

2021 GMP Symposium – preliminary agenda

Moving forward into the PK world: new drugs, new tools, new questions

20 to 22 October 2021 – Espace Diderot, Paris, France

DAY 1: 20th October 2021

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:

Organ-On-a-Chip: towards the in vitro human twin for pharmacokinetics, pharmacodynamics and toxicology predictions

Accurately replicate the main function of an organ or even a whole organism is one of the key challenges of the in vitro sciences. Today, Organ-On-a-chip system allows like never before to get close to this grail. This session will show how the dynamic flow, the connection between in vitro models (liver/ intestine/kidney, blood brain barrier), and the physiological modeling can, not only replicate, but most importantly extrapolate pharmacokinetics, and also pharmacodynamics and toxicology to the human situation.

J. Hubner (Berlin University), C. Legallais (UTC), A. Mabondzo (CEA, Université Paris Saclay, CERES Brain therapeutics)

Chairs: Y. Parmentier (Servier), F. Gattacceca (COMPO, CRCM, Aix-Marseille Université)

15:10 - 15:40

Coffee break and Poster session

15:40 - 17:10 SESSION 2:

Bioequivalence: from derisking strategies to regulatory support

The bioequivalence is an evolving field. Experiences of bioequivalence studies and regulatory issues will be shared including examples of the levothyrox case. Examples of PBPK modelling will be also presented to derisk bioequivalence along drug development!

D Concordet (ENVT), A. Garcia (AEMPS), I.L. Konstantinidis (Novartis),

Chairs: E. Chatelut (Oncopole Toulouse), O. Nicolas (Sanofi), Q. Nguyen (Ipsen)

17:10 - 18:05 Students Poster Blitz Chairs:

C. Troisi (PhD Student), M. Rachid (Genoscience Pharma)

18:05 - 20:30

Poster Session & Cocktail

DAY 2: 21st October 2021

8.00 – 8.30

Welcome Coffee/tea

8:30 – 9.30 KEYNOTE speaker:

Dr. Michael Zimmerman (EMBL - Medicen)

Microbiote contributions to drug metabolism and toxicity

Chair: Y. Parmentier (Servier)

09:30 - 10:00

Coffee break and Poster session

10:00 - 12:00 SESSION 3

Microbiota: Am I controlled by My Microbiota?

In recent years, we have been experiencing a real revolution through the discovery of the decisive role of the microbiota on health. The study of the impact of the microbiota is crucial for understanding the modulation mechanisms of this "complex system" on health evidencing the real need of valid in vitro models that can predict the significant role of microbiota in current therapies and diseases.

S. Blanquet (UCA), B. Levast (Maat Pharma), M. Pichon (CHU Poitiers), G. Rawadi (Ysopia),

Chairs: R. Barcham (Oroxcell), N. Gregoire (Poitiers University) M. Fonsi (Charles-River)

12:00 – 12:45

GMP Assemblée générale

12:45 - 14:00

Lunch & Posters

DAY 2: 21st October 2021

14:00 - 15:00 SESSION 4

PK/PD challenges in the development of virus-based gene therapy and strategies to modulate the PK/PD variability of antiviral drugs

In the development of antiviral chemical therapeutics or oncolytic viruses armed with therapeutic genes for cancer therapy, PK and PD data are key and clearly provide added value. However, the challenges of controlling the PK/PD variability of antiviral drugs in daily clinical practice differ from those associated with the development of oncolytic viruses. Specific examples and strategies will be discussed.

K. Bendjama (Transgene), C. Solas (UVE, AP-HM, Aix-Marseille Université)

Chairs: O. Nicolas (Sanofi), Y. Courbebaisse (Adocia), Q. Nguyen (Ipsen)

15:00 - 15:30

Coffee break and Poster session

15:30 – 17:00 SESSION 5

PK challenges in vaccine development.

Vaccines are peculiar medicines in many aspects. Indeed, optimal vaccine composition, formulation, route of administration and dose cannot be determined based on classical PK/PD approaches or experimental models. Innovative strategies used to tackle PK challenges faced in the development of vaccines will be discussed.

M. Amiji (Northeastern University), B. Combadière (Sorbonne University), P. Desert (Sanofi Pasteur)

Chairs: C. Bain (Active Biomarkers), A. Coquerel (Caen University), F. Gattacceca (COMPO, CRCM, Aix-Marseille Université)

17:00 - 18:00 ONE STEP ASIDE

Pr. Maxime Schwartz (Institut Pasteur)

Une histoire des vaccins, de celui contre la variole à ceux contre la COVID-19

Chair: A. Coquerel (Caen University)

19:30 Gala Dinner

DAY 3: 22nd October 2021

8.30 – 9.00

Welcome Coffee/tea

9:00 – 11.00 SESSION 6

Personalized medicine: how far are we?

Targeting the right treatment for the right patient at the right dose and time is now becoming a reality thanks to the new tools available. In this session will see how liquid biopsies, pharmacogenomics, biomarkers, modeling and digital tools can reach the target of such a personalized medicine to accelerate drug development and improve the drug efficacy and safety of marketed drugs.

F. Dayan (ExactCure), C. Pallaud (Novartis), A. Rostami (Certara), J. Turgeon (TabulaRasa HealthCare)

Chairs: N. Grégoire (Poitiers University), V. Aslanis (Galecto), O. Barberan (Elsevier), Y. Parmentier (Servier)

11.00 – 11.30

Coffee break

11.30 – 12.30 SESSION 7

Use of pharmacokinetics/pharmacodynamics in cell therapy

Cellular therapies are an emerging part of the new therapeutic arsenal. Many of them, currently under development, incorporate PK/PD data. PK/PD optimization of approved CAR-T immunotherapies and PK and PD profiles obtained in type 1 diabetes treated with artificial pancreas technology or after islet transplantation will be presented.

A Baruchel (APHP), E. Renard (INSERM1411, CHU Montpellier)

Chairs: V. Duval (Certara), C. Bain (Active Biomarkers), Y. Courbebaisse (Adocia)

12:30 - 12:45 Poster Awards

12:45 - 12:55 Closing remarks

12:55 – 14:00 Farewell Lunch