

3<sup>rd</sup> APV winter conference 2018

# Individualized Medicines for oral use – *visions and challenges*



25 to 26 January 2018  
Innsbruck, Austria

Course No. 6718



Hot Topics

## Target audience

The target audience are technicians and scientists who are involved in the pharmaceutical development and manufacturing of solid medicinal products and related medical devices. The addressed topics are important for scientific research, pharmaceutical R&D, manufacturing, packaging and business development.



## Objectives

Recent advancements in pharmacokinetic profiling, genetics, metabolics and improved knowledge in distinguished medicinal disciplines like paediatrics and oncology foster a patient-centered, fully individual and precise drug treatment in future. There are new fascinating options of drug treatment and medical care. The remaining question is whether we will have the required drug dosage forms for this ongoing shift of paradigm in modern medicine. Most oral dosage forms are monolithic solid drug carriers like tablets and capsules which hardly offer the required flexible dosing. It is unlikely that pharmaceutical industry will be able to provide monolithic dosage forms at multiple dose strengths for individual drug treatment. Fixed-dose combinations with combinations of several drug substances and numerous dose strengths in order to enable precise and patient-centered drug treatment will not be feasible due to technical and financial constraints.

This hot-topic seminar, organized by APV's new task force "Individual Medicines", is embedded in APV's winter conference series. It will tackle obstacles such as biopharmaceutical and regulatory evaluations of flexible dosing systems, but offer some recent ideas and products to approach the future in oral medicines.

The seminar will take place in the Austria Trend Hotel Congress in Innsbruck, Tyrol, Austria. Innsbruck is the capital city of Tyrol in western Austria and sometimes even called the capitol of the Alps. It is centered in a beautiful environment of alpine mountains and famous skiing resorts.

## How to get to Innsbruck?

Right in the heart of Europe, Innsbruck is very conveniently located. A well-developed road and rail network connects the Tyrolean capital to the world: A 12 autoroute (toll sticker required) leads from East (Munich, Salzburg, Brenner) to West (Arlberg arena).

Innsbruck may be reached by plane through Innsbruck airport or Munich airport. Convenient airport shuttles are available from both airports. In the winter season, there are many direct flights to Innsbruck airport, e.g. from Amsterdam, Berlin, Düsseldorf, Eindhoven, Frankfurt, London Gatwick, Moscow Domodedovo, Rotterdam, or Vienna.

Book early as there are numerous skiing tourist who fly to Innsbruck and move on to the very near, world-famous skiing resorts.

Thursday, 25 January 2018

09:00 to 18:00 h

## Programme

### Welcome & Introduction

Dr. Elke Sternberger-Rützel, Harro Höfliger  
Verpackungsmaschinen, Germany  
Prof. Dr. Jörg Breitzkreutz, Heinrich Heine University Düsseldorf,  
Germany

### Part 1: Visions and opportunities

#### Visions and solutions for oral individualized medicines

Prof. Dr. Jörg Breitzkreutz, Heinrich Heine University Düsseldorf,  
Germany

#### Drivers, diagnostics and opportunities for individualized drug therapies

Dr. Stephan Jäger, Roche Diagnostics GmbH, Germany

### Part 2: Regulations and present practice

#### Extemporaneous compounding of oral capsules in community pharmacies

Dr. Kirsten Seidel, Christian Albrechts University Kiel, Germany

### Part 3: Enabling technologies for individualized oral dosing

#### Instant preparations for orodispersible films

Dr. Jan Hendrik Finke, Technical University Braunschweig, Germany  
Denise Steiner, NextPharma, Germany

#### 2D/3D printing technologies in Pharma

Dr. Markus Dachtler, Gen-Plus GmbH, Germany

#### Inkjet Printing for On-Demand Manufacturing of Film-in-Capsule Dosage Forms

Prof. Dr. Andreas Zimmer, Karl-Franzens-University Graz, Austria

#### Case studies of innovative small batch production processes

Dr. Elke Sternberger-Rützel, Harro Höfliger  
Verpackungsmaschinen GmbH, Germany

#### Oral drug delivery devices – an overview of the demand and realized ideas

Joachim Lehmann, Röchling Oertl Kunststofftechnik GmbH,  
Germany

### Panel Discussion

#### Networking Dinner

*We are delighted to invite you to join us for dinner. Come and meet colleagues and specialists in your field from around the world in an enjoyable and relaxed atmosphere.*

