APV Expert Workshop
Drug-Device Combinations

06 to 07 March 2018
Dortmund, Germany

Course no. 6719

Hot Topics

Target group

- pharmacists and other scientists
- engineers and technicians
- everyone working in: pharmaceutical development, manufacturing, regulatory affairs, quality control or business development

MAKING SCIENCE WORK

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

Summary and objectives

The workshop is designed for professionals working in the pharmaceutical and medical device industry in the following areas: drug development, medical device development, manufacturing, quality control, quality assurance and regulatory affairs who are actively engaged with the development, manufacture and quality control of drug-device combination products.

This workshop which is organized by APV's MedTech Task Force addresses the regulatory requirements and technological challenges of drug-device combinations and related primary packaging components both for Europe and North America and goes along practica examples for different routes of administration and manufacturing technologies.

For the first 15 registered participants, a guided tour through a modern manufacturing facility for medical devices (Boehringer Ingelheim microParts, Dortmund) will be provided as additional value based on availability and approval.

Please note that the participation of each person to the facility tour has to be approved by Boehringer Ingelheim micropParts in regards to competitor protection rules. Each approved participant will get a separate confirmation. There is no legal right to participate in the guided tour.

APV's MedTech Task Force

Dr. Markus Petermeier
Merck KGaA, Darmstadt, Germany

Dr. Marc Rohrschneider
Novartis Pharma AG, Basel, Switzerland

Dr. Felix Weiland
Boehringer Ingelheim microParts, Dortmund, Germany

Programme

Tuesday, 06 March 2018, 09:00 to 17:30 h

Welcome and Introduction
Markus Petermeier, Merck KGaA
Felix Weiland, Boehringer Ingelheim microParts

How to implement a successful supplier - pharma cooperation? A short introduction
Felix Weiland, Boehringer Ingelheim microParts

Drug-Device combinations: Borderlines, current and future regulatory requirements
Mika Reinikainen, AbNovo Ltd.

Development and lifecycle management aspects of Drug-Device Combinations

Onboarding and development considerations for innovative device constituent parts of combination products
Marc Rohrschneider, Novartis Pharma AG

Systematic approach on Risk Assessment/Risk Based Approach/QbD/CQAs/Control Strategy for Drug-Device Combinations
Alexander Schloske, Fraunhofer Institut für Produktionstechnik und Automatisierung

Innovative device development and SMART devices – Is there a world before design control measures?
Jakob Lange, Ypsomed AG

Technical Regulatory aspects of Drug-Device Combinations for EU & US including new revision of ISO 13485
Andrea Kersebohm, Roche Diagnostics GmbH

Driving on a first-to-file regulatory pathway for innovative primary packaging – a case study
Horst Koller, HK Packaging Consulting GmbH

Networking dinner

APV Expert Workshop Drug-Device Combinations

Wednesday, 07 March 2018, 08:30 to 17:00 h

Welcome back
Markus Petermeier, Merck KGaA
Felix Weiland, Boehringer Ingelheim microParts

Case Studies and future trends for small molecules and biologics

Specific challenges for combination products for ophthalmic drug delivery
Hanns-Christian Mahler, Lonza AG

Modification of non-glass materials towards glass-like properties
Holger Krenz, SiO2 Medical Products

COP vials and RTF-Syringes
speaker requested

Extracable and Leachable Studies for Biologicals - Does the maximum daily administered dose approach apply to biologics?
Steven A. Watt, A&M Stabtest GmbH

Smart Devices and Clinical Studies – How Digital Technologies Enhance Patient Engagement
Eric Chanie, Merck Biopharma

Closing discussion
Markus Petermeier, Merck KGaA
Felix Weiland, Boehringer Ingelheim microParts

Facility tour at Boehringer Ingelheim microParts GmbH, Dortmund (approx. until 17:00 h)
Raphael Krampe, Boehringer Ingelheim microParts

Programm subjected to be changed


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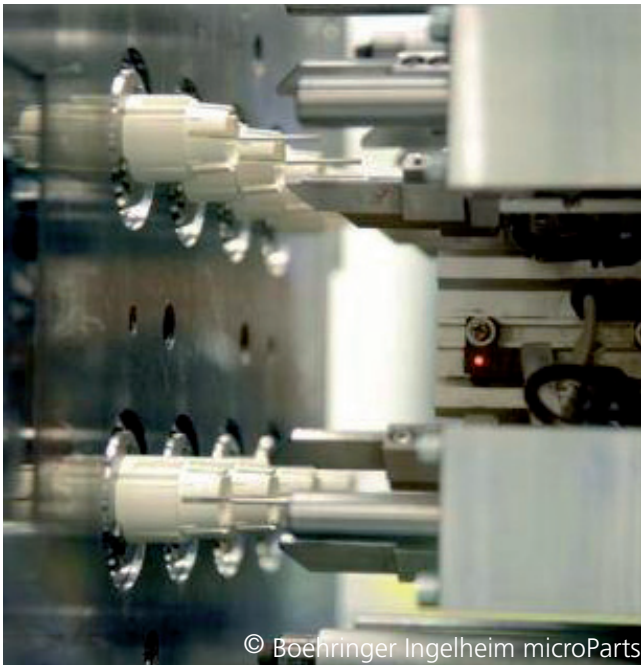
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Registration by fax 0049 6131 97 69 69 / by e-mail apv@apv-mainz.de

Location

Mercure Hotel Dortmund Centrum
Olpe 2
44135 Dortmund, Germany
phone 0049 231 543 200
fax 0049 231 574 354

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. 6719
06 March 2018 09:00 h
to 07 March 2018 17:00 h

Registration fee

Industry	1290 EUR
Authority/University	645 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-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

Mercure Hotel Dortmund Centrum
Olpe 2
44135 Dortmund, Germany
phone 0049 231 543 200
fax 0049 231 574 354

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

Deadline for special conference rate: 05 February 2018.

Special rate:
Single room incl. breakfast 112 EUR per night.

Mainz, October 2017

APV Expert Workshop - Drug-Device Combinations, 06 to 07 March 2018, Dortmund, Germany, Course no. 6719

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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