

# Formulating better medicines for children

Meeting the needs of the children

## 8<sup>th</sup> Conference of the European Paediatric Formulation Initiative

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

20 to 22 September 2016 Lisbon, Portugal · Course No. 6645



### Preconference Workshops

Workshop 1: How to construct/evaluate Paediatric Investigation Plans (PIPs)

Workshop 2: Case study – Benefit risk approach on dosage form design for paediatrics

**Soap box sessions – Poster session – Exhibition**  
**Early bird deadline 15 July 2016!**

Join us again for another informative and interactive conference on formulating better medicines for children.



International Association for Pharmaceutical Technology

# Formulating better medicines for children

Meeting the needs of the children

Dear Colleagues,

We are pleased to announce that the 8th EuPFI annual conference will take place on the 21st – 22nd September 2016 in Lisbon, Portugal. This Conference Series is the ideal forum to discuss and debate the issues/challenges of development of age appropriate dosage forms.

Although this meeting is well established on the paediatric calendar there are always those attending who are new to the area. Therefore two pre-conference workshops are held to provide much needed focus and interactive session on 1) benefits and risks of potential paediatric drug product and 2) to introduce the regulatory framework/quality section of PIPs and the data package that comes into licensing division when the product has reached the market authorisation submission stage.

This conference will focus on challenges and opportunities for developing paediatric products. You will hear on the views of the young people on effectively engaging with patients and the public in R&D. The other key topics that will be covered in this conference include Update on industry standard framework and suite of tools to develop safe and efficacious paediatric dosage forms, Minimum data/information set needed for the PIP submission or to improve the quality of data submitted on pharmaceutical development, Interactions between FDA, IPEC and IQ on excipients and paediatric formulations, Novel excipients and much more.

The programme for the EuPFI meeting is typically designed around the workstreams that comprise the EuPFI activity; Pharmaceutical Excipient, Taste masking and taste assessment method, Administration device, Age appropriate formulation and Biopharmaceutics. The innovation showcase provides an opportunity for businesses working in paediatric formulations to raise the profile of their technology and share potential applications. Shorts talks (soapbox sessions) from submitted abstracts will be presented at the meeting all of which provided opportunities for networking and the initiation of new collaborations. We encourage you to explore the EuPFI website which contains all the information you need to submit your abstracts.

The conference provides a platform to exchange/share many common goals/issues around both scientific and regulatory aspects related to pediatric formulation development.

We do hope that you will be able to join us for what promises to be a most useful conference and we are looking forward to welcoming you in Lisbon, city of seven hills.

**Catherine Tuleu, UCL School of Pharmacy, London, United Kingdom**  
**Jörg Breitzkreutz, Heinrich Heine University, Düsseldorf, Germany**

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The European Paediatric Formulation initiative (EuPFI) is a consortium of members working in a pre-competitive way on paediatric drug formulations. It was founded in 2007 with the aim of raising awareness of paediatric formulation challenges. Members are from academia, hospitals and the pharmaceutical industry (innovators, generics, CROs, specials and excipient manufacturers), with EMA as a continuous observer. The main objective of the EuPFI is to resolve scientific, technological and regulatory issues associated with paediatric formulation development by writing reflection papers, organising conferences, developing knowledge repositories and promoting dialogue through its website. Currently, there are five EuPFI workstreams, covering pharmaceutical excipients, age appropriateness of formulations, taste masking and taste assessment methods, biopharmaceutics, and administration devices.

