APV basics: Preformulation

APV basics

virtual meeting

04 - 05 February 2025
Online Seminar

Kurs-Nr. 7036

ONLINE SEMINAR

Research and Development

Target group

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.

APV MAKING SCIENCE WORK

Objectives

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 datadriven 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.

Chairman and speaker

Guy Van den Mooter
University of Leuven, Belgium

Guy Van den Mooter (°1964) obtained his Ph.D. in 1994 (university of Leuven - KU Leuven, pharmaceutical technology). Since 2009 he is full professor at the faculty of Pharmaceutical Sciences in the Drug Delivery and Disposition research group.

The focus of his research group is the formulation, process development and physical chemistry of drug-polymer solid dispersions, polymer coatings, and colon specific drug delivery. The main objective is to explore the relationship between the formulation, the process applied and the performance in terms of stability and drug release.

He has published ca. 330 full-length scientific papers in international peer-reviewed journals and several book chapters with more than 16.000 citations. His H-index = 66 (Web of Science). Since 2019 he is section editor of the European Journal of Pharmaceutical Sciences and editor of Pharmaceutics. He is vice dean of the faculty of Pharmaceutical Sciences of KU Leuven, responsible for teaching and education. He teaches courses of pharmaceutical technology, drug delivery, preformulation and physical chemistry in undergraduate and graduate programs. He is coordinator of the master program in industrial pharmacy.

Geert Verreck
Janssen R&D a devision of Johnson&Johnson

Dr. Geert Verreck is a Scientific Director and Fellow in Drug Product Development at Janssen R&D in Beerse, Belgium.

His expertise is in the area of oral solid development, from preformulation to early and late development as well as transfer to commercial manufacturing. Dr. Verreck specifically has expertise in enabling technology platforms such as hot melt extrusion, spray drying, bead coating, supercritical fluid technology and nanotechnology (particle size reduction via milling and electrostatic spinning). He started working for J&J in 1995 after graduating as a chemical engineer. In 2005 he received his Ph.D. in Pharmaceutical Sciences at the Catholic University of Leuven, Belgium. He has published 38 peer reviewed journal articles as author or co-author and holds 8 patents in the area of solid dispersions.

Dr. Verreck also presented approximately 90 meeting abstracts and delivered approximately 50 oral presentations. He is also the recipient or co-recipient of various recognitions including the ISASF (International Society for the Advancement of Supercritical Fluids) PhD thesis award (2005), the J&J Philip B. Hofmann Award (2006), the J&J Business Excellence Award (2008), the J&J Standards of Leadership Award (2009).

Programme

Tuesday, 04 February 2025 13:00 - 17:30 h CET

Basic preformulation

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

Wednesday, 05 February 2025 13:00 - 17:30 h CET

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

APV basics

The APV basics series covers pharmaceutical-technological topics from various fields, such as pharmaceutical engineering, the production of liquid or solid dosage forms, biopharmaceutics, and packaging.

The APV basics series is equally suited for practitioners who want to learn more about the theoretical background, as well as for those with a theoretical foundation who are looking for ways to apply their knowledge. It is also suitable for newcomers to the field of dosage forms, their development, and production. The APV basics series is aimed at professionals in the areas of development, analytics, production, and regulatory affairs.

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Registration

To register for the APV seminar, you can easily sign up online. Your registration will be processed promptly, and we are happy to assist you if you have any questions.

Once you successfully complete the online registration, you will receive a confirmation and an invoice via email.

Directly to the seminar/registration:

apv-mainz.de/en/events/seminars/details/seminar/7036

Registration fee

Industry	800,00 EUR
Authority/University	400,00 EUR
Students*	100,00 EUR

(free of VAT according to § 4,22 UStG)
electronic proceedings included.

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

Live Online Seminar

Course no.: 7036

Date

from 04 February 2025 13:00 h
to 05 February 2025 17:30 h

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Gemeinnütziger wissenschaftlicher Verein
International Association for Pharmaceutical Technology

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