

## Group of Metabolism and Pharmacokinetics

GMP is an organization gathering together scientists from the industry or the university involved in the practice of bioanalytic, pharmacokinetic and metabolism studies, whatever the areas of application (pharmacy, agro-chemistry, agro-veterinary, environment).

EDITED BY GMP BOARD 2020

NUMERO 5



Secretary  
Yann Courbehaisse (Adocia)  
President  
Florence Gattaceca (Aix-Marseille Université)  
Treasurer  
Ashwani Sharma (Biopredic)



Scientific Committee  
President  
Jérôme Henri (ANSES)



Scientific Committee  
Consultant  
Antoine Coquereil (Université Caen-Normandie)



Consultant treasurer  
Massimiliano Fonsi (Charles River)



Consultant  
Quyen Nguyen (Ipsen)



Consultant  
Fabrice Hurbin (Sanofi)



Webmaster  
Eric Helmer (Galapagos)

## THE PRESIDENT'S EDITORIAL

Dear colleagues, dear GMP members,

**2019** has been an intense year for GMP, thanks to the commitment of its **board** as a whole and particularly of its president **Sylvaine Cartot-Cotton** and its scientific committee (SC) president **Marion Millet**, who, for their 4th and last year at the service of GMP, spared no time nor energy. The **scientific committee** once again demonstrated its importance: the ideas of each one shared through fruitful discussions allowed the proposal of an original, diverse and relevant scientific program. Finally, **Eric Helmer**, our webmaster, with his customary discretion and self-denial, helped us as always to communicate with you via our website or by emails. It is hence a whole team that contributed to breathe life into GMP and to make things work, and that I warmly thank.



The GMP Board in Lyon in 2019

The traditional gatherings of our association have been **successful events**. Many of you took part assiduously into all **scientific sessions** offered during our symposium. The **satellite sessions** proposed for the first time on the sidelines of the symposium were also rewarding. The **gala evening** was a shared festive moment, which allowed us to relax and have fun together in an informal setting: this is also GMP! For all these events, we praise our **sponsors** and all who helped us to convince them.

**In 2020**, GMP faces many challenges. First, we need to meet our members' expectations by offering more seats for our annual symposium, while maintaining the warm conviviality of our meetings which are a valuable asset for quality, plainness and in-depth scientific discussions. The choice of **Institut Pasteur in Paris** for our next symposium should fulfill these criteria. We also wish to stimulate scientific interactions inside GMP: **more numerous and diverse events** (webinars, round-tables, commissions, ...) will be proposed. Our website and our communication tools will evolve as well. We also aim to limit our **ecological footprint**, by reducing paper printing and favoring recycling of badges for example. Finally, we are eager to continue our commitment towards the youngest scientists in our community. The **student membership rate** is officially launched, and other gestures as well are under consideration.

To meet these challenges, the GMP board can count on its two new members, **Quyen Nguyen et Fabrice Hurbin**, who joined us full of motivation and new ideas. The new board will meet in Montpellier as soon as March 6th, for an intense day of work. A **new SC** of 9 members has been formed, under the leadership of its president **Jérôme Henri** and its vice-president **Antoine Coquerel**. They are already at work to provide you with a scientific program that we are confident will meet your expectations in 2020.

In the present **newsletter**, you will discover our new SC, you will find information about our next symposium, the results of the 2019 symposium survey, a summary of the sponsorship offer for 2020 (we count on your help!), the procedure to benefit from the student membership rate, as well as a scientific overview on the current and future use of radioisotopes in DMPK during drug development. You are invited to propose topics for the next newsletters issues or webinars and to share your suggestions with us by email ([contact@gmp.asso.fr](mailto:contact@gmp.asso.fr)) or using social networks (join us on [linkedin!](#)).

Rest assured of our relentless commitment for the present and future of GMP.

*Florence Gattacceca, GMP president*

---

## LAUNCHING OF THE STUDENT RATE: starting now!



Dear students, GMP is happy to welcome your posters and oral "blitz" communications each year, and to reward the best performances. Welcoming students in our scientific community is indeed in the heart of GMP missions. To facilitate your entry, we decided with all our members to offer you from now on a **reduced 20€ yearly rate** (instead of 50€) to become a member of GMP, which should fit better with your student's incomes. We will then gain access to all our archives and enjoy all the GMP membership benefits. We hope that many of you will take advantage of this offer and will join us! Please share the offer!

### Process to follow:

- send an email to apply for student membership rate to our secretary Yann COURBEBASSE ([y.courbebaisse@adocia.com](mailto:y.courbebaisse@adocia.com)) and to Fabrice HURBIN ([Fabrice.Hurbin@sanofi.com](mailto:Fabrice.Hurbin@sanofi.com))
- You will be asked to provide evidence of student status
- Once your student status will be validated, you will be explained the remaining steps of the process.



*"Student posters" awards ceremony in 2019*

## REPORT OF SURVEY 2019

In total, **18 participants** shared their opinions and suggestions following the GMP 2019 symposium. We are grateful to them since these feedbacks are essential for our association to adapt its activities to your expectations.

The quality of the different sessions of the 2019 symposium has been rated as good or excellent by 2/3 to 94% of participants. The poster blitz, the session "PKPD modelling in oncology" and the conference by the keynote speaker have been **particularly appreciated**. Further increasing the sessions around drug **discovery and pre-clinical development** has been asked by some of you. **Satellite sessions** were a great success, with more than 75% of participants rating them excellent. Thanks to organizers!

