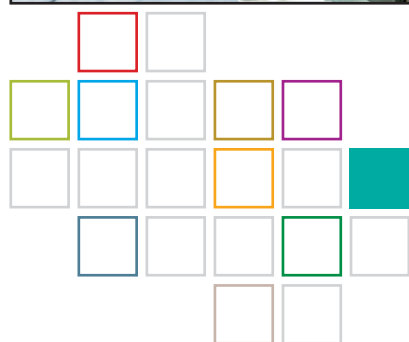


Hands-on workshop on Hot Melt Extrusion (HME)



30 Sept. to 01 October 2015
Karlsruhe, Germany

Course No. 6602



Pharmaceutical Manufacturing

- Drug development using Hot Melt Extrusion in the pharmaceutical industry
- Hands-on workshop on different extruders and downstream equipment
- Hands-on workshops on co-extrusion
- Hands-on workshops on cleaning

The HME hands-on workshop provides scientific and technical staff from pharmaceutical development, clinical trial supplies and process or technology transfer a good introduction to the establishment and application of this new technology.

For colleagues, without any prior knowledge, this hands-on workshop provides a comprehensive introduction to the technology, while for colleagues who already have experience with HME, the workshop offers the opportunity to deepen their knowledge in relation to specific procedures and methods. For employees from the production department, the workshop offers the opportunity to acquire the essential knowledge for the establishment of this new technology.



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



A seminar organised by the APV focus group Solid Dosage Forms

Objectives

Hot Melt Extrusion (HME), which is a manufacturing technique, successfully used by the plastic and food industry since decades, gains increasing relevance for the development and production of pharmaceuticals. Due to its advantages for formulation and the continuous and easily controllable process, this technology offers many advantages to realize a modern production of pharmaceuticals.

In the last few years, many pharmaceutical companies started using the HME technology in R&D departments. In the meantime, the transfer and the realization of this technology is about to happen, to make sure that the companies can develop and produce tailor made pharmaceuticals for the market. Furthermore, many companies start considering the HME technology as a real alternative and the first products are on the market.

The level of knowledge of and the experience with this technology in production, quality control and quality assurance, as well as even in many development departments, is often inadequate. Therefore, questions arise considering the technology, the process and its characteristics and most of all, if and how experiences made so far with traditional technologies can be transferred to the new technology.

All these points will be covered in this workshop. Next to the learning about understanding and using of Hot Melt Extrusion, this hands-on workshop will also offer support for implementations in the context of development projects of new pharmaceuticals – from early stage until scale-up, transfer and production for the market.

The focus is not only on authority requirements, technology, process parameters, formulation and development concepts, but also on practical implementation.

In the context of a hands-on workshop, participants will learn how to use the technology and the machine and they will follow 5 workshop stations; all theoretically learned topics can be transferred into praxis.

During these labs, extensive knowledge of successful screening for the appropriate process and formulation concepts, for the analysis of critical quality factors, for the determination and definition of relevant process parameters will be communicated, as well as scale-up concepts.

Delegates will highly benefit from the panel discussions as well as from the discussions in their workshop groups. This set-up will guarantee an interactive and interdisciplinary exchange between delegates and speakers.

This hands-on workshop will happen in cooperation with Thermo Fisher Scientific and all sessions and workshops will take place in laboratories run by Thermo Fisher Scientific in Karlsruhe, Germany.

All workshop speakers are well-known experts from industry and academia and all are acknowledged experts on HME. They will communicate the technology and its utilization and also demonstrate advantages and disadvantages of different devices, methods and processes.

Workshops will happen in small groups of 5; therefore, we need to limit the overall participant number. To make sure you will get the best out of this hands-on workshop, we cannot accept more than 25 participants.

Hands-on workshop on Hot Melt Extrusion (HME)

Agenda

Wednesday, 30 September 2015
09:30 to 18:00 h

Welcome address

Thobias Geissler
Katharina Paulsen
Thermo Fisher Scientific, Karlsruhe, Germany

Hot melt extrusion for Pharmaceutical Applications

Prof. Markus Thommes
Technische Universität Dortmund, Dortmund, Germany

Polymers and excipients for Hot Melt extrusion

Geert Verreck
Janssen R&D a division of Janssen Pharmaceutica N.V.,
Beerse, Belgium

Pre-scanning tools and process development

Katharina Paulsen
Thermo Fisher Scientific, Karlsruhe, Germany

Solid state characterization

Prof. Clare Strachan
University of Helsinki, Helsinki, Finland

Workshop Explanation and Group Assignment

Workshop session I:

- Process parameters
- Downstream processing

Networking dinner

Thursday, 01 October 2015
09:00 to 15:30 h

Welcome back

Co-extrusion

Julia Laukamp
Bayer HealthCare, Leverkusen, Germany

Scale up of a Hot Melt Extrusion process

Andreas Gryczke
BASF SE, Lampertheim, Germany
Katharina Paulsen
Thermo Fisher Scientific, Karlsruhe, Germany

PAT tools: NIR and Raman for HME

Lien Saerens
SEPS Pharma, Gent, Belgium

Workshop Explanation and Group Assignment

Workshops session II:

- Co-extrusion
- Cleaning

Wrap up

End of the session

Please note that for competitive reasons, individual participants can be excluded from the workshop.

Location

Thermo Fisher Scientific
Dieselstr. 4
D 76227 Karlsruhe

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

Date

Course no. 6602
from 30 Sept. 2015 09:30 h
to 01 Oct. 2015 15:30 h

Registration fee

APV member 1360 EUR
Non-member 1490 EUR
(free of VAT according to § 4,22 UStG)

Coffee breaks, luncheons, dinner and electronical proceedings included.

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.

Members of authorities pay half of the APV member's and non-member's registration fee respectively.

Hotel reservation

Schlosshotel Karlsruhe
Bahnhofplatz 2
76137 Karlsruhe, Germany
Telefon: +49 721 3832-0
Telefax: +49 721 3832-133

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

Deadline for special conference rate: 29 August 2015.

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

Mainz, May 2015

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.

- pay via invoice
- pay via credit card (fill in below)
- AMEX
- Visa
- Mastercard

Card Holder

Card No.

Valid until

CVC Code

Titel, First Name, Last Name *

Company Name *

Company Address *

Location *

Zip-Code *

Phone *

Department

E-mail Address Participant*

Order No. or Billing Address

APV Member

Non-Member

Date

Signature

*Mandatory

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

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

www.apv-mainz.de