

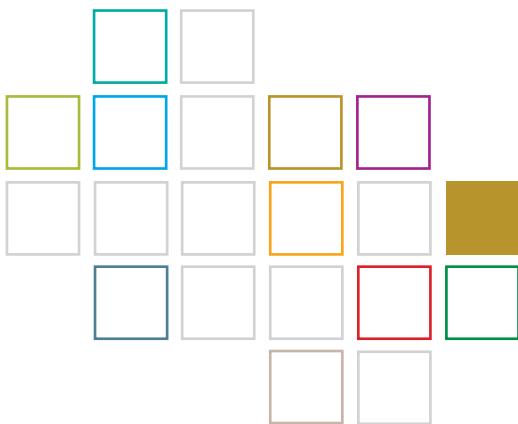
2nd Conference of the Patient Centric Medicines Initiative (PaCeMe In)

Tailor medicines for older patients in pharmaceutical development:
From new regulations to a rational science based process



05 to 06 June 2019
Berlin, Germany

Course no. 6782



Hot Topics

Target group

Employees of the pharmaceutical industry (formulation development, product development, clinical and commercial manufacturing, regulatory affairs, medical science and marketing) and academy (pharma technology and students). Hospital pharmacists, community pharmacists as well as regulatory authorities.

Patient Centric Medicines Initiative - a joined initiative by APV e.V. and GMS e.V.



A seminar organised by the APV focus group Solid dosage forms

Objectives and content

With the increasing regulatory demand for Real World Evidence, patient involvement in the drug development process is becoming an inevitable opportunity for the pharmaceutical industry. The inclusion of patients and their needs in the drug product design is essential for the use "as intended" as the patients are finally deciding to use and how to use the drug product for their health goals.

In order to prevent poor therapeutic outcomes, medication errors and non-adherence several regulatory considerations and guidelines have been published addressing the mismatch of patients perception and interface with the pharmaceutical drug products. Just to mention some recent ones, the EMA has stated their expectations for pharmaceutical product design in the "Reflection Paper on pharmaceutical development of medicines for use in the older population" and the FDA did so in their "Guidance to Industry on Safety Considerations for Product Design to Minimize Medication Errors". Additional regulatory documents provide guidance for the development like "Use of Liquids and/or Soft Foods as Vehicles for Drug Administration: General Considerations for Selection and In Vitro Methods for Product Quality Assessments", to address the needs of special patient populations and emerging real world drug administration pathways and four Guidelines on Patient-Focused Drug Development (PFDD), which are in development.

As an outcome of the 1st Conference on patient centric product development, the Patient Centric Medicine (PaCeMe) initiative was established early 2018 as a multidisciplinary industrial-academic collaboration to develop practical guidance to comply with future patient centric product development.

The 2nd conference on patient centric product development will take place on 5 and 6 June 2019 in Berlin (Germany). The conference is titled: Tailor medicines for older patients in pharmaceutical development: From new regulations to a rational science based process bring together key opinion leaders from different disciplines including patient representatives to provide their expertise and thoughts as well as to discuss the results of the PaCeMe Initiative stakeholders in workshops with the attendees. The objective is to provide a pragmatic road map and achieve a general consensus that we can do it and even better.

The multidisciplinary and distinguished speaker panel will touch on different aspects of patient centric drug product development, its importance for effectiveness and drug safety, and especially how this can become an integral mind set for drug product development.

Areas that will be discussed in details are:

- Ethical aspects of patient centric products for older and multimorbid patients
- Patient characteristics and needs from medical, epidemiological, sociological and pharmaceutical practice
- Thoughts and considerations on ongoing and future regulation
- Case studies of involving patients in drug development and product design
- Successful industrial development of a patient centric drug product

Finally, all conference attendees will be involved by a moderated interactive discussion on a proposed "road map" for patient centric drug product development as a way forward to a scientific rational, meaningful and commercially viable "road map" for patient centric product design.

Course leader

Sven Stegemann, Ph.D.
Capsugel and Graz University of Technology



Prof. Dr. Sven Stegemann is director, pharmaceutical business development at Capsugel, and professor of patient centric drug design and manufacturing at the Graz University of Technology, Austria. Over the course of his 18-year career at Capsugel, Dr. Stegemann has worked as an advisor to major pharmaceutical companies on ways to improve the design, development and manufacture of pharmaceutical products so they better address the individual needs of patients. In his academic role, Dr. Stegemann's focuses his research on the rational development of patient centric drug products and their associated manufacturing technologies, as well as education and training of students and young scientists. Dr. Stegemann is the founder and chair of the AAPS Focus Group on Patient-Centric Drug Development, Product Design, and Manufacturing as well as the founder and President of the Geriatric Medicine Society.