Mainz, July 2016



## Programme

### PRECONFERENCE WORKSHOP

**Tuesday, 20th September 2016, 16:00 to 19:00**

**16:00 - 17:10**

**Workshop 1: How to construct/evaluate Paediatric Investigation Plans (PIPs).**

Nasir Hussain, Medicines and Healthcare Products Regulatory Agency (MHRA), London, UK

**Workshop 2: Case study – Benefit risk approach on dosage form design for paediatrics**

Co-lead – Terry Ernest (GSK), Jenny Walsh (paediatric product development) and Smita Salunke (EuPFI), UK

**17:10 - 17:20 (Swap over and Settling)**

**17:20 - 18:30**

**Workshop 1: How to construct/evaluate Paediatric Investigation Plans (PIPs).**

Nasir Hussain, Medicines and Healthcare Products Regulatory Agency (MHRA), London, UK

**Workshop 2: Case study – Benefit risk approach on dosage form design for paediatrics**

Co-lead – Terry Ernest (GSK), Jenny Walsh (paediatric product development) and Smita Salunke (EuPFI), UK

**18:30 - 19:00 Wrap-up and Discussion**

**20:00 Networking Dinner**

**Wednesday, 21st September 2016, 8:30 to 18:00**

**8:30 - 9:00**

**Set-up and poster mounting**

**9:00 - 9:15**

**Welcome and Introduction**

Catherine Tuleu, Chair of EuPFI, UCL School of Pharmacy, London, United Kingdom  
Jörg Breitzkreutz, Heinrich-Heine-University, Düsseldorf, Germany

**9:15 - 9:55**

**PLENARY 1: Patient and Public Involvement – Views of young person**

Simon Stones, EULAR Young PARE, NIHR CRN: Children/Arthritis Research UK Paediatric Rheumatology Clinical Studies Group

**9:55 - 10:35:**

**PLENARY 2: SPaeDD-UK: Smart Paediatric Drug Development - UK Accelerating paediatric formulation development - An open innovation R&D project**  
Alastair Coupe, Pfizer Pharmaceuticals, Canterbury, UK

**10:35 - 11:10**

**Morning break, exhibition and poster presentations**

**Focus Session: Taste Masking & Taste testing**

Chair: Roy Turner, Novartis, Basel, Switzerland

**11:10 - 11:30**

**Cellular taste assessment models using the social amoeba *Dictyostelium discoideum*.**

Marco Coccorchio, School of Biological Sciences, Royal Holloway University of London, Egham, United Kingdom

**11:30 - 11:50**

**BitterDB: a database of bitter compounds (in silico prediction tool)**

Masha Niv, The Institute of Biochemistry, Food and Nutrition, The Hebrew University of Jerusalem, Israel

**11:50 - 12:00**

**Discussion**

**12:00 - 12:45**

**Soapbox Session I**

**Application of hot melt extrusion process for taste masking**

David Cheng Thiam Tan, AbbVie, Singapore

**Playing Hide and Seek with Isoniazid – Masking the Taste, Minimising Changes to Dissolution Performance**

Alison Keating, UCL School of Pharmacy, UK

**Enabling flexible dosing in orodispersible paediatric formulations by means of solvent casting and thermal inkjet printing**

Heidi Öblom, Abo Akademi University, Finland

**12:45 - 14:00**

**Lunch, exhibition and poster presentations**

**14:00 - 14:40**

**PLENARY 3: Minimum data/information set needed for the PIP submission or to improve the quality of data submitted on pharmaceutical development**  
Brian Aylward, Irish Health Products Regulatory Authority, Ireland

**Focus session: Administration Devices**

Chair: Jenny Walsh, Jenny Walsh Consulting, UK

**14:40 - 15:00**

**Combination Products development roadmap US/EU**  
Esmeralda Lousia Hermans, Janssen Research & Development, Belgium

**15:00 - 15:20**

**Human Factor Testing**

Torsten Gruchmann, Use-Lab GmbH, Steinfurt, Germany

15:20 - 15:30  
Discussion

15:30 - 16:10

*Afternoon break, exhibition and poster presentations*

16:10 - 17:00  
Soapbox Session II

Designing a multiparticulate administration device for paediatrics – a user based approach (2)  
Claire Lewis, University of Nottingham, UK

Palatability and acceptability of multiparticulate formulations: Adults vs. children comparison  
Felipe Lopez, UCL School of Pharmacy, UK

Suitability of Multiple Uncoated Mini-Tablets in Toddlers and Infants - A Randomized Controlled Trial  
Viviane Klingmann, University of Dusseldorf, Germany

