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

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

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

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

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 of APV/EuPFI (Non Academic, Non-Governmental)
Non-Member + Member of APV/EuPFI (Academic, Governmental)
Students (please enclose evidence)

Course No. 6645
Formulating better medicines for children in Lisbon, Portugal, 20 to 22 September 2016

Non-Member: 1255 EUR
Member of APV/EuPFI (Non Academic, Non Governmental): 1200 EUR
Member of APV/EuPFI (Academic, Governmental): 1350 EUR
Students (please enclose evidence): 250 EUR

For general information, please go to www.apv-mainz.de/en/seminare/sponsoring-exhibition/

Exhibition and Sponsoring

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

Please contact Antoinette Herbert
Phone +49 6131 9769-90
E-mail  ah@apv-mainz.de
Catherine Tuleu, Chair of EuPFI, UCL School of Pharmacy

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

16:00 - 17:10 Workshop 1: How to construct/evaluate Paediatric Investigation Plans (PIPs).

9:00 - 9:40 Nasir Hussain, Medicines and Healthcare Products Regulatory Agency (MHRA), London, UK

9:40 - 10:10 Alastair Coupe, Pfizer Pharmaceuticals, Canterbury, UK


10:40 - 11:00 Fang Liu, University of Hertfordshire, Harpenden, Hertfordshire, UK

11:00 - 11:30 Torsten Gruchmann, Use-Lab GmbH, Steinfurt, Germany

11:30 - 12:00 Claire Lewis, University of Nottingham, UK

12:00 - 12:45 Focus Session I

12:45 - 14:00 Lunch, exhibition and poster presentations

14:00 - 14:40 Poster presentations

14:40 - 15:00 Poster viewing and paper presentations

15:00 - 16:30 Focus session: Administration Devices

16:30 - 17:00 Discussion

17:00 - 17:30 Housekeeping

17:30 - 18:00 Social programme with networking dinner

18:30 - 19:00 Soapbox Session III

19:00 - 19:30 Discussion Day 2 / Housekeeping

20:00 Networking Dinner

21:00 - 22:00 Poster viewing and paper presentations

22:00 - 23:00 Discussion

23:00 - 24:00 Neonics for Pediatrics towards In-Depth Compliance and Performance. Speakers to be confirmed.

24:00 - 25:00 Chemistry Manufacturing and Controls Considerations in Paediatric Drug Development for Formulation Setting Applications. Speaker to be confirmed.

25:00 - 26:00 Break

26:00 - 27:00 Poster viewing and paper presentations

27:00 - 28:00 Discussion

28:00 - 29:00 Conference wrap-up/Discussion

Programme

PRECONFERENCE WORKSHOP

Tuesday, 20th September 2016, 14:00 to 19:00

16:00 - 17:16 Workshop 1: How to construct/evaluate Paediatric Investigation Plans (PIPs).

9:00 - 9:40 Nasir Hussain, Medicines and Healthcare Products Regulatory Agency (MHRA), London, UK

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12:00 - 12:45 Focus Session I

12:45 - 14:00 Lunch, exhibition and poster presentations

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14:40 - 15:00 Poster viewing and paper presentations

15:00 - 16:30 Focus session: Administration Devices

16:30 - 17:00 Discussion

17:00 - 17:30 Housekeeping

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18:30 - 19:00 Soapbox Session III

19:00 - 19:30 Discussion Day 2 / Housekeeping

20:00 Networking Dinner

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22:00 - 23:00 Discussion

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26:00 - 27:00 Poster viewing and paper presentations

27:00 - 28:00 Discussion

28:00 - 29:00 Conference wrap-up/Discussion

Programme is subject to change.
Programme

PRECONFERENCE WORKSHOP

Tuesday, 20th September 2016, 14:00 to 19:00

16:00 - 17:15 Workshop 1: How to construct/evaluate Paediatric Investigation Plans (PIPs).

