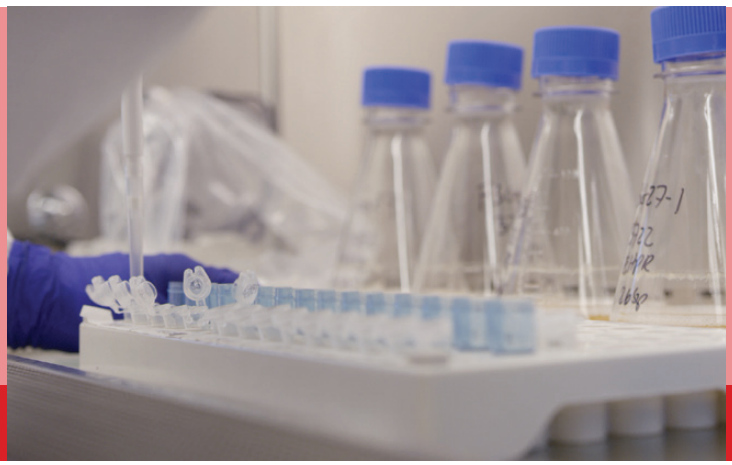
Advanced in-vitro and in-silico biopharmaceutics tools for oral drug delivery



26 - 27 March 2025
Porto, Portugal

Course no.: 7018

Biopharmaceutics

Target group

This course is designed for all scientists, biopharmaceutics, analytical as well as formulation scientists working in the field of oral delivery of synthetic molecules and related areas. The course would also be of interest to those working in closely related fields such as Clinical Pharmacology and Regulatory and those who wish to increase their knowledge of this highly interdisciplinary field.

MAKING SCIENCE WORK

Objectives

During clinical development, new drugs are typically first tested in healthy volunteers before investigating them in the patient population of interest. Understanding the difference in the gastrointestinal physiology of healthy (often male) volunteers in comparison to the actual patient population will help to understand the fate of the dosage form in the specific patient group and support scientists in setting up better PBPK models.

During day 1 of the course we will take a closer look into pediatric patients as well as older adults and geriatric patients. A group of patients that will significantly increase in the next couple of years. The United Nations projected that by 2050 the number of individuals aged 65 years or above across the world will be twice the number of children under age 5 and almost equivalent to the number of children under 12 years. In addition, we will increase our understanding with respect to overweight and obesity as already today 1 in 8 people in the world are living with obesity and numbers are increasing. If nothing is done, the global costs of overweight and obesity are predicted to reach US$ 3 trillion per year by 2030 and more than US$ 18 trillion by 2060.

On day 2, we will focus on recent advancements in in vitro tools including combined dissolution/permeation assays for the evaluation of solubility enhanced formulations and to investigate the impact of digestion on drug absorption to get useful insights from experts using these highly sophisticated dissolution methodologies. All this will help us in better understanding the fate of different oral dosage forms in the gastrointestinal tract.

Course leader

Susanne Page
F. Hoffmann-La Roche

Dr. Susanne Page studied Pharmacy at the Technical University Braunschweig. She did her diploma thesis at Jenapharm GmbH in the field of buccal delivery systems. In 2002 she completed her Ph.D, thesis investigating a new film coater at the Martin-Luther-University of Halle in the working group of Prof. Kleinebudde. She joined F. Hoffmann-La Roche AG in Basel in 2002 as a Formulation Scientist. Today she is an Expert Scientist with a strong focus on patient centric aspects in drug product development and drug delivery technologies.

Philippe Berben
F. Hoffmann-La Roche

Philippe Berben graduated as Pharmacist at KU Leuven (Belgium) in 2014. He obtained his PhD in 2018 at the lab of 'Drug Delivery and Disposition' under supervision of Prof. Dr. Patrick Augustijns at the same university. His PhD was part of the OrBiTo (Oral Biopharmaceutics Tools) initiative where he focused on the complexity of the gastrointestinal environment on intestinal drug absorption. Philippe has worked as a biopharmaceutics scientist at UCB (Belgium) and Idorsia (Switzerland). Today he is part of the biopharmaceutics team at F. Hoffmann-La Roche AG where he is supporting several projects at different stages of drug development.

