Successful Early Stage Development of Pharmaceuticals

5th to 6th March 2013

Darmstadt, Germany

Course No. 6475

Research and Development

drug delivery

Target Audience

This course is designed for all scientists, project and technical managers working in the field of early drug development in particular those involved in pharmaceutical profiling, candidate selection, preformulation and the development of formulations for Phase I. It takes into account the challenges and issues faced by scientists and managers in both Big Pharma and smaller companies. The course would also be of interest to those working in closely related fields such as Drug Discovery, Toxicology and Regulatory and those who wish to broaden their knowledge of this highly inter-disciplinary field.

APV
MAKING SCIENCE WORK

Arbeitsgemeinschaft für Pharmazeutische Verfahrenstechnik e.V.
Gemeinnütziger wissenschaftlicher Verein
International Association for Pharmaceutical Technology

Programme

Tuesday, 5th March 2013 10:00 to 17:30 h

Introduction by Chairs
Mathew Leigh
biorelevant.com
Croydon, United Kingdom

Louise Rosenmayr-Templeton
Tower Pharma Consulting
Vienna, Austria

Part 1: How pharmaceutics can support the identification of successful candidates from discovery

Selecting a good lead: The challenges, opportunities and realities faced during selection:
- The Big Pharma Experience

Marcus Brewster
Janssen Pharmaceutica N.V. A Division of Janssen Pharmaceutica
Beerse, Belgium

Selecting a good lead:
- Small/virtual company experience

Margaret Courtney
Vernalis
Winnersh, United Kingdom

Drug substance manufacturing for clinical development:
- Getting the drug substance on the right track

Robert Hett
RPD Rapid Pharma Development GmbH
Unterägeri, Switzerland

Part 2: Getting to know the biopharmaceutical aspects of your drug substance: The Good, the Bad, the Ugly – Introduction to the afternoon session – the Chairs

Biopharmaceutical classification of your compounds and the implications for further development
- Solubility and dissolution aspects

Stefania Beato
Novartis Pharma AG
Basle, Switzerland

Permeability aspects
- Techniques, basic methodology and what to look out for

Eleonore Haltner-Ukomadu
Across Barriers GmbH
Saarbrücken, Germany

Chemical and physical stability aspects (Polymorph)
- Techniques, basic methodology and what to look out for

Chris Frampton
Pharmorphix® Solid State Technology Services
Cambridge, United Kingdom

Preclinical in vitro testing: bridging the testing of formulations in preclinical Development to the clinic using biorelevant media
Prof. Jennifer Dressman
University of Frankfurt, Frankfurt am Main, Germany

Part 3. Role of delivery technology in getting compounds off the bench and into animals

Selecting the right chemical form: Salt/Co-crystal: just a chemical development issue?
- Techniques, basic methodology and how chemical links with formulation

Christoph Saal
Merck KGaA, Darmstadt, Germany

Panel Discussion with Speakers from Day 1

Wednesday, 6th March 2013 8:30 to 15:00 h

Delivery options for developing Intravenous formulations
- Their pros and cons for preclinical testing

Sebastian Ullrich
Gruenenthal GmbH, Aachen, Germany

Solubilisation of poorly soluble compounds delivery
- Techniques, basic methodology and what to look out for

Anette Müllertz
University of Copenhagen
Copenhagen, Denmark

Use of the amorphous state to promote delivery
- The pros and cons and key issues

Mark Saunders
Kuecept Ltd.
Hertfordshire, United Kingdom

Improving solubility using crystalline nanoparticles
- The technologies, benefits and drawbacks, key points when using this approach

Jouni Hirvonen
Univerisity of Helsinki
Helsinki, Finland

Part 4: From in vitro to in vivo

Tips and tricks to look out for when developing a formulation for the clinic
Jon Sutch
Patheon UK Ltd.
Milton Abingdon, United Kingdom

