Oral Biopharmaceutics Tools:
What's new and what's coming?

26 to 27 September 2017
Nuremberg, Germany

Course No. 6695

Research and Development

Target audience

Scientists working in the pharmaceutical industry in Formulation, Quality Control, Pharmacokinetics and Bioequivalance, and Regulatory Sciences, academic scientists with interest in Oral Biopharmaceutics and scientists working in Regulatory Authorities are invited to learn more about Oral Biopharmaceutics Tools.

Workshop organized in cooperation with

APV MAKING SCIENCE WORK

fip International Pharmaceutical Federation

Research and Development

A seminar organized by the APV focus group „Biopharmaceutis"

Objectives

- Assess the opportunities provided by biorelevant performance testing
- Examine case studies using biorelevant dissolution examinations to assess product performance attributes
- Communicate efforts to improve and facilitate the in vivo predictability of biorelevant tests
- Present PBPK modeling approaches for addressing the impact of oral absorption process on plasma levels
- Address strategies for linking quality control dissolution methods with biorelevant in vitro performance testing
- Discuss quality by design (QbD) applications, Process Analytical Technology (PAT) and physiologically based pharmacokinetic modeling
- Discuss discriminating methods and how to address process changes during the lifecycle of a drug product

Overview of the workshop

Dissolution testing is an important tool from early development to life cycle management of a drug product. With the Quality by Design (QbD) approach critical process parameters, material attributes and quality attributes are identified. Their impact on in-vitro dissolution and bioavailability are assessed.

In early development, biorelevant dissolution/release testing, i. e. the evaluation of luminal behavior of drug products in gastrointestinal lumen with in vitro methodologies, is useful for predictions of formulation and food effects on plasma levels. It is also utilized to decrease the number of in vivo studies required during the drug development process and to mitigate the risk related to in vivo bioequivalance studies.

Recent updates and case studies on these subjects will be discussed by scientists working in academia, industry and regulatory agencies from Europe, the US and Japan.

There will be a general discussion session at the end of workshop, as well as the opportunity for attendees to ask questions at the conclusion of each presentation.

Course Leaders

Horst-Dieter Friedel
Bayer AG, Germany

Jennifer Dressman,
Wolfgang Goethe University Frankfurt, Germany

Program

Tuesday, 26 September 2017 **13:00 to 18:00**

Welcome and Aims of the Workshop
Horst-Dieter Friedel, Bayer AG, Germany

Part 1. Oral Biopharmaceutics Tools – What's new?

Clinical relevance of dissolution testing in Quality by Design – the BioRAM concept
Jennifer Dressman, Wolfgang Goethe University Frankfurt, Germany

Oral Biopharmaceutics Tools. The OrBiTo Project
Uwe Münster, Bayer AG, Germany

Biorelevant dissolution testing: The Importance of in vitro / in vivo relationships
Peter Langguth, Johannes Gutenberg University Mainz, Germany

Biorelevant dissolution testing – Recent developments
Christos Reppas, University of Athens, Greece

Early stage preclinical tests which can guide dissolution methodology
Kerstin Julia Frank, Boehringer Ingelheim Pharma, Germany

Wednesday, 27 September 2017 **08:30 to 17:30**

Part 1. Oral Biopharmaceutics Tools – What's new?
Continuing

PBPK modelling – how it works
David Turner, Certara, United Kingdom

Prediction of in vivo performance from modified release dosage forms using biorelevant dissolution
Cord Andreas, Wolfgang Goethe University Frankfurt, Germany

Prediction of in vivo performance using biorelevant dissolution – an industrial perspective
David Sperry, Eli Lilly, United States

PBPK modelling – examples from the industry
Sheila Anne Peters, Merck KGaA, Germany

Part 2. Quality Control Applications

Quality by Design applications of drug critical process parameters (CPP)
Anita Nair, Merck KGaA, Germany

PAT tools and surrogate model development
Lorenz Liesum, Novartis, Germany

Linking QC methodology with Biowaivers and Bridging studies
Johannes Krämer, Phast GmbH, Germany

Part 3. Regulatory opportunities

EU perspectives on the role of dissolution testing on product design, control and approval
Mike Morris, former HPRA, Ireland

FDA perspectives on the role of dissolution testing on product design, control and approval
Arzu Selen, FDA, United States