Feasibility Assessment, Medicines and Healthcare Products Regulatory Agency (MHRA), London, UK.

Workshop 2: Case study - Benefit risk approach on dosage form design for pediatrics.

Tuesday, 20th September 2016, 10:45 to 11:45.

10:45 - 11:30

Jörg Breitkreutz, Heinrich Hene University, Düsseldorf, Germany

Workshop 3: Focus session: Excipients

Tuesday, 20th September 2016, 15:00 to 16:00.

15:00 - 16:00

Catherine Tuleu, Chair of EuPFI, UCL School of Pharmacy, London, United Kingdom.

11:30 - 11:45

Felipe Lopez, UCL School of Pharmacy, United Kingdom.

11:45 - 12:00

Alastair Coupe, Pfizer Pharmaceuticals, Canterbury, United Kingdom.

12:00 - 12:45

Davide Schonecker, Colorcon, IPEC Americas.

12:45 - 13:00

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

Focus Session: Biopharm.

Chair: Hannah Batchelor, University of Birmingham, United Kingdom.

13:45 - 15:00

Assessing food and vehicle effects for paediatric formulations; product development and clinical approaches

David Weier, Merck & Co Inc.

Terry Turner, Merck & Co Inc.

13:45 - 14:30

Title to be confirmed

Annie Finus, Finish Medicine Agency, Helsinki, Finland, Speaker to be confirmed

14:30 - 14:45

Interactive session on 1) benefits and risks of potential paediatric drug product and 2) to introduce the regulatory framework/lifecycle sector of PIPs and the database that comes into focus.

Chair: Terry Turner, Merck & Co Inc.

14:45 - 15:00

Discussion

Tuesday, 20th September 2016, 15:30 - 16:00.

Chair: Catherine Tuleu, Chair of EuPFI, UCL School of Pharmacy, London, United Kingdom.
**Programme**

**PRECONFERENCE WORKSHOP**

**Saturday, 24th September 2016, 16:00 to 18:00**

16:00 - 17:15 Workshop 1: How to construct/evaluate Paediatric Investigation Plans (PIPs)
  - FedPeRP, Medicines and Healthcare Products Regulatory Agency (MHRA), London, UK
  - Workshop 2: Case study - Benefit-risk approach on Asepsis form design for paediatrics
    - Corné ter Meulen, Erasmus University, Rotterdam, The Netherlands

17:10 - 17:20 (Swap over and settling)

17:20 - 18:30 Workshop 1: How to construct/evaluate Paediatric Investigation Plans (PIPs)
  - Heike Müller, Medicines and Healthcare Products Regulatory Agency (MHRA), London, UK
  - Workshop 2: Case study - Benefit-risk approach on Asepsis form design for paediatrics

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 morning

9:00 - 9:15 Welcome and Introduction
  - Catherine Tuleu, Chair of EU Paediatric Forum (EuPFI), UCL School of Pharmacy, London, UK

9:15 - 9:20 PLANNED - PlaqueOD UK: Smart Paediatric Drug Development - UK: Accelerating paediatric formulation development - An open innovation R&D project
  - Alan Cooke, BioPharmaceuticals, Cumbria, UK

9:20 - 9:30 Morning break, exhibit and poster presentations

**9:30 - 11:11 PRECONFERENCE WORKSHOP**

**9:30 - 11:11 Focus session: Innovation R&D Show Case**
  - New solutions for better compliance and performance
  - Catherine Tuleu, Chair of EuPFI, UCL School of Pharmacy, London, UK

11:11 - 20:15 Discussion

11:20 - 13:10 Development of a multiparticulate administration device for paediatrics - a user-based approach (2)
  - Diana Gerssen, Bill & Melinda Gates Foundation, United States

13:10 - 15:00 Workshop 1: How to construct/evaluate Paediatric Investigation Plans (PIPs)
  - Heike Müller, Medicines and Healthcare Products Regulatory Agency (MHRA), London, UK
  - Workshop 2: Case study - Benefit-risk approach on Asepsis form design for paediatrics