# 3<sup>rd</sup> APV winter conference 2018: Individualized Medicines for oral use

Friday, 26 January 2018

08:30 to 12:15 h

## Part 4: Clinical and biopharmaceutical considerations

Acceptability of orodispersible films in young children in comparison with mini-tablets

Dr. Viviane Klingmann, University Childrens Hospital Düsseldorf, Germany

Gastrointestinal variables affecting drug and formulation behavior: Multiparticulates versus monolithic dosage forms

Prof. Dr. Sandra Klein, Ernst Moritz Arndt University Greifswald, Germany

## Part 5: Recent case studies for individualized dosing by mini-tablets

LENA – individualized enalapril dosing for children from neonates to adolescents using orodispersible minitables

Prof. Dr. Jörg Breitzkreutz, Ethicare GmbH, Germany

Zalviso® - An innovative system for patient-controlled administration of sufentanil sublingual minitables for management of post-operative pain

Dr. Ingo Friedrich, Grünenthal GmbH, Germany

Final discussion

*Programme is subject to change*

## Announcement:

Friday, 26 January 2018

12:30 - 14:00 h

2nd Meeting of APV Task-Force "Individualized Medicines"  
Planning next steps

*All seminar participants are welcome to join the meeting (participation is free of charge).*

## Moderators



Prof. Dr. Jörg Breitzkreutz

Heinrich Heine University  
Institute of Pharmaceutics and  
Biopharmaceutics  
40225 Düsseldorf, Germany

Jörg Breitzkreutz is a pharmacist by training and finished his PhD in 1996 at the Institute for Pharmaceutical Technology and Biopharmaceutics in Münster under supervision of Prof. Gröning. From 1996 to 1997 he joined Thiemann Arzneimittel GmbH in Waltrop, Germany, and from 1997 to 2004 the University of Münster to work on his habilitation on paediatric drug formulations. In 2004 he became professor for pharmaceutical technology at the Heinrich-Heine-University in Düsseldorf, Germany. Since 2010 he is the president of the International Association of Pharmaceutical Technology (APV). His research focuses on paediatric drug formulations, orphan drugs and process analytical technologies.



Dr. Elke Sternberger-Rützel

Division Leader Pharma Service  
Harro Höfliger Verpackungsmaschinen  
GmbH  
71573 Allmersbach im Tal, Germany

Elke Sternberger-Rützel studied pharmacy at the FU Berlin and Eberhard-Karls-Universität Tübingen until 1998. Thereafter she started 1998 to earned her doctorate in Pharmaceutical Technology at the Karl Ruprecht University Heidelberg. She is also a pharmacist specializing in pharmaceutical technology. After completing her doctorate, she worked in the pharmaceutical development department of Grünenthal GmbH (2002-2006) as laboratory manager for packaging development, stability studies and packaging of clinical test samples. Later in the R & D department of Catalent Pharma Solution (Schorndorf, Germany) (2006-2009) as a packaging developer with a focus on microdosing, as interim head of department and project manager. Subsequently, she was hired as Pharma Trendscout and Innovation Manager at Robert Bosch GmbH Packaging Pharma (2009-2012). Since 2013 she has been working for Harro Höfliger GmbH as Head of Test Facilities within Pharma Services.

## Location

Austria Trend Hotel Congress  
Innsbruck  
Rennweg 12a  
6020 Innsbruck  
Austria  
Phone: +43 512 2115-0  
Fax: +43 512 2115-500  
email: congress@austria-trend.at

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

3rd APV winter conference:  
**Individualized Medicines for oral use – visions and challenges**  
Course no. 6718  
from 25 January 2018 09:00 h  
to 26 January 2018 12:15 h

## 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.

## Registration fee

**Early Bird fee: 15 December 2017**  
Industry 1290 EUR  
Authorities/Academia 645 EUR  
Students\* 155 EUR

### Regular fee

Industry 1490 EUR  
Authorities/Academia 745 EUR  
Students\* 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.

## Hotel reservation

Austria Trend Hotel Congress  
Innsbruck  
Rennweg 12a  
6020 Innsbruck  
Austria  
Phone: +43 512 2115-0  
Fax: +43 512 2115-500  
email: congress@austria-trend.at

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

Deadline for special conference rate: 11 December 2017.

Special rate:  
Single room incl. breakfast buffet from 107 EUR per night.

Mainz, November 2017

### 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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