Japanese perspectives on the role of dissolution testing on product design, control and approval
Tomokazu Tajiri, Astellas, Japan

Final Discussion

Program is subject to change

Contact Person of APV Headquartes

For further information please contact the course advisor:

Anna-Maria Pötzl
Congresses and Course Management

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Speakers

David Sperry
Eli Lilly, United States

Dr. Sperry is a Research Advisor in Small Molecule Drug Development at Lilly Research Laboratories. He obtained a B.S. degree in chemistry from Indiana University, Bloomington, IN and a Ph.D. degree in chemistry from the University of Rochester, Rochester, NY. After receiving his degree, he took a postdoctoral research scientist position at Pharmacia & Upjohn where he developed an Artificial Stomach Duodenum model and studied its utility in drug development. Shortly thereafter, he accepted a research scientist position at Pharmacia (later Pfizer), working in the area of in vitro methods and biopharmaceutics. He then moved to Bausch and Lomb where he developed commercial ophthalmic formulations for late stage molecules.

Tomokazu Tajiri
Astellas, Japan

Dr. Tomokazu Tajiri joined Yamanouchi Pharmaceutical Co., Ltd. (current Astellas Pharma Inc.) in 2003, and he is senior researcher in Analytical Research Laboratories and be responsible for development of analytical test methods for new drug applications (NDA)/ marketing authorization application (MAA). He also worked at the EU satellite-laboratory in the Netherlands as associate scientific director from 2014 to 2016.

David Turner
Certara, United Kingdom

Dr Turner is a Principle Scientist at Simcyp Limited located in Sheffield, UK with lead responsibility for the oral absorption modelling team. His first degree was in Biochemistry after which he obtained an MSc in Computer Science. He obtained his PhD in 1996 from Sheffield University in Cheminformatics and QSAR Modelling. Subsequently, he worked as a Postdoctoral Researcher in the same group for several years developing spectral descriptors for QSAR modeling and molecular similarity scoring. From 1999 he spent three years in the Computational Drug Discovery Group at Synt:em SA, a biopharmaceutical company based in Nîmes, France, involved mainly in early discovery virtual screening projects.He joined Simcyp Limited in late 2004 where his main responsibilities currently lie with the physico-chemical aspects of the development of the Simcyp Population-based ADME Simulator particularly the PBPK oral absorption and tissue distribution models and QSAR model development. He is currently Principal Investigator on a two-year US FDA funded grant for the development of PBPK Modelling tools for handling Supersaturating Drug Products.

A seminar organized by the APV focus group „Biopharmaceutis"

Cord Andreas
Wolfgang Goethe Universität Frankfurt, Germany

Cord Andreas received the pharmacy degree with distinction at the Goethe University in Frankfurt in 2012 and is currently working as a PhD student at the Institute of Pharmaceutical Technology of the Goethe University in Frankfurt under supervision of Professor Dr. Jennifer Dressman. The focus of his studies involves the prediction of the absorption of modified release dosage forms using biorelevant in-vitro and in-silico tools. Parallel to the PhD program, he attends further education courses to become expert pharmacist for pharmaceutical analysis. Throughout his studies, Cord Andreas has conducted research stays in pharmaceutical companies including Bayer in Germany, Roche in the USA and Astellas in Japan.

Jennifer Dressmann
Wolfgang Goethe Universität Frankfurt, Germany

Jennifer Dressman is Professor of Pharmaceutical Technology and Director of the Institute of Pharmaceutical Technology at the Goethe University in Frankfurt am Main, Germany. She received her B. Pharm degree in Pharmacy from the Victorian College of Pharmacy, Melbourne in 1976 and her Ph.D. in 1980 from the University of Kansas in the USA under the direction of Prof. Takeru Higuchi. From 1980 to 1983 she held positions as Senior Scientist at Burroughs Wellcome and Interx/Merck before joining the Pharmaceutics Faculty at the University of Michigan (USA) as an Assistant Professor. In 1989 she was promoted to Associate Professor, with tenure, at the same university and in 1994 took up her current position.