Key points for putting together the CMC section of regulatory dossier for Phase 1
Johannes Bartholomäus
Pharmakreativ Pharmazeutische Entwicklungsberatung
Aachen, Germany

Successful Early Stage Development of Pharmaceuticals

Course Instructors

Mathew Leigh trained as a research pharmacist and in 1997 he completed his PhD on injectable liposome formulations at the London School of Pharmacy. For the next four years he worked as formulator in the field of semi-solids. In 2002 he set up Phares Drug Delivery AG and was responsible for the commercialization of formulation services and technologies. He is the inventor on 10 patents for delivery systems and pharmaceutical technology. He now works at biorelevant.com on the development of next generation biorelevant media products, which are designed specifically for dissolution and solubility testing.

Louise Rosenmayr-Templeton is a pharmacist with over 18 years experience in pharmaceutical product development and project management. In 2002 she set up Tower Pharma Consulting, a boutique consultancy based in Vienna, which provides a variety of scientific, technical and project management services to pharmaceutical/biotech companies and government agencies. Its primary focus is on formulation science, product development and drug delivery technologies.

Prior to setting up her business Louise worked in various capacities for Abbott Labs (UK and USA), the Élan Corporation (Ireland) and Boehringer Ingelheim (Austria). She graduated from Strathclyde University, UK in 1986 with first class honours and obtained her PhD in the field of novel drug delivery from Nottingham University, UK.

Objectives

This course will guide participants through the challenges and pitfalls of early drug development from candidate selection, characterisation and initial formulation studies to preparing the CMC section of regulatory dossiers for Phase I. It will examine the issues from both a Big Pharma and small company perspective. Topics covered include the following:

- The realities faced when selecting a lead candidate and how to improve the chances of success
- Characterising drug compounds in terms of their solid state, solubility, dissolution and permeability properties and the impact these have on the development pathway
- Strategies for overcoming challenges such as poor water solubility when formulating for pre-clinical, toxicology and the first human studies
- Preparing the CMC section for Phase I

Registration by fax +49 6131 9769-69

MAKING SCIENCE WORK

Location

WELCOME HOTEL DARMSTADT
Karolinenplatz 4
64289 Darmstadt
Phone: +49 6151 3914-0
Fax: +49 6151 3914-444

Date

Course No. 6475
from 5th March 2013 10:00
to 6th March 2013 15:00

Registration fee

APV/ipec member 1360 EUR
Non-member 1490 EUR
(free of VAT according to § 4,22 UStG)
Coffee breaks, lunches, dinner and proceedings included.

Registration

APV-Geschäftsstelle
Kurfürstenstraße 59
55118 Mainz/Germany
Phone: +49 6131 9769-0
Fax: +49 6131 9769-69
e-mail: apv@apv-mainz.de

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

Members of authorities pay half of the APV member's and non-member's registration fee respectively.

Hotel reservation

WELCOME HOTEL DARMSTADT
Karolinenplatz 4
64289 Darmstadt
Phone: +49 6151 3914-0
Fax: +49 6151 3914-444

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

Deadline for special conference rate: 29th January, 2013.

Special rate:
Single room incl. breakfast buffet from EUR 109,00 per night.

Mainz, January 2013

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.

Visa
Mastercard

Card holder

Card no.

Valid until

CVC Code

Titel, First Name, Name

Company Name

Company Address

Location

Zip-Code

Phone

Fax

e-mail Address | Order no

Position in Company | Department

☐ APV Member ☐ Non-member

Date | Signature

Arbeitsgemeinschaft für Pharmazeutische Verfahrenstechnik e.V.
Gemeinnütziger wissenschaftlicher Verein
International Association for Pharmaceutical Technology

www.apv-mainz.de

APV-Geschäftsstelle
Kurfürstenstraße 59
55118 Mainz/Germany
Phone: +49 6131 9769-0
Fax: +49 6131 9769-69
e-mail: apv@apv-mainz.de