommendations for children
Morel, Sylvain et. al., Alpha MOS, Toulouse, France

Compatibility Of Y-Site Administration Of Medications With A Standard 3-In-1 Parenteral Nutrition Admixture for Pediatrics
Ingunn, Tho et. al., University of Tromsoe, Tromsoe, Norway

Soap box session 2 – Thursday 22nd September 2011

Development of Clonidine HCL Orodispersible Film For Paediatric Population
Danso Fady et. al., London School of Pharmacy, London, United Kingdom

Flavoring Of Commercial Oral Liquid Pharmaceutical Products
Embrechts, Roger et. al., Janssen pharmaceuticals, Beerse, Belgium

Steady state pharmacokinetics of the novel AZT/3TC FDC tablets in HIV-infected children
Kayitare Egide et. al., University of Ghent, Ghent, Belgium

Development and Evaluation Using Electronic Tongue of Taste-Masked Drug for Paediatric Medicines
Thanh Huong, Hoang Thi et. al., University Lille Nord, Lille, France

Acceptance of drug-free minitablets in young children
Spomer, Natalie et. al., University Children’s Hospital, Düsseldorf, Germany
Key Plenary Topics

- EMA PIP Experiences Including Biologicals
- Exploring a Risk Management Approach Towards Developing the Optimal Paediatric Formulation: Industry Case Studies
- WHO and EMA Draft Guideline on Pharmaceutical Development of Medicines for Paediatric Use
- FDA Contribution to Developing Paediatric Formulations and Transatlantic Collaboration
- Pharmacokinetics in Children
- Quality of Ingredients in Paediatric Medicines

Topics for Oral and Poster Presentations

- Excipients
- Taste Masking and Taste Testing
- Administration Devices
- Extemporaneous and Industry Verified Preparations
- Developing Age Appropriate Formulations/Compliance-Adherence Issues
- Formulating Paediatric Medicines for Developing Countries
- Lessons Learned from PIP Submissions

Social Programme:

A wine tasting and a networking dinner will give the participants the opportunity to get together.

Exhibition and sponsoring:

Sponsoring and exhibition opportunities: We are glad to tailor a sponsor package (starting from 2000 EUR) according to your wishes. As an exhibitor you will be also invited to attend the sessions and network at the Get Together Dinner in the evening that is part of the conference programme. At the Hilton the poster presentations will be again integrated in the exhibition, ensuring that participants are around the exhibition stands as much as possible. Price for a table top space with table, chairs and power supply is 990 EUR plus one mandatory full conference registration (register before July 1st, to take advantage of the early bird fee!).

Please contact the APV headquarters
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EuPFI

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Formulating better medicines for children

Register by Friday 1st July 2011 to take advantage of the early bird fee

Course No. 6386
Formulating better medicines for children
in Strasbourg, France, 21st to 22nd September 2011

Date
Course No. 6386 from 21st Sept. 2011 10:00 to 22nd Sept. 2011 15:00

Location
Hilton Strasbourg Hotel
1, Avenue Herrenschmidt
67000 Strasbourg, France
Phone: +33 3 8837-4148
Fax: +33 3 8825-5503

Early bird Full fee
Non-Member (Non Academic, Non Governmental) 875 EUR 975 EUR
Member of APV (Non Academic, Non Governmental) 745 EUR 845 EUR
Non-Member (Academic, Governmental) 325 EUR 375 EUR
Member of APV (Academic, Governmental) 260 EUR 310 EUR
Students (please enclose evidence) 195 EUR 225 EUR

Registration
All correspondence regarding the conference should be addressed to:
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Kurfürstenstraße 59
55118 Mainz/Germany
Phone: +49 6131 9769-0
Fax: +49 6131 9769-69
e-mail: apv@apv-mainz.de
You will receive a confirmation of your registration with the invoice.

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