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

14 to 15 November 2018
Berlin, Germany

Course no. 6748

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.

Geriatric Medicine Society

APV MAKING SCIENCE WORK

Arbeitsgemeinschaft für Pharmazeutische Verfahrenstechnik e.V.
Gemeinnütziger wissenschaftlicher Verein
International Association for Pharmaceutical Technology

Objectives and content

Improving health and wellbeing of patients through effective and safe drug products remains to be the key driver for the sustainability of the pharmaceutical industry. To address poor therapeutic outcomes and medication errors, patient centric drug product design is increasingly becoming an integral part of drug product development and a regulatory requirement.

In the **"Reflection Paper on pharmaceutical development of medicines for use in the older population"** the European Medicines Agency (EMA) has stated their expectations for future product submissions in August 2017 as well as the FDA put forward draft guidance in July 2018 on the **"Use of Liquids and/or Soft Foods as Vehicles for Drug Administration: General Considerations for Selection and In Vitro Methods for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.

"Tailor medicines for older patients in pharmaceutical development: From new regulations to a rational science based process" is the title of the 2nd Patient Centric Medicines Conference providing in depth and breadth experience from key clinical, academic and industrial stakeholders. Moreover through interactive break-out-discussions practical approaches to implement patient drug design are discussed and shared.

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
- Patients' own view on needs and expectations

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

In break-out-discussions, practical approaches towards patient centric drug product design and development for a defined patient populations will be discussed and developed together with all attendees. The outcome should serve as a roadmap for formulation development scientists and other stakeholders involved in drug product design and development.

Programme

Wednesday, 14 November 2018
09:00-17:00 h

Welcome and introduction
Sven Stegemann, Graz, Austria

Pharmacotherapy in older and multimorbid patients – A Geriatrician perspective
Manfred Gogol, University of Heidelberg, Heidelberg, Germany

Longevity and the ethical responsibility of healthcare
Maria Cristina Polidori, University Clinic Köln, Cologne, Germany

Understanding the healthcare needs of patients with Rheumatoid Arthritis
Dr. Anja Strangfeld, Deutsches Rheumaforschungszentrum Berlin, Epidemiology Group, Berlin, Germany

Pharmacotherapy to older and multimorbid patients in hospital setting
Matthieu Piccoli, University Hospital Paris Centre, Paris, France

2nd Patient Centric Medicines Conference

Panel discussion

Ethical guideline for older people to engage the individual person and caregivers into medical research
Laurence Hugonot-Diener, EFGCP, Brussels, Belgium

The Reflection Paper and beyond – the regulatory pathway
Dr. Diana van Riet-Nales, Medicines Board of Netherlands, Utrecht, Netherlands

Optimizing devices by including patients behavior and feedback in the development
Anna Maria Ciciliani, Boehringer Ingelheim, Ingelheim, Germany

Development of a patient centered information leaflet
Katharina Braun, BAGSO, Bonn, Germany

Panel discussion

Networking dinner

Thursday, 15 November 2018
09:00-17:00 h

Welcome
Sven Stegemann, Graz, Austria

Patient experience of living with diseases and pain
Judy Birch, Patient Ambessador, London, United Kingdom

Studying swallowability of oral dosage forms in the very young and shifting the paradigm in pediatric formulation
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

Break out session 1 (PaCeMe In Packaging work stream moderation):
Considerations, priorities and concepts for multimorbid patients (with impaired hand function)

Break out session 2 (PaCeMe In QbD/ Formulation work stream moderation):
Considerations, priorities and concepts for multimorbid patients (with polypharmacy and cognitive impairements)

Break out session 1 outcomes

Break out session 2 outcomes

Panel discussion

Closing

Programm subjected to be changed

Registration by fax 0049 6131 97 69 69 / by e-mail apv@apv-mainz.de

Location

Hyperion Hotel Berlin

Prager Straße 12
10779 Berlin, Germany
phone 0049 30 236250 0
fax 0049 30 236250 450
mail hyperion.berlin@h-hotels.com

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

Date

Course no. 6748
14 November 2018 09:00 h
to 15 November 2018 17:00 h

Registration fee

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

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

Coffee breaks, luncheons, dinner and electronic proceedings included.

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

Registration

APV-Headquarters
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.

Hotel reservation

Hyperion Hotel Berlin

Prager Straße 12
10779 Berlin, Germany
phone 0049 30 236250 0
fax 0049 30 236250 450
mail hyperion.berlin@h-hotels.com

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

Deadline for special conference rate: 15 October 2018.

Special rate:
Single room incl. breakfast from 109 EUR per night.

Mainz, August 2018

2nd Patient Centric Medicines Conference , 14 to 15 November 2018, Berlin, Germany, Course no. 6748

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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