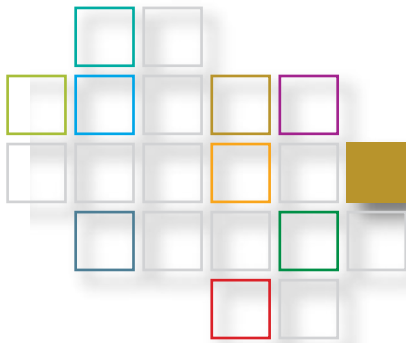


# Medicines for older adults: Getting prepared for the scientific and regulatory evolution



07 to 08 November 2017  
Graz, Austria

Course No. 6704



Hot Topics

In cooperation with





## Objectives & Contents

Increasing life expectancy and longevity is leading to significant change in future patient populations challenging the traditional drug development and healthcare provision. The majority of patients in primary care will be characterized by very high age, multimorbidity and polypharmacy living and managing their therapy independently or with the support of care giving relatives.

This trend has recently been recognized by healthcare professionals as well as the European Medicines Agency (EMA) putting forward the "EMA geriatric medicines strategy" in 2011. The latter one brought forward a Geriatric Medicines Strategy Roadmap 2015 and will shortly publish a **Reflection Paper on quality aspects for medicines for older people**. In addition the FDA and EMA have released guidance concerning considerations for product design to minimize medication errors that also addressed the diversity of the different end-user groups (geriatric, pediatric populations etc.)

Traditionally drug product development is very much focused on the physicochemical properties and biopharmaceutical performance of the drug product to achieve the therapeutic outcomes in the clinical trials. When facing the real world patient populations with age related impairments, multi-morbidity and complex medication schedules the therapeutic outcomes, so called effectiveness, often fall short on expectations. There is increasing evidence that poor adherence, medication errors, difficulties in managing, handling and administering the existing drug products are major root causes.

Patient centric pharmaceutical drug product development and design to address the needs of patient will become the next quantum leap to enhance effectiveness, health outcomes and quality of life for older patients. Understanding the characteristics patient population and including these in the Targeted Quality Product Profile (TQPP) will effectively guide drug product development towards patient centric drug product. Patient centric drug product development and design has the objective to facilitate the independent medication management by the patient, improve adherence, drug safety, effectiveness and as such reduce the overall healthcare costs.

This interactive workshop aims to provide understanding of the older and multi-morbid patient population, up-date on the emerging regulations on medicines development for older people, provide a process to develop age and patient centric drug products as well as discuss potential drug product solutions and opportunities for the pharmaceutical industry.

## Preliminary Programme

Tuesday, 07 November 2017

09:00 to 18:00

### Welcome and Short Introduction into the topic

Sven Stegemann

Graz University of Technology/Capsugel, Graz, Austria

Carsten Timpe

F. Hoffmann-La Roche Ltd., Basle, Switzerland

### Disruptive demographics – Longevity as a personal and societal opportunity

Sven Stegemann

### Part I: The older patient population: characteristics & needs

#### The older patient in clinical practice

Regina Roller-Wirnsberger

Medical University Graz, Graz, Austria

#### Safe drug administration: Are the products suitable for older patients?

Susanne Schlacher, Medical University Graz, Graz, Austria

#### Disease and age related swallowing dysfunctions in older adults and its impact on oral drug therapy

Julia Schiele, AbbVie, Ludwigshafen, Germany

### Part II: The older patient population and drug use

#### Studying patient behavior in drug therapy management – Finding from a patient study

Ariane Schenk, Charité Berlin, Berlin, Germany

#### Pharmaceutical packaging: Investigation into older patient centered design

Felix Ecker

University of Fulda, Fulda, Germany

### Part III: Industrial and academic considerations for drug development for older patients

#### Challenges and opportunities to include patient centered design in industrial drug development

Carsten Timpe

#### An industrial experience in developing pediatric drug formulation

Terry Ernest, GSK, Ware, United Kingdom

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Dosage forms for older patients, why there are none?  
Daniel Bar-Shalom, University of Copenhagen, Copenhagen,  
Denmark

Wednesday, 08 November 2017 08:45 to 15:30

## Part IV: Drug device combination products for older patients

Learning from human factors and ergonomics: How to design medical products for patients  
Markus Feufel, University of Technology Berlin, Berlin, Germany

Case study: Development of an injectable for Rheumatoid Arthritis patients  
Helene Knopper  
F-Hoffmann-La Roche Ltd., Basle, Switzerland

The use of ICT in drug therapy to older adults – opportunities for product development  
Günter Schreier, Austrian Institute of Technology, Graz, Austria

## Part V: Regulatory Framework and perspectives

Quality aspects of medicines for older adults – the EMA Reflection paper  
Diana van Riet-Nales, Medicines Evaluation Board Netherlands, Utrecht, The Netherlands and European Medicines Agency (EMA), London, United Kingdom

Developing medicines for pediatrics: what have we learned  
Sandra Klein, University of Greifswald, Greifswald, Germany

## Part VI: Technology provides presentations

Multiparticulate formulations for sprinkle use: a patient centric and versatile platform  
Capsugel

## Part VII: Older Patient Medicine Initiative

Panel discussion:  
Towards solutions – where do we go from here

Wrap-up and farewell

## Exhibition and Sponsoring

We are glad to tailor a sponsor package (starting from 1000 EUR) according to your wishes.

**For general information, please go to [www.apv-mainz.de/en/seminare/sponsoring-exhibition/](http://www.apv-mainz.de/en/seminare/sponsoring-exhibition/)**

As an exhibitor you will be also invited to attend the sessions and the networking dinner in the evening. At the venue the coffee breaks will again be integrated in the exhibition, ensuring that participants are around the exhibition stands as much as possible. Price for a tabletop space with table, chairs and power supply is 990 EUR plus one mandatory full conference registration.

**Please contact Antonia Herbert**

Phone +49 6131 9769-90

e-mail [ah@apv-mainz.de](mailto:ah@apv-mainz.de)

## Location

Hotel Das Weitzer  
Grieskai 12 - 16  
8020 Graz  
Austria  
Phone: +43 316 703-400  
Fax: +43 316 703-629

## Date

from 07 Nov. 2017 09:00  
to 08 Nov. 2017 15:30

## Registration

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

Special rate:

Single room incl. breakfast buffet from 95 EUR per night.

## Registration fee

Course no. 6704  
Industry 1490 EUR  
Authorities/Academia 745 EUR  
Students\* 178 EUR  
(free of VAT according to § 4,22 UStG)  
Coffee breaks, lunches, dinner and electronic proceedings included.

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

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## Hotel reservation

Hotel Das Weitzer  
Grieskai 12 - 16  
8020 Graz  
Austria  
Phone: +43 316 703-400  
Fax: +43 316 703-629  
email: reservations@weitzer.com

Deadline for special conference rate: 11 September 2017.

Special rate:  
Single room incl. breakfast buffet from 102 EUR per night.

Participants should make their own hotel reservation referring to the APV seminar.  
Mainz, March 2017

Deadline for special conference rate: 25 September 2017.

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.

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

### 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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