Lorenz Liesum
Novarts, Germany

Global Statistics and PAT Head within Manufacturing Science and Technology, Novartis Technical Operations

Lorenz studied Chemistry and Mathematics and holds a Ph.D. in Physical Chemistry from ETH Zurich.
He started his industrial career as an analytical scientist in chemical and pharmaceutical development at Roche and Novartis. Since more than 10 years he is working in the field of Process Analytical Technology and was involved in regulatory QbD filings. He is leading the Statistics and PAT group within global Manufacturing Science and Technology in Novartis Technical Operation supporting the production sites globally for all statistical relevant topics and managing PAT and QbD implementation with a strong focus on NIR spectroscopy and multivariate statistical process control.

Kerstin Julia Frank
Boehringer Ingelheim Pharma, Germany

Dr. Kerstin Frank is a pharmacist by training and has a PhD in pharmaceutical technology and biopharmaceutics from the University of Southern Denmark in Odense. In October 2012, she joined the pharmaceutical development department of Boehringer-Ingelheim as post doc working on the IMI project OrBiTo (oral biopharmaceutic tools). During her postdoc she investigated new in vitro tools for biopharmaceutical evaluation of oral formulations. Since 2013, she is heading an early formulation development lab in the drug delivery technology group at Boehringer-Ingelheim, focusing on formulation technologies for poorly soluble compounds. Dr. Kerstin Frank has (co-) supervised various bachelor, master and PhD projects on innovative in vitro tools for biopharmaceutical analysis.

Horst-Dieter Friedel
Bayer AG, Germany

Dr. Friedel has about 30 years experience in Pharmaceutical Industry and is currently heading the department External Affairs in Corporate Quality, Process & Knowledge Management at Bayer AG in Berlin.
Previous positions: He was responsible for the Pharmaceutical Quality System of Bayer HealthCare. He headed an analytical department for pharmaceutical drug products under development and achieved extensive international experience in product development, dissolution testing, stability studies, laboratory automation, computer validation, and regulatory submissions. He was involved in the development of solid oral dosage forms with fast dissolving and extended release characteristics, parenteral drug products, liposomes, suspensions and aerosols.

Johannes Krämer
Phast GmbH, Germany

Dr. Krämer is the founder and managing director of the "PHAST group" with sites in Germany, France, and Switzerland. Since 1987, he is working in the field of dosage form performance testing. He obtained his degree in pharmacy from Frankfurt University. After specializing in pharmaceutical analysis, he obtained his Ph.D. in pharmaceutical technology and biopharmacy from Heidelberg University.

Arzu Selen
FDA, Untied States

Associate Director for Scientific Outreach and Communications

Peter Langguth
Johannes Gutenberg University Mainz, Germany

Peter Langguth is Pharmaceutical scientist by training and Professor of Pharmaceutical Technology and Biopharmaceutics at the School of Pharmacy and Biochemistry, Johannes Gutenberg University Mainz, Germany. He did undergraduate studies in Pharmacy at the Johann Wolfgang Goethe University in Frankfurt, where he also received a Ph.D. in 1985 with Prof. Ernst Mutschler on the improvement of transdermal and intestinal permeability of In 1996 Prof. Langguth joined Astra Hässle AB in Mölndal, Sweden, as Group Leader in Drug Absorption Research. Since 1998 Dr. Langguth is Head of the Department of Pharmaceutical Technology and Biopharmaceutics at the Johannes Gutenberg University in Mainz. From 2003 to 2005 he was Associate Dean of the Faculty of Chemistry and Pharmacy and from 2005 to 2008 he served as Dean for the Faculty of Chemistry, Pharmacy and Earth Sciences at that University.

Mike Morris
former HPRA, Ireland

John Michael Morris, Ph.D. was Director Scientific Affairs at the Health Products Regulatory Authority (HPRA) of Ireland, in Dublin, Ireland, until he retired at the end of 2015. Dr. Morris was formerly Pharmaceutical Director, IMB, responsible for the assessment of quality data (CMC data) and before that Senior Pharmacist at the Irish National Drugs Advisory Board. Dr. Morris obtained a degree in Pharmacy and a Ph.D. from the University of Manchester (UK). Dr. Morris was the EU member of the ICH Q6A Expert Working Group, and in 2003 led the Group for the revision of the ICH Guideline Q3B, subsequently EU topic leader and then Chair of ICH Q4B pharmacopoeial harmonization. In 2004 he was elected to the position of Chairman of the European Pharmacopoeia Commission until 2007 and he remained a member of the Commission until 2016.

