Biopharmaceutics meets Formulation Development – Setting justified Drug Delivery Targets

21 - 22 May 2025
Kassel, Germany

Course no. 7048

Research and Development

Target group

This seminar is addressing Pre-formulation scientists, Formulation development scientists, DMPK Scientists (Biopharmaceutics), Related disciplines (auch as regulatory affairs, project management…), Modelling and Simulation scientists (DMPK and Formulation related) as well als all members from Health Authorities.

MAKING SCIENCE WORK

Research and Development

A seminar organised by the APV focus group Drug Delivery

Summary

One central goal in developing medicinal products is to have for the drug just the right dose for the right time at site of action to assure optimal therapy for the patient. To achieve this central goal an understanding of drug delivery and its relation to the formulation is key.

PK/PD correlation links pharmacokinetics and pharmacodynamics to establish and evaluate dose-concentration-response relationships and subsequently describe and predict the effect-time courses resulting from a drug dose. On the other hand, the drug release profile from the formulation forms the input to the pharmacokinetic profile.

Thus, a well-characterized PK/PD model is an important tool in guiding the design of future experiments and trials for the preclinical, clinical and of course formulation development of drugs. It can be used with preclinical data to mathematically describe the dynamic in vivo behavior of new drug candidates, and to predict human exposure and effect based on preclinical models as well as directing demands in drug release profiles. In the clinical phase of product development it can also be used to further optimize dosing and formulations for target patient groups.

During this seminar you will learn how PK/PD can be used together with in vitro and in vivo models to help you during formulation development to explore the advantage of tailor-made drug delivery solutions and to better evaluate drug release and efficacy.

Goal

Bring together Industry, Academia and Regulatory and offer a platform for exchange of opinions, challenges and expectations related to the topic.

Chair

Dr. rer. nat. Uwe Hanenberg
Recipharm, Germany

Dr. Uwe Hanenberg studied Pharmacy, holds a PhD in pharmaceutical analytics and is specialized pharmacist for analytics.

Uwe acts as head of product implementation for Recipharm. He is responsible for proposing, implementing and executing the Product Development strategy that assures science driven, timely development of new products or services.

Uwe has 25 years of experience in the pharmaceutical industry with Bayer, Altana, Grünenthal and Catalent. His areas of expertise are oral formulation development, oral manufacturing technologies, stick pack technologies and pharmaceutical contract services and project management.

Programme

Wednesday, 21 May 2025, 10:30 - 18:00 h

Welcome & Coffee

Let's be theoretical: Basics of Biopharmaceutics
- What is biopharmaceutics about?
- Which tools do we apply?
- How do we connect biopharmaceutics and formulation development?

Christian Wagner, Merck, Germany

Basics of preclinical formulation development and clinical formulation development
- What is the scope of my work
- What is the input and output of my work
- How do I start development
- Biopharmaceutical classification system (BCS)
- What Info do I need for my daily work (and how can the biopharmaceutical scientist help)
- Which tools do I use on a daily basis; how do they work
- How does a formulator use biopharmaceutical data
- Where is the value for a biopharmaceutical scientist
- Pitfalls to avoid

Meike Harms, Merck, Germany and Dejan Lamesic, Catalent, Germany

Let's get practical: Biopharmaceutic work approaches in pharmaceutical industry and beyond
- Case examples with a focus on how to use physiologically-based biopharmaceutics modeling to support formulation development and project progression
- A highly-connected discipline – interfaces and functions
- The world outside the own microcosmos – cross-functional collaborations between industry partners (and health authorities)

Christian Wagner, Merck, Germany

Successful collaboration between biopharmaceutics and formulation development
Prerequisites
- Examples of (standardized) processes in industry, biopharmaceutics squad and working group
- Experience and case studies from industry

Michael Hofmann, F. Hoffmann-La Roche, Switzerland

Modelling & Simulation – Basics
IVIVC M&S to support drug product development and specifications
- Introduction general model types and regulatory applications
- Opportunities related to virtual bioequivalence
- Examples of importance of quantity, quality and mechanistic understanding of data available
  - Sample size and in vivo variability
  - Changes in study design and conduct (e.g. sampling times, population, bioanalytical method)
  - Changes in drug product characteristics (e.g. composition, manufacturing process)
  - Changes in drug substance (e.g. particle size, solid dispersion)

- Multidisciplinary aspects that should be aligned to guide modelling efforts for specific applications
  - Purpose to interpret comparative bioavailability results and guide dissolution method and/or product development
  - Purpose to support specification setting in QC method
  - Purpose to waive in vivo bioequivalence studies

Paula Muñiz Piniella, CTI, Spain

Networking dinner

Thursday, 22 May 2025, 09:00 - 16:00 h

How is Modelling and Simulation applied in Industry, in Focus: PBPK and PBBM

- Status in industry
- Application in industry
- PBPK and PBBM
- Textbook and experience
- Value for formulators
- Tips and tricks
- Pitfalls to avoid

