

2020 First GMP Virtual Symposium



When DMPK is out of sight but not out of mind

From 18th of September to 23rd of October 2020

DAY 1: 18th September 2020

11:00-12:00 OPENING SPEAKER

Impact of antibiotic therapy on the bacterial diversity of the intestinal microbiota
Charles Burdet, IAME Inserm, Paris, France

Chairs: N Gregoire (Poitiers Univ.), J Henri (Anses)

DAY 2: 25th September 2020

10:30-12:00 SESSION 1

10:30-11:15 1.1 IN VITRO TESTING

An *in vivo* like 3D hepatic liver spheroid system for studies of aetiology and treatment of chronic drug hepatotoxicity and hepatic fibrosis
Magnus Ingelman-Sundberg, Karolinska Institute, Stockholm, Sweden

Chairs: M Rachid (Genoscience Pharma), Y Courbebaisse (Adocia)

11:15-12:00 1.2 ARTIFICIAL INTELLIGENCE

Machine Learning Approach to Forecast Chemotherapy-Induced Haematological Toxicities in Patients with Rhabdomyosarcoma
Vesna Cuplov, SmartC, Marseille, France

Chairs: C Serdjebi (Biocellvia), Y Parmentier (Servier), Q Nguyen (Ipsen)

DAY 3: 2nd October 2020

10:30-12:00 SESSION 2

10:30-11:15 2.1 IN VITRO TESTING

A fluid-dynamic Multi-In Vitro Organ-MIVO device as alternative approach for in vitro drug testing

Silvia Scaglione, React4life, Genoa, Italy

Chairs: M Rachid (Genoscience Pharma), M Fonsi (Charles River)

11:15-12:00 2.2 INNOVATIVE THERAPIES

Car-T cell development and registration – Opportunities for the application of Pharmacometrics

Rik De Greef, Certara, Oss, The Netherlands

Chairs: V Duval (Certara), F Gattacceca (Aix-Marseille Univ.)

DAY 4: 9th October 2020

10:30-12:00 SESSION 3

PK challenges in pediatric drug development

Chairs: R Barcham (Oroxcell), L Del Frari (Pierre Fabre), F Hurbin (Sanofi), A Coquerel (Caen Univ.)



10:30-11:00 3.1 Prediction of midazolam pediatric plasma profiles for multiple routes of administration using physiologically based pharmacokinetic model

Maxime Le Merdy, Simulation Plus, Basel, Switzerland

11:00-11:30 3.2 PopPK/PD scaling from adults to children using priors: A case example with Alirocumab

Elisa Calvier, Sanofi, Montpellier, France

11:30-12:00 3.3 Use of model informed extrapolation in regulatory submissions - Examples

Flora Musuamba Tshinanu, EMA, Brussels, Belgium

DAY 5: 16th October 2020

15:00-16:30 SESSION 4

DDI risk assessment and evaluation in pharmaceutical development

Chairs: O Barberan (Elsevier), O Nicolas (Sanofi), Y Parmentier (Servier), A Sharma (Senzagen)

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15:00-15:30 4.1 PBBM application to support formulation changes, prediction of pH related DDI and impact of beverages on exposure to acalabrutinib

Xavier Pepin, AstraZeneca, Macclesfield, UK

15:30-16:00 4.2 Drug-drug interactions of therapeutic proteins

Antoine Deslandes, Sanofi, Alfortville, France

16:00-16:30 4.3 Ivabradine metabolite PBPK modelling: CYP3A4 mediated DDI risk evaluation in adults and children

Jennifer Lang, Manchester Univ., Manchester, UK

DAY 6: 23rd October 2020

10:30 – 11:00 Student presentation blitz AWARDS



11:00 – 12:00 Assemblée générale du GMP

Je vote!