Christos Reppas
University of Athens, Greece

Christos Reppas is Professor of Pharmaceutics, Department of Pharmacy, National and Kapodistrian University of Athens (NKUA), Greece. He received his B. Pharm degree in Pharmacy from NKUA in 1982 and his Ph.D in 1986 from the same University. From 1988 to 1989 he completed a postdoctoral fellowship in Pharmaceutics at the University of Michigan (USA) and then he joined NKUA in 1989 as a Lecturer. He has held research positions with the University of London (UK), the University of Michigan (USA), Glaxo R&D (UK) and the University of Frankfurt (Germany).

Uwe Münster
Bayer AG, Germany

Uwe is a pharmacist by training. He obtained his PhD from the Free University of Berlin in 2003, where he worked on drug targeting to the hair follicle using lipid nanoparticles. After a 2-years postdoctoral stay at the Salk Institute in La Jolla, California, Uwe started at Bayer in 2006. First, in the department of Research Pharmacokinetics, later on as lab head within Chemical and Pharmaceutical Development. During his time with Bayer Uwe has been focusing on biopharmaceutical prediction models for oral drug candidates. Specifically, he is interested in how physicochemical properties of API and formulation determine the biopharmaceutical performance of oral drugs. Uwe has been participating in the IMI initiative Orbito, representing Bayer as one of the 28 collaboration partners from industry and academia.

Anita Nair
Merck KGaA, Germany

Dr. Anita Nair completed her PhD in Pharmaceutical Technology from Goethe University, Frankfurt where she worked extensively on the biowaiver concept of drug products and published several biowaiver monographs. She is a pharmacist and completed her Bachelor and Masters degree in Pharmacy from the University of Mumbai, India. She is Head of Laboratory, responsible for solubility and physico-chemical characterization of new chimical entities, in Central Analytics at Merck KGaA in Darmstadt, Germany. Her research interests focus on analytical characterization of new chemical entities including physico-chemical characterization of research compounds and development candidates, using dissolution methods for evaluation of in vivo performance of drugs and dosage forms after oral administration and optimizing the performance of dosage forms intended to enhance systemic absorption of poorly soluble drugs.

Sheila Annie Peters
Merck KGaA, Germany

Dr. Sheila Annie Peters heads the Translational Quantitative Pharmacology group at Merck Darmstadt. Her areas of expertise in DMPK includePhysiologically-based pharmacokinetic (PBPK)-Phamacodynamics(PD) modeling, and PK/PDand drug-drug interactions.In her previous position at AstraZeneca, Mölndal, shedeveloped a generic whole-body PBPK model in MATLAB® which she used to support several drug discovery and early development projects across different R&D sites with innovative approaches to identifying potential limitations to drug disposition. She led the development of a pulmonary PBPK model for inhaled drugs incollaboration with Pharmaceutical Development at AstraZeneca.

Registration by fax +49 6131 9769-69

Location

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Registration

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e-mail: apv@apv-mainz.de

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

Date

from 26 September 2017 13:00
to 27 September 2017 17:30

Registration fee

Industry	1490 EUR
Authorities/Academia	745 EUR
Students*	178 EUR

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

Coffee breaks, lunch, dinner and electronic proceedings included.

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

Hotel reservation

Derag Livinghotel Nürnberg
Obere Kanalstraße 11
90429 Nürnberg
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Phone: +49 911 92950

Special rate:
Single room from 181 EUR per night.
Deadline for special conference rate:
30 July 2017.

NOVINA Hotel Wöhrdersee
Nürnberg City
Dürrenhofstraße 8
90402 Nürnberg
Germany

Phone: +49 911 274665

Special rate:
Single room from 151 EUR per night.
Deadline for special conference rate:
27 August 2017.

Hotel reservation with special conference rate is only valid by using the following link:

german version:
https://hotels.nuernbergmesse.de/de/hotelangebote/APV-2017

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https://hotels.nuernbergmesse.de/en/hotelangebote/APV-2017

Participants should make their own hotel reservation.

Mainz, February 2017

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Registration
As soon as you have found a seminar of your interest, it is very easy to register for it via fax, 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.

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