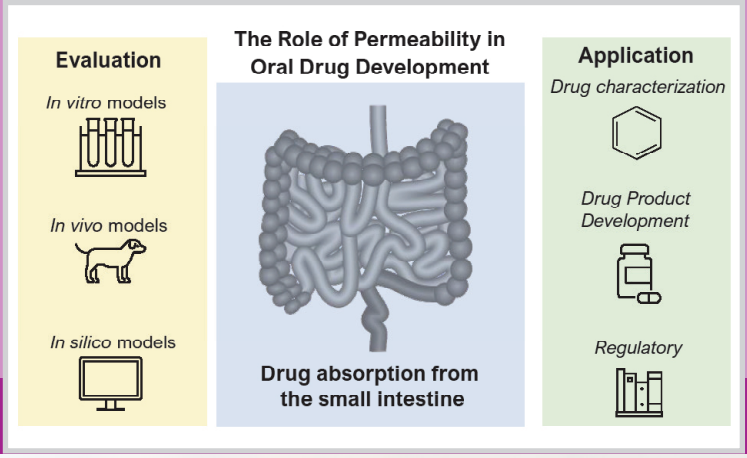
# The Role of Permeability in Oral Drug Development




virtual meeting

**22-23 November 2022**
**Online Seminar**

**Course no. 6913**

ONLINE SEMINAR

## Research and Development

### Target group

This seminar is intended for all scientists with an interest in oral drug absorption. This includes academics and early stage researchers (graduate students), scientists from the Pharmaceutical Industry working in Research and Development (e.g. Discovery, Drug Metabolism and Pharmacokinetics, Formulation and Process Design, Analytics, Clinical Pharmacology) and in Regulatory Affairs as well as those working in related departments in Regulatory Authorities.

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# Research and Development

A seminar organised by the focus group Biopharmaceutics

## Objectives

The primary goal of the seminar is to explore the various methodologies that are being used to determine drug permeability in the gastrointestinal tract and to identify how they are applied in the different stages of drug development (Discovery, Preclinical Development and Clinical Development).

Experts in the various methods applied to measure/estimate permeability values, ranging from in silico and in vitro predictions all the way through to studies in humans, will share their experience and expertise. During the panel sessions, the participants will have the opportunity to ask specific questions and interact directly with the experts. The intention is to not only describe the various methods but also to point out potential flaws and assumptions which can affect the results and their interpretation, and to establish best practices for each method as well as the selection of the most appropriate method in each stage of drug development. In addition, the impact of permeability estimations on PK predictions in PBPK modelling and the degree to which excipients can affect drug permeability in clinical studies will be addressed.

At the end of the seminar, the participants will know:

- about the various methods used for measuring/ estimating permeability including their advantages and limitations,
- about the latest developments in measuring permeability,
- how to select the most appropriate method for a given situation in the development of an oral drug product,
- about the challenges around reliability of permeability assessment,
- how to apply permeability values in PBPK modeling and
- to what degree excipients are likely to affect drug permeability.

## Referenten

**Prof. Dr. Jennifer Dressman**
**University of Frankfurt**
**Fraunhofer Institute, DE**

Jennifer Dressman, who recently retired as Professor of Pharmaceutical Technology at the Goethe University in Frankfurt am Main, Germany, has been working with the Fraunhofer Institutes in Germany since 2018 to establish a formulation group within the new Institute of Translation Medicine and Pharmacology. Prof. Dressman's research interests focus principally on predicting the in vivo performance of drugs and dosage forms after oral administration. She is best known for pioneering the use of Biorelevant dissolution testing and her contributions to combining dissolution testing with physiologically based pharmacokinetic modelling in order to achieve quantitative predictions of oral drug absorption. In recognition of her research excellence, she has been made a Fellow of the AAPS, the CRS, AJPST and the FIP. In 2008 she was awarded the Distinguished Scientist Award of the FIP and in 2017 was named the International Woman Pharmaceutical Scientist of the Year by the APSTJ. In 2022 a special issue of the Journal of Pharmaceutical Sciences was dedicated to her contributions to the Pharmaceutical Sciences.