Michael Hofmann, F. Hoffmann-La Roche, Switzerland

GI physiology: insights from imaging studies and implications for predictive dissolution testing

- Investigation of gastrointestinal physiology in fasted and fed state
- Interplay between oral drug delivery systems and gastrointestinal physiology
- Role of water intake
- Translation of findings into predictive dissolution testing

Werner Weitschiess, University of Greifswald, Germany

Case Studies

Moderator: Uwe Hahnenberg, Catalent, Gernany

How to find the right formulation strategy

Translating Pre/clinical results into formulation strategy (and vice versa: which value does the biopharmaceutic scientist get out of formulation development data)

- Case studies of unsuccessful application
- Case studies of successful application of translation of biopharmaceutical results
  - Zydis Selegilin
  - Concerta

Setting clinical relevant specification – Expectations from the authority

- Definition "clinical relevant specification"
- Discussion of the term "clinical" in "Setting clinical relevant specification"
- Link between "Critical Quality Attributes" and "In vivo performance"
- Why is "setting clinical relevant specs" important
- Link to safety and efficacy
- Typical example of a relevant specification (dissolution)
- Expectation from the Authority
- Conclusions and Outview

speaker tbd

In-vitro-in-vivo correlation – Bridging between Biopharmaceutics and Product Development

- Introduction : Why IVIVC matters
- Regulatory Guideline : Foundation for compliance
- Challenges in Classic IVIVC methods
- Modern solutions for enhanced correlation
- Designing safe and open collaboration spaces
- Translating clinical insights into Formulation targets

Ramesh Jagadeesan, Recipharm, Germany

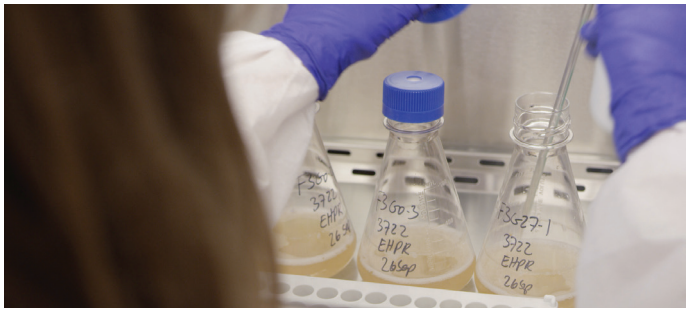
How to apply models and supportive methods in Development

- How does Industry understand "Setting clinical relevant specification" (phase appropriate)
- Where scientifically relevant /where not relevant
- Current application in industry
- Related Cost
- Case study
- Stimulus for Final Discussion

Erik Doevendans, Scendea, Netherlands

Setting clinical relevant specification – Panel Discussion

Programme subjected to change!



Registration by email to anmeldung@apv-mainz.de

Location

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Phone: 0049 6 0561 52050
reservierung.kas21@gchhotelgroup.com

Date

Course no.: 7048
from 21 May 2025 10:30 h
to 22 May 2025 16:00 h

Registration fee

Industry	1590 EUR
Authority/University	795 EUR
Students*	240 EUR

(free of VAT according to § 4,22 UStG)

Coffee breaks, luncheons, dinner and electronic proceedings included.

* Limited places for full time students available; written evidence must be submitted.

Registration

APV-Geschäftsstelle
Kurfürstenstraße 59
55118 Mainz/Germany
Phone: 0049 6131 97 69 0
E-mail: anmeldung@apv-mainz.de
Web: www.apv-mainz.de

You will receive a confirmation of your registration with the invoice.

Hotelreservation

Wyndham Garden Kassel
Heiligenröder Str. 61 61
34123 Kassel
Germany
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Participants should make their own hotel reservation referring to the APV seminar with the code „APV".

Special rate: Single room incl. breakfast from 104 EUR per night. Deadline for rate: 09 April 2025.

Biopharmaceutics meets Formulation Development, 21-22 May 2025, Kassel, Course no. 7048

Registration
As soon as you have found a seminar of your interest, it is very easy to register for it via e-mail or online. We will process your registration promptly and certainly are available for any questions that may arise.

Registration confirmation
After your registration was successfully processed, you will receive a confirmation.

Before the event
A few days before the event starts, you will receive important information about the seminar, such as time, date, addresses etc.

After the event
You will receive a certificate confirming your participation. Furthermore, we would like to ask you to fill-in our evaluation sheet to make sure we get better every time.

Follow-up
After the event, we are open to receive any suggestions and critique that might arise during the seminar and will certainly help you with further questions you may have.

Declaration of consent in respect of data protection

☐ By registering for this seminar, I agree that the APV uses my data for the purpose of processing the order and provides me with all relevant information.

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