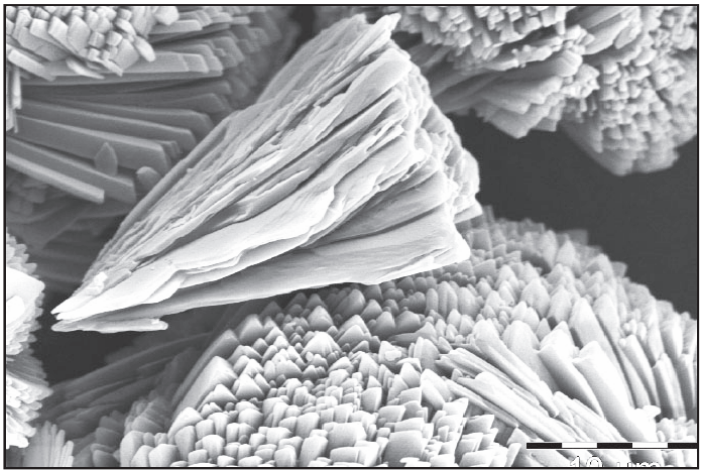
APV basics: Preformulation



18 to 19 April 2018

Brussels, Belgium

Course no. 6722

Research & Development

Target Audience:

This short course is intended to provide a useful background on contemporary solid state and solution characterization of API's as well as to provide a framework for translating these data into useful formulations. The course is designed to be useful to both scientists new to the field as well as the experienced pharmaceutical researcher with an eye towards the state of the art and future direction.

MAKING SCIENCE WORK

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

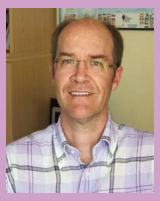
Preformulation is an essential step in the pharmaceutical development of an API. It is the process by which candidate drugs are characterized with respect to the appropriateness to be formulated and processed to a useful dosage form. During this phase of the development, information about the physicochemical properties (e.g., solubility, ionization behavior, solid state properties,…), biopharmaceutical properties (e.g., permeability through bio-membranes) and stability profile (physical, chemical, compatibility with excipients, etc.) of the drug candidate is collected. This information guides the formulation scientist as it will dictate many of the possible formulation and processing approaches.

This basic course is divided into three parts. In the first part, fundamental physicochemical and biopharmaceutical concepts are discussed including solubility and dissolution rate, ionization behavior, partitioning, solid state properties (polymorphism, amorphous and crystalline state), salts and salt selection, physical and chemical stability, powder properties and drug absorption profiling. Analytical techniques to assess solid state properties such as X-ray diffraction, differential scanning calorimetry, dynamic vapour sorption and thermogravimetric analysis are briefly discussed and illustrated with examples.

In a second module, automation and down-scaling of preformulation assessments will be discussed. This is presented in the contest of dosage form type selection where both conventional and enabled formulation concepts are in scope. The use of biopharmaceutical tools is especially important in distinguishing among strategies with the goal being the simplest approach capable of delivering the API of interest by the designated route. These decision trees include filters to help the pharmaceutical scientists based on data-driven guidelines. In this section, both in silico tools as well as 96-well plate technology will be included.

The last module of the course is dedicated to at-scale translation of information garnered from both preformulation and formulation decision tree assessments. That is, how data associated with the design space associated with API properties, pharmaceutical inputs and biopharmaceutical characterization is use to develop robust and bioavailable dosage forms. In addition, the importance and selection of excipients in this context is also assessed. These principles are highlighted with case studies and real-world pharmaceutical examples wherein both simple and complex dosage forms are reviewed.

Chairmen and speaker:



Guy Van den Mooter
University of Leuven
Leuven, Belgium

Geert Verreck
Janssen R&D
Beerse, Belgium

Programme

Wednesday, 18 April 2018, 11:00 to 18:00

Basic preformulation

- Solubility
- Ionization
- Log p
- Solid state characterization
- Powder properties
- DSC, XRD, FTIR, Raman
- Permeability

Thursday, 19 April 2018, 09:00 to 15:00

Applied preformulation and at-scale translation

- Automated screening:
    - Super saturation
    - Solid dispersions
    - Powder rheology
- Scale up, real time and real scale examples of applying preformulation data in conventional and enabling technology development

Panel discussion

Programme is subject to change

Registration by fax +49 6131 9769-69

MAKING SCIENCE WORK

Location

Park Inn by Radisson Brussels Airport
Grentstraat 3
1831 Brussels (Diegem)
Belgium
Phone: +32 2 302 75 00
Fax: +32 2 302 75 99

I herewith repealable authorise APV to use my E-mail address to send me APV relevant material including current programme information. My acceptance can be cancelled at any time in writing.

Date

Course no. 6722
from 18 April 2018 11:00
to 19 April2018 15:00

Registration fee

Industry	1290 EUR
Acadmia/Authorities	645 EUR
Student*	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.

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.

Hotel reservation

Park Inn by Radisson Brussels Airport
Grentstraat 3
1831 Brussels (Diegem), Belgium
Phone: +32 2 302 75 00
Fax: +32 2 302 75 99

Room reservation with following link: http://bit.ly/2gPS6A3

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

Deadline for special conference rate: 21 March 2018

Special rate:
Single room incl. breakfast buffet from 155 EUR per night.

Mainz, January 2018

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.

☐ pay via invoice
☐ pay via credit card (fill in below)
- ☐ AMEX
- ☐ Visa
- ☐ Mastercard

Card Holder

Card No.

Valid until

CVC Code

Title, First Name, Last Name *

Company Name*

Street/No. or P.O. box*

Location*

Zip-Code*

Phone*

Department*

E-mail Address Participant*

Order No. or Billing Address

Date Signature

*Mandatory

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