**PD Dr. Mirko Koziolek**
**AbbVie Germany, DE**

PD Dr. Mirko Koziolek is a Principal Research Scientist I in NCE Formulation Sciences at AbbVie Germany. He received his PhD in Biopharmacy and Pharmaceutical Technology from the University of Greifswald in 2014 under the supervision of Prof. Werner Weitschies. Following his doctorate, Mirko spent 12 months in the group of Prof. Christopher Porter at the Monash Institute of Pharmaceutical Sciences in Melbourne, Australia. In 2016, Mirko returned to the University of Greifswald to continue his research on the in vitro and in vivo characterization of drug release from oral dosage forms. This work included the design and optimization of biorelevant in vitro tools such as the GastroDuo as well as the application of different in vivo techniques such as MRI or telemetric capsules to study GI physiology and the in vivo behavior of oral formulations in humans. In October 2019, Mirko joined AbbVie in Ludwigshafen, Germany, where he is responsible for biopharmaceutical support of drug product development. Mirko is author/co-author of 50+ peer-reviewed publications and is a regular reviewer for various journals in the field of Pharmaceutical Sciences. In the recent European COST action on "Understanding Gastrointestinal Absorption Processes (UNGAP)", he served as co-lead of the working group "Food-drug interface".

# The Role of Permeability in Oral Drug Development

## Programme

### Tuesday, 22 November 2022 13:00 - 17:00 h (CEST)

**Welcome and introduction**
Jennifer Dressman and Mirko Koziolek

### Session 1: Introduction and permeability in preclinical stages

**The Role of Permeability in Pharmaceutical Development**
- Definition of permeability
- Preclinical, clinical and post-approval (SUPAC; Generics)
- Regulatory requirements for permeability data
- Current challenges

Mario Mezler, Abbvie

**In silico methods used to estimate permeability in preclinical development**
Pär Matsson, University of Gotheburg

**Challenges and innovations in Cell Monolayer studies**
- Advantages and disadvantages of cell types
- Efforts to optimize cells
- Laboratory to laboratory variability – where does it come from?
- Standardization of methods – best practices? Choice of benchmark APIs?
- How to handle new types of APIs e.g. protacs and peptides

Patrick Augustijns, KU Leuven

**Animal-based methods to study permeability**
- Perfusions, PK, mass balance

David Dahlgren, Uppsala University

### Session 2: Emerging methods for permeability determination in preclinical development

**Emerging methods I. Organ on a Chip**
Andreas Dietzel, University of Braunschweig

**Emerging methods II Human tissue based models**
Marco Metzger, ISC Würzburg

**Panel Discussion**
- Current Gaps/Challenges and how to address them?

### Wednesday, 23 November 2022 13:00 - 17:00 h (CEST)

### Session 3: Role of permeability in clinical development

**Challenges of using preclinical permeability estimates for PBPK modeling**
- Discrepancies among published values – how to handle?
- Conversion of Papp to Peff – best practice?
- Should we scale up the Peff to make the model work?

Rodrigo Cristofoletti, University of Florida

**Overview of methods used to determine permeability in clinical development**
- Bioavailability and $F_{abs}$
- Mass balance studies
- Loc-I-gut and other perfusions
- Smart Pills

Werner Weitschies, University of Greifswald

**Unmet needs: Models for Colonic Absorption**
Maria Vertzoni, National Kapodistrian University of Athens

**Excipients and Permeability – Separating Effect from Artefact,**
Jim Polli, University of Maryland

**Permeation Enhancers – where are we?**
Fiona McCartney, University College Dublin

**Emerging methods: e-Pille**
Jenny Dressman

**Wrap-up**

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**Registration fee**

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|---|---|
| Industry | 900,00 EUR |
| Authority/University | 450,00 EUR |
| Students* | 150,00 EUR |

(plus valid VAT)

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

**Registration**

Registration for this seminar is available online at https://www.apv-mainz.de/en/seminar/events.

We will process your registration immediately and send you a confirmation by email.

If you have any questions, please contact us by phone or email.

**Registration: www.apv-mainz.de/en/seminare/events/**

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