15:00 - 16:00 Lunch, exhibition and poster presentations

16:00 - 16:10 Focus session: Designing a multiparticulate administration device for paediatrics - a user-based approach (2)
  - Diana Gerssen, Bill & Melinda Gates Foundation, United States

16:10 - 17:00 Workshop 1: How to construct/evaluate Paediatric Investigation Plans (PIPs)
  - Heike Müller, Medicines and Healthcare Products Regulatory Agency (MHRA), London, UK
  - Workshop 2: Case study - Benefit-risk approach on Asepsis form design for paediatrics

17:00 - 17:10 Paediatrical development for poorly soluble drugs

17:10 - 17:20 Medicine accessibility in children: an original tool for standardized evaluation
  - Fabrizio Fusi, Crescita, Milano, Italy

17:20 - 17:30 Discussion

17:30 - 18:00 Housekeeping

18:00 Social/programme with networking dinner

18:00 - 19:00 Find us on Twitter EU Paediatrics

19:00 - 20:00 Plenary 3: Minimal data/information set needed for paediatric Clinical Trials

**Friday, 23rd September 2016, 8:30 to 18:00**

8:30 - 9:00 Breakfast, exhibition and poster presentations

9:00 - 9:15 Workshop 1: How to construct/evaluate Paediatric Investigation Plans (PIPs)
  - Heike Müller, Medicines and Healthcare Products Regulatory Agency (MHRA), London, UK
  - Workshop 2: Case study - Benefit-risk approach on Asepsis form design for paediatrics

9:15 - 9:20 Workshop 1: How to construct/evaluate Paediatric Investigation Plans (PIPs)
  - Heike Müller, Medicines and Healthcare Products Regulatory Agency (MHRA), London, UK
  - Workshop 2: Case study - Benefit-risk approach on Asepsis form design for paediatrics

9:20 - 10:00 Lunch, exhibition and poster presentations

10:00 - 10:10 Focus session: Clinical Studies Group
  - Clinical Studies Group

10:10 - 11:00 Workshop 1: How to construct/evaluate Paediatric Investigation Plans (PIPs)
  - Heike Müller, Medicines and Healthcare Products Regulatory Agency (MHRA), London, UK
  - Workshop 2: Case study - Benefit-risk approach on Asepsis form design for paediatrics

11:00 - 11:10 Workshop 1: How to construct/evaluate Paediatric Investigation Plans (PIPs)
  - Heike Müller, Medicines and Healthcare Products Regulatory Agency (MHRA), London, UK
  - Workshop 2: Case study - Benefit-risk approach on Asepsis form design for paediatrics

11:10 - 11:20 Workshop 1: How to construct/evaluate Paediatric Investigation Plans (PIPs)
  - Heike Müller, Medicines and Healthcare Products Regulatory Agency (MHRA), London, UK
  - Workshop 2: Case study - Benefit-risk approach on Asepsis form design for paediatrics

11:20 - 12:10 Focus session: Dosage forms design for paediatrics
  - Co-lead – Terry Ernest (GSK), Jenny Walsh (paediatric-product development) and Sminta Salunke (EuPFI), UK

12:30 - 14:00 Poster and poster presentations

14:00 - 15:30 Workshop 1: How to construct/evaluate Paediatric Investigation Plans (PIPs)
  - Heike Müller, Medicines and Healthcare Products Regulatory Agency (MHRA), London, UK
  - Workshop 2: Case study - Benefit-risk approach on Asepsis form design for paediatrics

15:30 - 16:00 Workshop 1: How to construct/evaluate Paediatric Investigation Plans (PIPs)
  - Heike Müller, Medicines and Healthcare Products Regulatory Agency (MHRA), London, UK
  - Workshop 2: Case study - Benefit-risk approach on Asepsis form design for paediatrics

