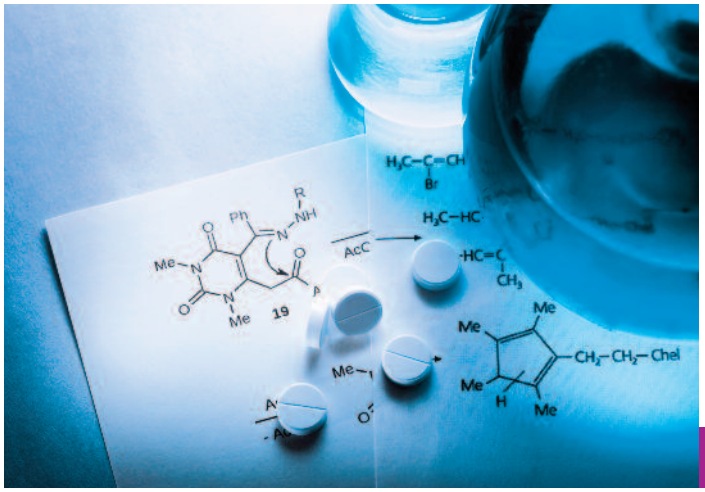
# APV Master Class

# AMORPHOUS SOLID DISPERSIONS

- amorphous systems and ASDs
- formulation, characterization, stability and bioavailability



07 to 09 November 2017
Ludwigshafen, Germany

in cooperation with

abbvie

Course No. 6703

## Research and Development

hands-on formulation and analytics workshops at AbbVie

## Target audience

Scientists and managers in pharmaceutical research and development, production, quality assurance, project management, product management and life cycle management.

APV
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# Research and Development

**A seminar organized by the APV focus group „Solid Dosage Forms"**

## Objectives

In recent years the number of new chemical entities which are poorly water soluble (BCS II and IV compounds), and for this reason poorly absorbed, has significantly increased. This confronts 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. One option to tackle this challenge is the development of an amorphous systems. The number of publications appearing in literature has shown that this field gained a lot of interest from researchers all over the world. Furthermore, in recent years a number of new launched products are using this formulation principle. This APV master class provides a systematic up-to-date approach of how to develop such systems from early stage of development up to launch.

## Overview of the master class

In the first session of the master class we are setting the scene by providing an introduction to amorphous systems and explaining the theoretical aspects for their stabilization. After comparing different amorphous systems, e.g. polymeric based, co-amorphous systems and mesoporous silica, we will gain a deeper understanding in predicting the miscibility of drugs in polymers from a thermodynamic standpoint. The session will be completed by presenting a structured development approach for amorphous systems. The next session on formulation development and technology selection for amorphous solid dispersions will start with an overview of the different manufacturing technologies available for polymeric based amorphous systems. Subsequently, more detailed knowledge on formulation composition and process parameter selection will be shared for the two key technologies: hot melt extrusion and spray drying.

On the second day we will continue with a critical review of the stability of amorphous systems by looking into phase separation in liquid as well as in solid state and the effect water can have on the system. Furthermore, a number of advanced analytical tools for the characterization of these systems with particular focus on the physical nature of the drug substance in the system will be presented.

Later during the day, the knowledge gained so far can be consolidated in a roundtable discussions as well as in a workshop focusing on different analytical and formulation aspects.

Day three will continue with analytical methods, but this time with particular focus on the release mechanism of polymeric based amorphous solid dispersions. Furthermore, topics such as in-vivo-in-vitro correlation and biorelevant dissolution tests will be covered. As a continuation of the session on formulation development and technology selection from day 1 the focus in the second session of the day is on manufacturing technologies for co-amorphous systems and mesoporous silica as well as on downstream processing and continuous manufacturing of amorphous solid dispersions. Last but not least the conference will conclude with regulatory aspects and a quarter of a century experience of amorphous solid dispersions.