Programme

Wednesday, 05 June 2019, 09:00 - 17:00 h

Welcome and introduction

Sven Stegemann, Graz University of Technology, Graz, Austria

Pharmacotherapy to older dementia patient in hospital setting

(tbc)

Understanding the healthcare needs of patients with Rheumatoid Arthritis

Dr. Anja Strangfeld, Deutsches Rheumaforschungszentrum Berlin, Epidemiology Group, Berlin, Germany

Ethical guideline for older people to engage the individual person and caregivers into medical research

Laurence Hugonot-Diener, EFGCP, Brussels, Belgium

Panel discussion

Longevity and the ethical responsibility of healthcare

Maria Cristina Polidori, University Clinic Köln, Cologne, Germany

The EMA Geriatric Medicine strategy – Frail patients and the consideration for product design

Francesca Cerreta, EMA, Amsterdam, The Netherlands

Introducing the FDA's PFDD Guideline

Sandry Kweder, FDA, United States

Optimizing devices by including patients behavior and feedback in the development

Anna Maria Ciciliani, Boehringer Ingelheim, Ingelheim, Germany

Promoting interdisciplinary discussion on practical medication issues

Dr. Diana van Riet-Nales, Medicines Board of Netherlands, Utrecht, Netherlands

Panel discussion

Networking dinner

Programme

Thursday, 06 June 2019, 09:00 - 16:30 h

Session 2: Excipients

Welcome

Sven Stegemann, Graz University of Technology, Graz, Austria

Pharmacotherapy in older and multimorbid patients – A Geriatrician perspective

Manfred Gogol, University of Heidelberg, Heidelberg, Germany

Patient Reported Outcomes in clinical trials to capture patient experience with a new therapy

Viviane Klingmann, University Children's Hospital Düsseldorf, Düsseldorf, Germany

Learning from Patient Reported Outcomes (PRO) to collect patient needs

Lars Joensson, Grünenthal, Aachen, Germany

Results from an observational study of older patients acceptability of medicine usage

Fabrice Ruiz, ClinSearch, Paris, France

Studying swallowability of oral films in pediatric patients

Ahmad Ghoniem, Tesa Labtec GmbH, Langenfeld, Germany

Drug product design to address multiple factor of older and multimorbid patients

Sarah Barthold, Glatt, Binzen, Germany

Patient Centric Medicines (PaCeMe) Initiative Outcome report

Moderated interactive discussion all participants

- Presentation and Discussion of a proposal of a "road-map" of patient centric product development.
- Collecting feedback, adjusting "road-map" and addressing road-blocks

Conclusion of the Panel discussion

Closing

Registration by fax +49 6131 97 69 69 or by email apv@apv-mainz.de



Location

Abba Berlin Hotel
Lietzenburger Str. 89
10719 Berlin, Germany
phone 0049 30 887 186 0
fax 0049 30 880 078 51
mail berlin-events@abbahotels.com

Registration fee

Industry 1490 EUR
Authority/University 745 EUR
Students* 178 EUR

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

Coffee breaks, luncheon, 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: 0049 6131 97 69 0
Fax: 0049 6131 97 69 69
E-mail: apv@apv-mainz.de
Web: www.apv-mainz.de

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

Hotelreservation

Abba Berlin Hotel
Lietzenburger Str. 89
10719 Berlin, Germany
phone 0049 30 887 186 0
fax 0049 30 880 078 51
mail berlin-events@abbahotels.com

Participants should make their own hotel reservation referring to the APV seminar. Deadline for special conference rate: 03 May 2019. Special rate: Single room incl. breakfast from 125,00 € per night excl. city tax.

Mainz, March 2019

Date

Course no.: 6782
from 05 June 2019 09:00 h
to 06 June 2019 16:30 h

2nd Patient Centric Medicines Conference , 05 to 06 June 2019, Berlin, Germany, Course no. 6782

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.

Declaration of consent in respect of data protection

By registering for this seminar, I agree that the APV uses my data for the purpose of processing the order and provides me with all relevant information.

I also agree that APV may contact me for the purpose of exchanging similar information by email or post.

Your data will not be shared with third parties. You have a right of withdrawal at any time without giving reasons.

All other information can be found in our privacy policy (www.apv-mainz.de/en/imprint/data-protection-statement/).

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International Association for Pharmaceutical Technology

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