Tackling the Challenges of Poorly Soluble and Poorly Permeable Drugs

16 - 17 June 2016, Berlin, Germany
Course no. 6637

The APV high-toned conferences are dedicated to challenging pharmaceutical topics which will be discussed in a thorough and comprehensive way from different scientific and regulatory perspectives by international best-known specialists in their area of daily work or research. These conferences are unique meeting places for networking and top-class education in one go.
SUMMARY AND OBJECTIVES:
In recent years the number of newly discovered oral drug candidates which are poorly water soluble (BCS II), and for this reason poorly absorbed, has significantly increased. Other compounds have a high water solubility but are poorly absorbed from the Gastro-Intestinal-Tract, because they are poorly permeable (BCS III) and, moreover, quite a number of the oral drug candidates are poorly soluble as well as poorly permeable when administered orally (BCS IV). These properties of the drug molecules confront the pharmaceutical industry with enormous challenges for selecting adequate pharmaceutical formulations and manufacturing technologies which are suitable for all stages of research, development and manufacturing of such drug candidates, especially in the times of the Quality-by-Design (QbD) paradigm.

This APV Conference provides a systematic up-to-date approach of how to tackle the R&D challenges of poorly soluble and poorly bioavailable drugs.

DAY 1:
In the introductory session of the conference reasons for the increasing number of BCS class II-IV candidates will be discussed and the consequences for oral formulations for humans will be highlighted. Moreover, the particular challenges for selecting the right animal models in preclinical development of BCS class II-IV compounds will be presented.

Subsequently, a couple of presentations will elaborate the difficulties of early formulation development to support both pharmacological and toxicological animal testing and formulation approaches for enhancing GI absorption. The session will be completed by an outlook on how in-vitro models can help to predict oral availability of BCS class II-IV formulations.

The next session on formulation approaches will start with an overview of the types of formulations currently used for BCS class II-IV compounds and which of them were launched already. The Market Place will provide further insight into different technologies and will give you the opportunity to get into contact with the exhibitors and their proposed solutions to the challenges of poorly soluble/poorly available compounds.

DAY 2:
On the second day the formulation development session will continue with a critical review of various specific formulation approaches proposed and used for BCS class II-IV compounds as well as there “hypes.” This session will be closed by a case study on a poorly soluble compound in a pediatric formulation.

After the scene will have been set for regulatory aspects, requirements and expectations on BCS class II-IV products and their formulations, an interactive session on development strategies with round table discussions and workshops as well as a summary of how the results of these individual round tables and workshops might form the basis of a general development strategy for poorly soluble and poorly available drug candidates will conclude the conference.

During and between all sessions QbD spotlights will link the challenges resulting from the physico-chemical and biopharmaceutical properties of BCS II-IV compounds to today’s expectations of Quality-be Design development.
TARGET GROUP:
Scientists and managers in pharmaceutical research and development, production, quality assurance, project management, marketing, product management and life cycle management.

ORGANIZATION COMMITTEE:
Johannes Bartholomäus, Pharmakreativ Consulting, Aachen and Institute of Pharmaceutical Technology, TU Braunschweig, Germany

Georg Böck, Group Head Pharmaceutical Development, Boehringer Ingelheim Pharma GmbH & Co. KG, Biberach, Germany

Peter van Hoogevest, Head of Scientific Department, Lipoid GmbH, Ludwigshafen, Germany

Sandra Klein, Department of Pharmacy, Institute of Biopharmaceutics and Pharmaceutical Technology, University of Greifswald, Germany

Susanne Page, Group Head Formulation Research and Development F. Hoffmann-La Roche Ltd, Basel, Switzerland

Simone Wengner, Head of Product Development, Catalent Pharma Solutions, Eberbach, Germany
Thursday, 16 June 2016, 09:00-18:30 h

Opening Remarks
Johannes Bartholomäus
Georg Böck

Setting the Scene

Morning Session
Chairs:
Johannes Bartholomäus
Sandra Klein

Introduction
Why are the numbers of BCS Class II, III and IV APIs increasing and what challenges evolve from them?
Peter Sieger
Boehringer Ingelheim Pharma GmbH & Co KG, Biberach, Germany

Challenges and chances for oral absorption of BCS II, III and IV APIs in the human GI tract
Salah Amasheh
Institute of Veterinary Physiology, FU Berlin, Germany

Absorption of Poorly Soluble/Permeable Molecules. Utility of Physiologically based Models Integrating In Vitro Data and In Vivo Animal Data to Predict Human Absorption. Strategy and Case Studies
Neil John Parrott
F. Hoffmann-La Roche Ltd, Basel, Switzerland

QbD Input

Afternoon Session
Chairs:
Georg Böck
Susanne Page

Preclinical Development

Formulations for Animal Testing: a GPS Approach to PK/PD and Tox Formulations (Dose, Excipients, Species, Route of Administration)
Jochem Alsenz
F. Hoffmann-La Roche Ltd, Basel, Switzerland

Review on absorption enhancement for BCS III/IV (in animal studies)
Anna-Lena Ungell
UCB New Medicines, Braine-l’Alleud, Belgium
What can be predicted by in-vitro models and correlated with in-vivo situations?
Peter Langguth
University of Mainz, Germany

QbD Input
Formulation Development
What types of formulations are currently marketed for BCS II, III and IV APIs?
Tugrul Kararli
PharmaCircle, Encinitas, United States

Market Place Session
Reception and Discussions in the Exhibition Area
City Tour and Networking Dinner
Friday, 17 June 2016, 08:30-17:00 h

Morning Session
Chairs:
Peter van Hoogevest
Simone Wengner

QbD Input
Formulation Development
Nanomedicine – Current Trends in Parenteral and Oral Nano Formulations
Bernd Riebesehl
Novartis Pharma AG, Basel, Switzerland

Use of Phospholipid Excipients in Oral Dosage Forms for Poorly Bioavailable Drug Substances
Peter van Hoogevest
Lipoid GmbH, Ludwigshafen, Germany

Lipid Based Systems Enabling Systemic Delivery of Low Permeable Molecules
Vincent Plassat
Catalent Pharma Solutions, Beinheim, France

Amorphous Formulations – Balancing Supersaturation and Physical Stability
Susanne Page
F. Hoffmann-La Roche Ltd, Basel, Switzerland

Industrial Applications for Enabling Formulations
Albertina Arien
Janssen R&D, Beerse, Belgium

Case study on poorly soluble compounds for pediatric formulations (incl. PIP)
Albertina Arien
Janssen R&D, Beerse, Belgium

Afternoon Session
Chairs:
Johannes Bartholomäus
Georg Böck

QbD Input
Regulatory view
The Regulatory View on Biopharmaceutic Improvements
Henrike Potthast
BfArM, Bonn, Germany

The Toxicological View
Roland Frötschl
BfArM, Bonn, Germany

Requirements and Challenges in Approval of Novel Excipients
Christian Becker
BASF SE; Ludwigshafen, Germany

Development strategies
Introductory statement/impulse

Roundtable Discussions/Workshops
Part I
- Correlation Animal-Human (best animal PK model)
- Current and upcoming technologies to enhance BA

Part II
- In-Vitro-In-Vivo Correlation
- Quality by Design

Presentation from Roundtables and Combination into a development process

QbD Output and Concluding Remarks
Johannes Bartholomäus
Georg Böck
Registration by fax +49 6131 9769-69

Tackling the Challenges of Poorly Soluble and Poorly Permeable Drugs CN 6637

Mainz, March 2016

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

Deadline for special conference rate: 15 May 2016.

Special rate:
Single room incl. breakfast buffet from 109 EUR per night.

Hotel reservation
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