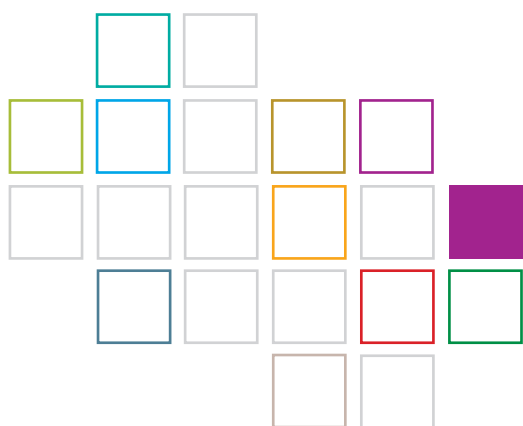


Biopharmaceutics meets Formulation Development – Setting justified Drug Delivery Targets



11 to 12 April 2019
Frankfurt/Main, Germany

Course no. 6768



Research and Development

Target group

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



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.

Goals

- Bring together Biopharmaceutics and formulation development experts
- Inform about current use of modelling and simulation and how it impacts the work of formulation development experts and overall project timing
- Understand key success parameters by case studies
- Discuss "setting clinical relevant specifications" from the view of industry, authority and scientists

Chair



Dr. rer. nat. Uwe Hanenberg
Catalent, Germany

Dr. rer. nat. Uwe Hanenberg (1965) studied Pharmacy at the University of Marburg between 1987 and 1991. In 1997 he received his Ph.D. in Pharmaceutical Chemistry. Since 1999 he holds the title "Specialized Pharmacist for Analytics (Fachapotheker für Analytik)".

Uwe has 18 years of experience in the pharmaceutical industry with Bayer, Altana Pharma, Grünenthal and Catalent in Quality Control, Quality Assurance, Product Development, Manufacturing, Packaging and related Projectmanagement. Uwe is since more than 20 years member of of the APV and of the DPhG.

His areas of expertise are oral formulation development, oral manufacturing technologies, stick pack technologies and pharmaceutical contract services.

Currently Uwe acts as Product Development Director at Catalent Schorndorf and acts further as Director for Science and Technology for Catalent Europe.

Programme

Thursday, 11 April 2019, 10:30 - 16:30 h

Basics of biopharmaceutics and overview of work approaches

- What is the scope of my work
- What is the input and output of my work
- What Info do I need for my daily work (and how can the formulation scientist help)
- Which tools do I use on a daily basis; how do they work
- What do I think is the important result (of my work) for the Formulator
- Where is the value for a formulation scientist
- Pitfalls to avoid

Simone Hansmann, 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

Dieter Becker, Vivo Drug Delivery and Dejan Lamesic, Catalent, Germany

Biopharmaceutic work approaches in pharmaceutical industry

- Examples of Standard work approaches
- Know how: How do you combine and apply the tools in detail
- Interfaces between the functions

Simone Hansmann, Merck, Germany

Successful collaboration between biopharmaceutics and formulation development

- Prerequisites
- Examples of (standardized) processes in industry
- Experience from Industry

Neil John Parrott, F. Hoffmann-La Roche, Switzerland

Modelling & Simulation – Basics

- Why is Modelling and Simulation useful
- Which Models/Simulations are used
- Application in industry
- In which cases (e.g. BCS class) does modelling and simulation makes sense
- Examples (successful and failed)
- What do I calculate, how do I calculate, what is the result and what is done with the result
- How reliable are these results
- Where/What is the link to / value for Pre-/Formulation
- Acceptance of results by industry and authority

Monica Rodriguez, Dynakin, Spain

Networking dinner / social program

Friday, 12 April 2019, 09:00 - 16:00 h

How is Modelling and Simulation applied in Industry

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

Neil John Parrott, F. Hoffmann-La Roche, Switzerland

How to bring together In vivo and in vitro

- Basics
- Guidelines
- Classic methods, modern methods
- Safe Space
- How to translate clinical data into a target dissolution profile (biorelevant)
- How to align formulation strategy with clinical strategy

Martin Müller Zsigmondy, Novartis, Switzerland

Case Studies

Moderators: Sandra Klein,, University of Greifswald, Germany/
Uwe Hahnenberg, Catalent, Germany

How to find the right formulation strategy

Translating Pre/clinical results into formulation strategy (and vice versa: which value does the biopharmaceutical 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

Henrike Potthast, BfArM, Germany

Setting clinical relevant specification – Voice of the industry

- How does Industry understand “Setting clinical relevant specification”
- Where scientifically relevant /where not relevant
- Current application in industry
- Related Cost
- Experience in praxis
- Stimulus for Final Discussion

Johannes Krämer, Phast, Germany

Programme subjected to be changed!



Registration by fax +49 6131 97 69 69 or by email apv@apv-mainz.de



Location

Flemming's Express Hotel Frankfurt
Poststraße 8
60329 Frankfurt/Main
Phone: 0049 69 37003 500
Fax: 0049 69 37003 333
conference.fra.express@flemings-hotels.com

Registration fee

Industry	1490 EUR
Authority/University	745 EUR
Students*	178 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
Fax: 0049 6131 97 69 69
E-mail: apv@apv-mainz.de
Web: www.apv-mainz.de

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

Hotelreservation

Flemming's Express Hotel Frankfurt
Poststraße 8
60329 Frankfurt/Main
Phone: 0049 69 37003 500
Fax: 0049 69 37003 333
conference.fra.express@flemings-hotels.com

Participants should make their own hotel reservation referring to the APV seminar.

Special rate: Single room incl. breakfast from 89 EUR per night.
Deadline for rate: 13 March 2019.

Date

Course no.: 6768
from 11 April 2019 10:30 h
to 12 April 2019 16:00 h

Mainz, December 2018

Biopharmaceutics meets Formulation Development, 11-12 April 2019, Frankfurt/M, Course no. 6768

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.

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.

I also agree that APV may contact me for the purpose of exchanging similar information by email or post.

Your data will not be shared with third parties. You have a right of withdrawal at any time without giving reasons.

All other information can be found in our privacy policy (www.apv-mainz.de/en/imprint/data-protection-statement/).

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