**Domestic arrangements** were judged excellent by the majority of you, but improvements have been suggested to us about the **food** provided during the symposium and the gala dinner, particularly regarding the consideration of people with food restrictions.

**Diverse topics** were proposed for future scientific events, about **innovative therapies** (nanomedicines, cell therapies, immunotherapies), *in silico* tools (PBPK, QSP, QSAR, molecular modelling), **particular clinical studies** (micro-dosing, special populations), **specific subjects** such as exotical enzymes or inhalation. We will try our best to integrate these subjects into the program of the next symposium or for other events such as webinars.

Based on opinions expressed during the General Assembly and reaffirmed in this survey, it appears that new interaction modes are awaited : **round-tables**, writing of **publications** presenting GMP opinions and proposals, **trainings** during the year. Finally, more than  $\frac{3}{4}$  of you are ready to abandon printed booklets if an **app** is provided for the next symposium. We are working on it!

Thanks a lot for your advice and for your cheerings which will help us to better meet your expectations.



*Memories from satellite sessions 2019*

---

## SCIENTIFIC COMMITTEE 2020

For the fifth consecutive year, a scientific committee, involving volunteer GMP members, has been set up because we believe that involving our members is the go-to of the GMP and is very efficient. The scientific committee **president Jerome Henri** (French Agency for Health & Safety) and its **Vice-president Antoine Coquerel** (Caen University) have been very happy to welcome, in addition to the GMP board members, nine members of our association which volunteered after the call for applications.

Cindy Khaldi-Serdjebi (Genoscience Pharma), Yannick Parmentier (Servier), Rola Barcham (Oroxcell) and Olivier Barberan (Elsevier) were already part of the scientific committee last year and have renewed their participation for this year. The new members of the 2020 scientific committee are Laurence Del Frari (Pierre Fabre), Madani Rachid (Genoscience Pharma), Olivier Nicolas (Sanofi), Nicolas Grégoire (Université de Poitiers) and Vincent Duval (Certara). We thank all of them warmly!

This scientific committee is composed of scientists from various backgrounds (pharmaceutical and Biotech companies, CROs, scientific software and service providers and also academic institutes) with the aim to offer you a rich scientific program at the service of science and innovation.

You are more than welcome to share with us **any idea or suggestion** regarding the scientific program for our 2020 symposium in Paris. Please contact us at [contact@gmp.asso.fr](mailto:contact@gmp.asso.fr).



Olivier Barberan



Rola Barcham



Cindy Khaldi



Yannick Parmentier



Laurence Del Frari



Vincent Duval



Nicolas Grégoire



Olivier Nicolas



Madani Rachid

### Scientific committee 2020

## 2020 SYMPOSIUM: CALL FOR SPONSORS !

The next GMP symposium will take place in **Institut Pasteur in Paris** from **21<sup>st</sup> to 23<sup>rd</sup> of October 2020**. **In the very heart of Paris, this prestigious place will host again our entertaining discussions.** We hope to see many of you there! Program to follow!



To provide you with optimal symposium conditions, at an achievable price, we are seeking sponsors. GMP is offering four sponsorship levels:

SPONSOR LEVEL	CONTRIBUTION
PLATINUM	From 5000 €
GOLD	From 3000 to 5000 €
SILVER	From 1200 to 3000 €
BRONZE	From 400 to 1200 €

For **more details** about the **advantages associated** with each sponsorship level, you will find our full sponsorship offer on our website: <https://gmp.asso.fr/wp-content/uploads/2020/02/2020-gmp-sponsorship-opportunities.pdf>

Please do not hesitate to distribute this offer around you, to allow us to offer you an exceptional symposium. We count on each of you!



## RADIOACTIVITY IN PHARMACOKINETICS

by Marion Millet (Pierre Fabre)

Radioactivity is usually used from the candidate selection for performing **regulatory PK in vivo studies** as mass balance and distribution studies. Radiolabeled compounds are also useful for performing metabolism studies because the monitoring and the quantification of metabolites is facilitated.

ICH S9, an **EMA guideline** dedicated to the nonclinical evaluation of anticancer pharmaceuticals, mentions that the above listed studies are not required for the first in human studies.

In the case of **biologics**, the package for starting a clinical development is different and the radiolabeled compound is not needed either. ICH S6(R1) advises us to take care “in the interpretation of studies using radioactive tracers incorporated into specific amino acids because of recycling of amino acids into proteins/peptides non-related to the ADME profile of the drug.”

At the same time, the management of radioactivity is more and more cumbersome and expensive.

For these reasons, alternative strategies have been used by pharmaceutical companies such as:

- the identification and the semi-quantification of metabolites by **non-radioactive bioanalytical methods**, often using mass spectrometry (the quantification is possible when standards are available). This implies important bioanalytical efforts, in terms of development and method validation.
- the use of **NMR** (nuclear magnetic resonance) method when possible from the chemical structure of the drug (Haitao Hu DMD 2017)
- the use of **QIMS** (quantitative imaging mass spectrometry).

The radioactivity use in drug development is helpful despite its drawbacks and will always be a valuable tool in almost all pharmaceutical developments (small molecules, ADC). Indeed, radioactivity does have certain distinct advantages, particularly in consideration of quantitative needs associated with the “metabolites in safety testing” (MIST) developments and to highlight covalent binding, although the current trend seems to delay or reduce its use as much as possible.



**NEXT WEBINAR: March 11<sup>th</sup> 2020, 12-1 pm**

**PBPK models: mechanistic plausibility drives predictive performance**

Tips and tricks from **Pieter Anneart** (KU Leuven, Belgium)

*Invitation coming soon*