16:00 - 17:30 Focus session: Combination Products development roadmap US/EU
  - Esmeralda Lousia Hermans, Janssen Research & Development, New Jersey, USA

17:30 - 18:00 Workshop 1: How to construct/evaluate Paediatric Investigation Plans (PIPs)
  - Heike Müller, Medicines and Healthcare Products Regulatory Agency (MHRA), London, UK
  - Workshop 2: Case study - Benefit-risk approach on Asepsis form design for paediatrics

18:00 - 19:00 Plenary 4: New solutions for better compliance and performance

**Saturday, 24th September 2016, 9:15 to 18:00**

9:15 - 10:00 Focus session: Clinical Studies Group
  - Clinical Studies Group

10:00 - 10:10 Focus session: Clinical Studies Group
  - Clinical Studies Group

10:10 - 10:20 Focus session: Clinical Studies Group
  - Clinical Studies Group

10:20 - 11:10 Workshop 1: How to construct/evaluate Paediatric Investigation Plans (PIPs)
  - Heike Müller, Medicines and Healthcare Products Regulatory Agency (MHRA), London, UK
  - Workshop 2: Case study - Benefit-risk approach on Asepsis form design for paediatrics

11:10 - 12:00 Focus session: Clinical Studies Group
  - Clinical Studies Group

12:00 - 13:00 Lunch, exhibition and poster presentations

13:00 - 14:00 Workshop 1: How to construct/evaluate Paediatric Investigation Plans (PIPs)
  - Heike Müller, Medicines and Healthcare Products Regulatory Agency (MHRA), London, UK
  - Workshop 2: Case study - Benefit-risk approach on Asepsis form design for paediatrics

14:00 - 15:30 Focus session: Innovation R&D Show Case**

15:30 - 16:00 Focus session: Innovation R&D Show Case**

Dear Colleagues,

We are pleased to announce that the 8th BiLuFF annual congress will take place on 29th to 30th September 2016 at the Hertfordshire Conference Centre, Hatfield, Hertfordshire, UK. The congress will bring together scientists, technologists and regulators from academia, industry, government and the pharmaceutical industry to discuss and debate the challenges of paediatric drug development.

The programme for the BiLuFF meeting is typically around the workshops that comprise the EuPFI activity. Pharmaceutical Experts, taste masking and taste evaluation method, Administration device, Appropriate formulation and bio-pharmaceutics. The innovation showed how one opportunity for businesses involved in paediatric formulations to take the profile of their technology and share potential applications. Talks about how to overcome barriers from submitted abstracts will be presented at the meeting of all which provided opportunities for networking and the initiation of new collaborations. We encourage you to explore the BiLuFF website which contains all the information you need to submit your abstracts.

The programme provides a platform to exchange views on many good ideas around both scientific and regulatory aspects related to paediatric formulation development.

We 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 London, city of seven hills.

Catherine Tuleu, UCL School of Pharmacy, London, United Kingdom

The European Paediatric Formulation Initiative (EUPFI) is a consortium of members working in a co-competitive way on paediatric drug formulations. The consortium was founded in 2007 with the aim of raising awareness of paediatric formulations challenges. Members are from academia, hospitals and the pharmaceutical industry, innovation, generics, CROs, and other stakeholders. EUPFI s mission is to improve scientific, technological and regulatory aspects associated with paediatric formulation development by writing reflection papers, organizing workshops, providing guidelines, and promoting dialogues. Through its website, currently there are five EUPFI working groups, covering pharmaceutical scientists, experts of appropriate formulations and taste assessment methods, biopharmaceutics, and administration devices.

