



## **35<sup>th</sup> GMP SYMPOSIUM PRELIMINARY PROGRAM**

**18-20 October 2023, Paris, France**

On behalf of the GMP Board and the Scientific Committee, it is our great pleasure to share with you the preliminary program of the 35<sup>th</sup> GMP symposium that will be held **at Espace Centenaire, Paris (75012). Registration will be open in May.**

We hope to see you there with the exciting scientific and social programs.

### **Day 1 - 18 Oct 2023**

**12.30 - 13:30**

**Arrival and Registration  
Welcome Coffee/Tea**

**13:30 - 13:40**

**Welcome to 2023 GMP Symposium**

**13:40 - 15:10 **Session 1****

**Translation of Drug-Drug-Interaction from In-Vitro to In-Vivo**

Microphysiological systems aim to mimic the complex structure, microenvironment and physiological functions of human organs, so it has gradually become an ideal tool for in vitro ADMET, drug-drug-interaction and pharmacological studies. The aim of the session is to highlight the advantages of those models and how to translate the data generated to the human situation in particular for DDI predictions.

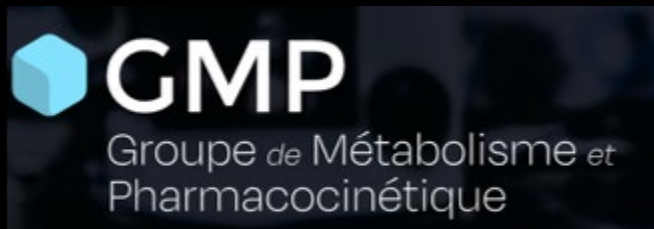
**15:10 - 15:40**

**Coffee Break and Poster Session**

**15:40 - 17:10 **Session 2****

**Update on Drug Metabolism Strategy**

Over the last years, the field of metabolite investigations has evolved. New guidelines requirements and the emergence of new modalities and new technologies foster the choice of new strategies for the metabolite profiling studies. This session will provide



an overview on last trend for metabolite identification for biologics and small drugs, including the impact on DDI assessment.

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

We welcome student abstracts in the field of pharmacology (ADME, PK, PD, PBPK, DDI). All submitted abstracts will be reviewed by the selection committee and chosen to be part of a poster presentation and short-oral presentation. A “Best Student presentation” awards will be announced during the GMP Congress 2023.

The program is open to all students at the Undergraduate, Masters, and Doctoral levels. Presenters must be present during the congress.

**18:05 - 19:30**

**Poster Session & Cocktail**

**Day 2 - 19 Oct 2023: What's new in the Biologics World?**

**8.00 - 8.30**

**Welcome Coffee/Tea**

**8:30 - 9.30 Key Note Speaker: Immunogenicity**

**09:30 - 10:00**

**Coffee Break and Poster Session**

**10:00 - 12:00 Session 3**

**New Approaches in PK Modelling and QSP of Biologics**

The world of Biologics is expanding with new entities and new targets, thus requiring new approaches to understand the PK and interactions with its biological environment. This session will present how modelling is used to assess new targets and support the development of new biological drugs.

**12:00 - 12:45**

**GMP Assemblée Générale**

**12:45 - 14:00**

**Lunch & Posters**



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**14:00 - 15:30 Session 4**

### **Spotlighting on Bioanalytical Data for Biologics PK Interpretation**

Understanding the pharmacokinetics and pharmacodynamics of biologic therapeutics, and the bioanalytical methods they rely on, is key to build an optimal drug development plan. As the development of the drug progresses, so do the methods used for bioanalysis. The reliability of the bioanalytical results is a prerequisite for correct interpretation of PK profiles. Therefore, for pivotal nonclinical and clinical studies, it is essential to employ well-characterized and fully validated bioanalytical methods to yield accurate and reliable results. This session will provide an overview of the methodologies and illustrate the topic with a few examples from in-vivo preclinical cases to clinical settings.

**15:30 - 16:00**

### **Coffee Break and Poster Session**

**16:00 - 17:00 Session 5**

### **New Trends in PK and Immunogenicity Assessments in Ophthalmology**

Over the last 10-15 years the treatment options in ophthalmology have considerably evolved. Injections of monoclonal antibodies and smaller proteins have emerged as a new standard of treatment, and recently gene therapy has also been introduced. In this session a few examples will be presented that highlight the new challenges of assessing PK and immunogenicity in ophthalmology and how to define the dose.

**17:00 - 18:00 One Step Aside**

### **Impact of Contaminants/Drugs on Public Health and Environment assessed by PBPK**

In a global context of environmental crisis, the chemical risk assessment is a matter of public health and environmental protection. This session will provide an overview on how PBPK modelling plays a key role for this risk assessment.

**19:30**

### **Gala Dinner**



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## Day 3 - 20 Oct 2023

**8.30 - 9.00**

**Welcome Coffee/Tea**

**9:00 - 11.00 Session 6**

**Supporting Decision-Making in Drug Development**

Decision making occurs at all stages of drug development. Optimus Project from FDA as well as different tools such as clinical pharmacology and/or pharmacometrics are key to support decision making. In this session we will hear about examples of how to improve drug development decision-making.

**11.00 - 11.30**

**Coffee Break**

**11.30 - 12.30 Session 7**

**Digital Data Sciences in Drug Development**

The use of digital tools and their impact on drug development will be discussed in this session. Illustration will be performed with case studies on Omics Sciences, Biomarkers and Digital Biomarkers along R&D value chain.

**12:30 - 12:45 Poster Awards**

**12:45 - 12:55 Closing Remarks**

**12:55 - 14:00 Farewell Lunch**