Programme

Wednesday, 26 March 2025 08:45 - 17:30 h

Welcome and Housekeeping
Susanne Page, F. Hoffmann-La Roche,
Philippe Berben, F. Hoffmann-La Roche

Panel 1: Performance of pharmaceuticals in the pediatric population

Paediatric oral drug delivery: where are we at?
Catherine Tuleu, University College London

How do we include Paediatric populations into the Biopharmaceutics Classification System?
Hannah Batchelor, University of Strathclyde

How does the co-administration of food and drinks affect the oral bioavailability of pediatric medicines?
Sandra Klein, University of Greifswald

Simulating gastrointestinal drug behaviour and absorption in paediatric patients
Matthias Van der Venken, MSD Belgium

Navigating the challenges of administering medicines through enteral feeding tubes
Frank Karkossa, University of Greifswald

Panel discussion - Pediatric Patients
All speakers from the morning

Panel 2: Tackling the health care challenges of the future - Obesity and an aging population: How does it impact performance of pharmaceuticals population

Successful medication use in older adults and geriatric patients
Henriette Hummler, Aenova Group

Oral drug absorption in older adults – an AGePOP perspective
Maria Vertzoni, National and Kapodistrian University of Athens

Integrating Global Sensitivity Analysis with PBPK Models to Assess Parametric Influences (in Older Populations)
Andreas Lehmann, Merck Healthcare KGaA

The risk of physicochemical DDI in polymedicated patients
Alvaro Lopez, Abbvie

Drug Dosing in Patients with Obesity and following Bariatric Surgery: Can we predict?
Catherijne Knibbe, St. Antonius Ziekenhuis

PBPK modeling after subcutaneous administration
Erik Sjögren, Uppsala University and Pharmetheus

Panel discussion - Obesity and Ageing
All speakers from the afternoon

Networking dinner

Thursday, 26 March 2025 08:45 - 17:30 h

Welcome and Housekeeping
Susanne Page, F. Hoffmann-La Roche,
Philippe Berben, F. Hoffmann-La Roche

Panel 1: Assessing the performance of solubility enhanced formulations

Solubility enhanced formulations - current trends and future perspectives (focus on ASDs & Lipid based systems)
Susanne Page, F. Hoffmann-La Roche,
Rene Holm, University of Southern Denmark

Evaluating the performance of immediate release high-risk products (based on ICH Guideline M13A)
Christos Reppas, National and Kapodistrian University of Athens

Utilizing in vitro dissolution-permeation data for the assessment of supersaturated systems (Impact of type of membranes and surface area)
Martin Brandl, University of Southern Denmark

In vitro characterization of lipid based formulations – how to obtain in vivo relevancy
Rene Holm, University of Southern Denmark

Assessment of lipid systems using combined lipolysis and permeation assays
Christel Bergström, Uppsala University

Panel discussion - In vitro tools for solubility enhanced formulations
All speakers from the morning

Panel 2: Sophisticated In-vitro tools for immediate and modified release dosage forms

A systemic approach for in vitro testing of physiologically relevant aspects of the human GI tract
Philipp Schick, University of Greifswald

An introduction to the Dynamic Intestinal Absorption Model (DIAMOD®): principles and case examples
Philippe Berben F. Hoffmann-La Roche

Applications of tiny-TIM and TIM-1 models in Drug Product Development
Alvaro Lopez, Abbvie

In vitro dissolution testing for modified release dosage forms - Use of alternative buffer systems
Josef Al-Gousous, University of Mainz

Plan your dissolution tests the smart way - simulating the variability of fasted gastric conditions with bio-predictive dissolution tests and pharmacokinetic modeling
Dorota Danielak, Physiolution

Panel discussion - In-vitro tools for IR and MR dosage forms
All speakers from the afternoon

Closing and Summary
Susanne Page, F. Hoffmann-La Roche,
Philippe Berben, F. Hoffmann-La Roche

Registration by email info@apv-mainz.de

Location

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Date

Course no.: 7018
from 25 March 2025 08:45 h
to 26 March 2025 17:30 h

Registration fee

Industry	1690	EUR
Authority/University	845	EUR
Students*	250	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: info@apv-mainz.de
Web: www.apv-mainz.de

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

Hotel reservation

Please book your hotel yourself. We recommend to book the hotel room with hotel booking platforms such as hrs.com or booking.com.

Advanced biopharmaceutical IV and IS tools for ODD, 26-27 March 2025, Gaia-Porto, Portugal, Course no. 7018

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

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