GMP
Groupe de Métabolisme et Pharmacocinétique

2019 GMP Symposium – preliminary agenda

DMPK-centred approach to predict Drug Efficacy and Safety

16th - 18th October 2019 - Château de Montchat | Lyon | France

DAY 1: 16th October 2019

12.30 - 13:30
Arrival and Registration
Welcome Coffee/tea

13:30 - 13:40
Welcome to 2019 GMP symposium

13:40 - 15.10 SESSION 1

Drug related transporter DDI: let's open the Pandora's box
If metabolizing enzymes are pretty well mastered in term of DDI prediction and clinical outputs, drug transporters remain more challenging. Where do we stand now with regard to assessing risk related to drug transporters starting from in silico predictions to clinical impacts and evaluation, **this is the time to open the Pandora's box.**
Chairs: Y. Parmentier (Servier), O. Barberan (Elsevier) A. Sharma Eurosafe)

15:10 - 15:40
Coffee break and Poster session

15:40 - 17:10 SESSION 2

How to predict dermal absorption? What is new in this field?
Dermal route is a classical route of administration for many drugs, but a lot of questions are still to be addressed such as the role of skin transporters in the absorption, the building of PBPK models and how to use PK-PD data to select the good candidate. This session will try to answer to these questions!
Chairs: R. Barcham (Oroxcell), M Millet (Pierre Fabre), Y. Courbebaisse (Adocia)

17:10 - 18:05 Students Poster Blitz
Chairs: M Millet (Pierre Fabre), S. Cartot-Cotton (Sanofi)

18:05 - 20:30
Poster Session & Cocktail

DAY 2: 17th October 2019

8.00 – 8.30
Welcome Coffee/tea

8:30 – 10:00 SESSION 3

Bioanalysis of endogenous and Xenobiotic macromolecules LC-MS/MS and/or Immuno-methods?
An insight in the progress done combining immunocapture with LC-MS/MS quantification to optimize specificity and sensitivity in the field of biologics. A new multiplexed quantitative space for drug and biomarkers in clinical studies? What are the next challenges?
Chairs: Y. Courbebaisse (Adocia), S. Cartot- Cotton (Sanofi), Y. Parmentier (Servier)

10:00 - 10:30
Coffee break and Poster session

10:30 - 12:00 SESSION 4

PKPD modelling in oncology
The rate of approval of anticancer drugs remains low compared to other therapeutic areas. Advances in Model Informed Drug Development may help to fill the gap: some illustrations are presented.
Chairs: M. Tod (CHU Lyon), F. Hurbin (Sanofi), A. Coquerel (Caen University)

12:00 – 12:45
GMP Assemblée générale

12:45 - 14:00
Lunch & Posters

DAY 2: 17th October 2019

14:00 – 15:00
KEYNOTE speaker: Pr. Marc Pallardy
State of art and recent evolution in safety assessment of new drugs (small and large molecules)
Chair: A. Coquerel (Caen University)

15:00 - 16.00 SESSION 5

Estimating the clinical starting dose in human from preclinical data: theory and practice
Decisions on strategies for development of a new medicine and the experimental approaches used to assemble information relevant to the safety (and efficacy) of clinical trials must be science-based, made and justified on a case-by-case basis. In particular, pre-clinical safety assessment may raise specific difficulties because the nature of the target is more specific to humans. Attention should be given to the calculation of the first-in-man dose and to the subsequent dose escalations approach. This session will try to address these questions, presenting some real-life case studies.
Chairs: C. Amara (Sanofi), L. Penard (Charles River), C. Khaldi-Serdjebi (Genoscience Pharma), M. Fonsi (Citoxlab)

16:00 - 16:30
Coffee break and Poster session

16:30 – 17:30 SESSION 5 (continued)

17:30 - 18:15 ONE STEP ASIDE
Chairs: F. Gattacceca (Smartc, CRCM, Aix- Marseille Université)
Forensic science

19:30
Gala Dinner at Victoria Hall

DAY 3: 18th October 2019

8.30 – 9.00
Welcome Coffee/tea

9:00 – 10.30 SESSION 6

PK in renal and hepatic impaired subjects: regulatory aspects and implications in clinical development
Most of small molecules are eliminated either through renal and/or hepatic pathways. Clinical studies in special populations such as patients with hepatic or renal impairment or hemodialysed patients are then requested to support New Drug Application (NDA). Case studies illustrating the specific features and requirements of those studies will be presented in this session.
Chairs: S. Goutelle (CHU Lyon), Q. Nguyen (IPSEN), F. Hurbin (Sanofi)

10.30 – 11.00
Coffee break

11.00 – 12.00 SESSION 7

Future of modelling: case studies
In the current scientific literature, few papers address the question of the future of modeling. The aim of this session is to show, with real case examples applied to drugs and pathologies, that this future is already there. Examples from academia or industry will illustrate how systems biology and artificial intelligence can be implemented to enhance population and physiologically-based PK modeling.
Chairs: F. Mazuir (Poxelpharma), J. Henri (ANSES), F. Gattacceca (Smartc, CRCM, Aix- Marseille Université)

12:00 - 12:15 Poster Awards

12:15 - 12:25 Closing remarks

12:25 – 14:00 Farewell Lunch