March, July 2016

The European Paediatric Formulation Initiative (EUPFI) is a consortium of members working in a co-competitive way on paediatric drug formulations. The consortium was founded in 2007 with the aim of raising awareness of paediatric formulations challenges. Members are from academia, hospitals and the pharmaceutical industry, innovation, generics, CROs, and other stakeholders. EUPFI s mission is to improve scientific, technological and regulatory aspects associated with paediatric formulation development by writing reflection papers, organizing workshops, providing guidelines, and promoting dialogues. Through its website, currently there are five EUPFI working groups, covering pharmaceutical scientists, experts of appropriate formulations and taste assessment methods, biopharmaceutics, and administration devices.
Important Dates
Conference early bird registration – 15 July 2016
For more information go to www.eupfi.org/8th-conference/

Exhibition and Sponsoring
For general information, please go to www.apv-mainz.de/en/seminare/sponsoring-exhibition/

Registration
Please use the booking form.

Payment
You will receive a confirmation of your registration should be addressed to:

Social charges

Date
Course No. 6645
deadline
July 15, 2016

Registration:

Early bird
Full 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 of APV/EuPFI (Non Academic, Non Governmental)
Non-Member + Member of APV/EuPFI (Academic, Governmental)
Students (please enclose evidence)

registration fee:

Early bird
Full 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)

Special rate:

For organisational questions
Institute of Pharmaceutical Technology (UCL) 
Kurfürstenstraße 59
55118 Mainz, Germany
Phone: +49 6131 9769-0
Fax: +49 6131 9769-69
Email: adm@eupfi.org
Website: www.eupfi.org

For scientific questions
UCL School of Pharmacy
29-39 Brunswick square
London WC1N 1AX
Phone: +44 20 7753 5942
Fax: +44 20 7753 5941
Email: spas@ucl.ac.uk
Website: www.eupfi.org

Hotel reservation
For further information and booking hotel accommodation please contact:

Kurfürstenstraße 59
55118 Mainz, Germany
Phone: +49 6131 9769-0
Fax: +49 6131 9769-69
Email: apv@apv-mainz.de

Contact Formulation Initiative

European Paediatric Formulation Initiative

Meeting the needs of the children

Formulating better medicines for children

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.

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

### Preconference Workshops

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

### Conference Secretariat

For organisational questions
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
Kurfürstenstraße 59
55118 Mainz/Germany
Phone: +49 6131 9769-0
Fax: +49 6131 9769-46
Email: admin@eupfi.org
Website: www.eupfi.org

### Important Dates

Conference early bird registration – 15 July 2016
For more information go to www.eupfi.org/8th-conference/

### 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/

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).

### Conference Early Bird Registration

Register before July 15, to take advantage of the early bird fee!

<table>
<thead>
<tr>
<th>Category</th>
<th>Early Bird Fee</th>
<th>Full Fee</th>
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<tr>
<td>Non-Member (Non Academic, Non Governmental)</td>
<td>1225 EUR</td>
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<td>Member of APV/EuPFI (Non-Academic, Non Governmental)</td>
<td>1095 EUR</td>
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<td>Non-Member (Academic, Governmental)</td>
<td>525 EUR</td>
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<td>Member of APV/EuPFI (Academic)</td>
<td>460 EUR</td>
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<td>Students (please enclose evidence)</td>
<td>230 EUR</td>
<td>270 EUR</td>
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<td>Workshop price additional to registration fee:</td>
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<tr>
<td>Non-Member + Member of APV/EuPFI (Non-Academic, Non-Governmental)</td>
<td>330 EUR</td>
<td>380 EUR</td>
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<td>Non-Member + Member of APV/EuPFI (Academic, Governmental)</td>
<td>180 EUR</td>
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<td>Students (please enclose evidence)</td>
<td>90 EUR</td>
<td>115 EUR</td>
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### 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.

### Hotel reservation

- European Paediatric Formulation Initiative (EUPFI)
- Kurfürstenstraße 59
- 55118 Mainz, Germany
- Phone: +49 6131 9769-0
- Fax: +49 6131 9769-46
- Email: admin@eupfi.org

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

### Card holder information

- Name: __________________________
- Address: _______________________
- Card type: ______________________
- Card number: _________________
- Expiry date: _________________
- CVV code: _________________