Focus Session: Age Appropriateness of Formulations  
Chair: Fang Liu, University of Hertfordshire, Hartfield, United Kingdom

17:00 - 17:20  
Paediatric development for poorly soluble drugs  
Carsten Timpe, F. Hoffmann-La Roche, Basel, Switzerland

17:20 - 17:40  
Medicine acceptability in children : an original tool for standardized evaluation  
Fabrice Ruiz, ClinSearch, Malakoff, France

17:40 - 17:50  
Discussion

17:50 - 18:00  
House keeping

19:00

*Social programme with networking dinner*

**Thursday, 22nd September, 2016, 08:30-15:30**

8:50 - 9:00  
Brief introduction Day 2 / Housekeeping  
Catherine Tuleu, Chair of EuPFI, UCL School of Pharmacy, London, United Kingdom  
Jörg Breitreutz, Heinrich-Heine-University, Düsseldorf, Germany

Focus session: Excipients  
Chair: Floriane Sequier, AstraZeneca, United Kingdom

9:00 - 9:40  
Excipients update – Interactions between FDA, IPEC and IQ on Inactive ingredient database and paediatric formulations  
Dave Schonecker, Colorcon, IPEC America

9:40 - 10:10  
Lactose in medicines: safety concerns?  
Massimo Montalto, Università Cattolica del Sacro Cuore, Rome, Italy

10:10 - 10:40  
Innovation Show Cases

Novel Solutions for Pediatrics towards Better Compliance and Performance  
Eduardo Jule, Capsugel, France

Chemistry Manufacturing and Controls Considerations in Pediatric Drug Formulation Development for Low Resource Setting Applications, Speaker to be confirmed

10:40 - 11:00

*Morning break, exhibition and poster presentations*

11:00 - 11:45  
Soapbox Session III

The VALID-project: Development of a new paediatric formulation of valaciclovir  
Diane Bastiaans, Radboud University Medical Center, Netherlands

An evaluation of tools via patient-reported outcome measures to assess the acceptability of existing oral liquid medicines within a paediatric inpatient population.  
Punam Mistry, University of Birmingham, UK

Age related biorelevant dissolution testing for paediatric formulations  
Giovanna Mencarelli, University of Bath, UK

11:45 - 12:15  
Snapshot on EuPFI-IQ workshop - Challenges and Strategies to Facilitate Formulation Development of Pediatric Drug Products  
Trupti Dixit, Takeda Development Center Americas, US

Announcement of PCCA poster winner (12:15 - 12:30)

12:30 - 13:45

*Lunch, exhibition and poster presentations*

Focus Session: Biopharm  
Chair: Hannah Batchelor, University of Birmingham, United Kingdom

13:45 - 14:05  
Assessing food and vehicle effects for paediatric formulations: preclinical and clinical approaches  
David Harris, Merck & Co Inc.

14:05 - 14:25  
Feedback from EuPFI-IQ/M-CERSI Workshop June 2016 – session on co-administration with food  
Ann Marie Kaukonen, Fimea Finnish Medicines Agency, Helsinki, Finland

14:25 - 14:45  
Predicting performance in paediatric populations with PBPK modeling and biorelevant in vitro data  
Nikoletta Fotaki, University of Bath, United Kingdom

14:45 - 15:00  
Discussion

15:00 - 15:30  
Conference Wrap-up/Discussion


# Important Dates

Conference early bird registration – 15 July 2016

For more information go to [www.eupfi.org/8th-conference/](http://www.eupfi.org/8th-conference/)

## Topics for oral and poster presentations

1. Developing paediatric drug formulations
2. Excipients
3. Taste masking and taste testing
4. Administration devices
5. Modification of dosage forms required for children
6. Age appropriateness of formulation/compliance-adherence issues
7. Formulating paediatric medicines for developing countries
8. Lessons learned from PIP submissions
9. Biopharmaceutics

Again with PCCA poster award 



## Exhibition and Sponsoring

We are glad to tailor a sponsor package (starting from 1000 EUR) according to your wishes.