## Program

**Tuesday, 07 November 2017** **09:00 to 17:50**

Welcome and aims of the workshop
Susanne Page and Katharina Paulsen

### Part 1. "Setting the scene"

25 years of extrusion
Jörg Rosenberg, AbbVie, Germany

Introduction to amorphous systems
- Theoretical aspects for stabilization
- Glass-forming ability and physical stability of drugs

Marc Descamps, University of Lille, France

Polymeric based ASD vs. co-amorphous systems vs. mesoporous silica
Guy Van den Mooter, Universtiy of Leuven, Belgium

Optimizing early phase development of amorphous solid dispersion formulation thorough application of modeling tools
Samuel Kyerematen, AbbVie, Germany

Structured development approach
Nicole Wyttenbach, F. Hoffmann-La Roche, Switzerland

### Part 2. Manufacturability/ formulation development and technology selection for ASDs

Overview on manufacturing technologies for polymeric based ASD
Reto Maurer, F. Hoffmann-La Roche, Switzerland

HME: Formulation composition and defining the process parameters
Thomas Quinten, Janssen R&D, Belgium

HME: Scale-Up incl. change of extruder type
Damir Zecevic, AbbVie, Germany

Spray drying: Formulation composition and defing the process parameters with a speciall focus on the effect of solvents
Guy van den Mooter, University of Leuven, Belgium

Scaling up of the spray drying process from micro to commercial scale manufacturing
Marianne van Steenwinckel, Janssen R&D, Belgium

# APV ASD Master Class

## Wednesday, 08 November 2017 08:30 to 17:00

### Part 3. Stability incl. advanced analytical methods

Detecting and quantifying crystalls
- An analytical challenge
- Methods suitable for routine testing
- Sample preparation
- Do's and don'ts
- Limitations, Dissolution
- Impact of crystallinity on drug release

Holger van Lishaut, AbbVie, Germany

Characterization of ASD by advanced analytical methods
Duncan Craig, University College London, United Kingdom

Emerging technologies: Trans Raman, µCT, SONICC, "Terahertz" Raman
Sankaran Anantharaman, AbbVie, Germany

Formation of colloidal/particulate sates in contact with water
- water disersibility & phase separation phenomena
- Flow Field-Flow fractionation & MALLS

Martin Brandl, University of Southern Denmark, Denmark

### Part 4. Roundtable discussion
Setting of Specifications for residual crystallinity

### Part 5. Lab section
Workshop in groups on analytics and formulation

**Networking dinner and roundtable discussion**
Biorelevant dissolution testing vs 100% release in a QC test

## Thursday, 09 November 2017 08:30 to 16:00

### Part 6. Bioavailability/dissolution & preclinical & clinical studies

Release mechanism of polymeric based ASD
Martin Brandl, University of Southern Denmark, Denmark

Biorelevant dissolution methods
Karin Rosenblatt, AbbVie, Germany

### Part 7. Manufacturability/ special technologies for ASDs

Co-amorphous systems: A new answer to an old problem?
Elisabeth Lenz, Gen-Plus GmbH & Co. KG, Germany

Technologies for mesoporous silica
Guy Van den Mooter, University of Leuven, Belgium

### Part 8. Manufacturability for final DP

Downstream processing of ASDs to solid dosage forms
Susanne Page, F. Hoffmann-La Roche, Switzerland

HME: Use of PAT for process monitoring
Karsten Rebner, Reutlingen University, Germany

### Part 9. Last but not least ...

Regulatory considerations on ASD during registration
Jobst Limberg, BfArM, Germany *(requested)*

Longterm stability of ASDs
- A quarter of a century experience
- Kinetically vs thermodynamically stabilized systems and how to assess these
- Propensity to recrystallize
- Case study with 25 years old sample

Gerd Wöhrle, AbbVie, Germany

### Final Discussion

*Program is subject to change*

## Course Leaders

Susanne Page
F. Hoffmann-La Roche, Switzerland

Katharina Paulsen
AbbVie, Germany

# Registration by fax +49 6131 9769-69

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## Location

AbbVie Deutschland
GmbH & Co. KG
Knollstr.
67061 Ludwigshafen
Germany

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

## Date

from 07 November 2017 09:00
to 09 November 2017 16:00

## Registration fee

| | |
|---|---|
| Industry | 1890 EUR |
| Authorities/Academia | 945 EUR |
| Students* | 230 EUR |

(free of VAT according to § 4,22 UStG)

Coffee breaks, lunchs, dinners 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

Best Western Plus Delta Park Hotel
Keplerstraße 24
68165 Mannheim
Germany

Phone: +49 621 44 51 805 0

Special rate:
Single room from 118 EUR per night. Deadline for special conference rate: 09 October 2017.

Participants should make their own hotel reservation.

Mainz, April 2017

## APV ASD Master Class

## Course no. 6703

**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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