**For general information, please go to [www.apv-mainz.de/en/seminare/sponsoring-exhibition/](http://www.apv-mainz.de/en/seminare/sponsoring-exhibition/)**

As an exhibitor you will be also invited to attend the sessions and network at the networking dinner in the evening. At the conference center the poster presentations will again be integrated in the exhibition, ensuring that participants are around the exhibition stands as much as possible. Price for a tabletop space with table, chairs and power supply is 990 EUR plus one mandatory full conference registration (register before July 15, to take advantage of the early bird fee!).

**Please contact Antonia Herbert**

Phone +49 6131 9769-90

e-mail [ah@apv-mainz.de](mailto:ah@apv-mainz.de)



## Date

Date Course No. 6645

from 20 September 2016 16:00  
to 22 September 2016 16:00

Registration times for workshop participants:  
20 September 2016 15:00

Registration times for conference participants:  
21 September 2016 08:00

Set up and poster mounting times:  
21 September 2016 08:30

## Location

### Novotel Lisboa

Avenida José Malhoa, 1  
1 A 1099-051 Lisboa, Portugal  
Phone: +351 21 7244800  
Fax: +351 21 7244801

## Hotel reservation

### Novotel Lisboa

Avenida José Malhoa, 1  
1 A 1099-051 Lisboa, Portugal  
Phone: +351 21 7244800  
Fax: +351 21 7244801  
email: H0784@accor.com

Participants should make their own hotel reservation referring to the APV seminar. For registration please use booking form.

Deadline for special conference rate:  
20 July 2016.

Special rate:  
Single room incl. breakfast buffet from  
105,00 EUR per night.

Mainz, July 2016

## Conference Secretariat

### For organisational questions

International Association for  
Pharmaceutica Technology (APV)  
Kurfürstenstraße 59  
55118 Mainz, Germany  
Phone: +49 6131 9769-0  
Fax: +49 6131 9769-69  
Email: apv@apv-mainz.de  
Website: www.apv-mainz.de

### For scientific questions

EuPFI  
UCL School of Pharmacy  
29-39 Brunswick square  
London WC1N 1AX  
Phone: +44 20 7753 5846  
Fax: +44 20 7753 5942  
Email: admin@eupfi.org  
Website: www.eupfi.org

Register by 15 July 2016 to take advantage of the early bird fee

Non-Member (Non Academic, Non Governmental)

Member of APV/EuPFI (Non Academic, Non Governmental)

Non-Member (Academic, Governmental)

Member of APV/EuPFI (Academic, Governmental)

Students (please enclose evidence)

### Workshop prices additional to registration fee:

Non-Member + Member APV/EuPFI (Non-Academic, Non-Governmental)

Non-Member + Member of APV/EuPFI (Academic, Governmental)

Students (please enclose evidence)

Do you want to participate in the Workshops: yes  no

Course No. 6645

## Formulating better medicines for children

in Lisbon, Portugal, 20 to 22 September 2016

Title, First Name, Name

Company/institution name

Company/institution address

Phone

Fax

e-mail address participant

Order no.

Position in Company/institution

Department

APV/EuPFI member

Non-member

Date

Signature

Early bird	Full fee
1225 EUR	1325 EUR
1095 EUR	1195 EUR
525 EUR	575 EUR
460 EUR	510 EUR
230 EUR	270 EUR
330 EUR	380 EUR
180 EUR	205 EUR
90 EUR	115 EUR

## Registration

All correspondence regarding the conference should be addressed to:

APV  
Kurfürstenstraße 59  
55118 Mainz/Germany  
Phone: +49 6131 9769-0  
Fax: +49 6131 9769-69  
e-mail: apv@apv-mainz.de  
Website: www.apv-mainz.de

You will receive a confirmation of your registration with the invoice.

- pay via invoice  
 pay via credit card (fill in below)
- Visa  
 Mastercard  
 Amex

Card holder: \_\_\_\_\_  
Card no.: \_\_\_\_\_  
Valid until: \_\_\_\_\_  
CVC code: \_\_\_\_\_