Practical training: tableting

- Hands-on experiments
- Single punch and rotary presses
- Process parameters and technical basics
- Excipients and formulations
- Multilayer tablets

APV basics

06 - 07 November 2024
Berlin, Germany

Course no. 6996

Pharmaceutical Manufacturing

Target group

This course addresses everyone who is not yet an expert in theory or practice of tableting. This includes people in development, production and quality control who are new to the field and those who predominantly only have theoretical knowledge. The course is suitable for both academic employees and experienced laboratory or production employees who want to achieve a general understanding of processes, formulations and their interactions and to gain an up-to-date overview of tabletting.

In cooperation with

KORSCH
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APV
MAKING SCIENCE WORK

Pharmaceutical Manufacturing

This seminar is organised by the APV focus group on solid dosage forms.

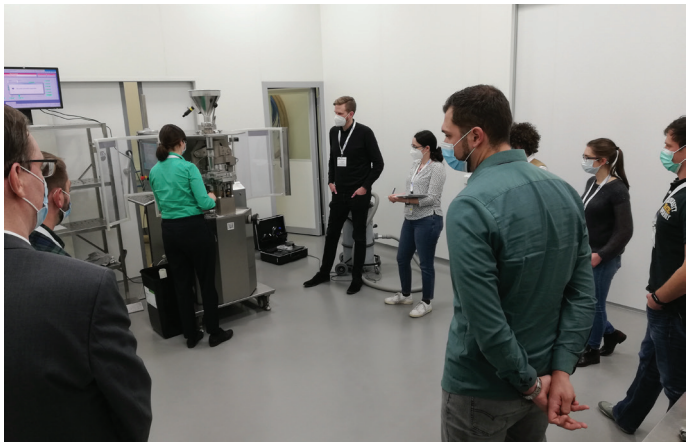
Course leader

Prof. Dr. Annette Bauer-Brandl

Annette Bauer-Brandl is an accredited pharmacist with a doctoral degree in Pharmaceutics (Dr. rer.nat.). After research positions in Wellcome (London, UK), Novartis (Basle CH), and University of Freiburg, Germany, she moved to University of Tromsø, Norway. There she was involved in starting cand. pharm. curriculum; her current position in Odense also embraced start-up of the cand. pharm. curriculum. She serves at the EDQM (European Directorate for Quality of Medicines) in the Expert Group 12 (Dosage Forms and Methods) and the Danish Medicines Agency. She published a handbook on Formulation, Manufacturing and Quality Assurance of Solid Dosage Forms ("Die Tablette", 4th ed. 2022). Her research is focussed on the solid state of drug substances, solvation of drug molecules in different solvents, and dissolution. The main interest is on prediction of oral bioavailability of poorly soluble drugs from enabling formulations such as tablets. Her group has invented a novel biomimetic barrier (Permeapad®) that allows permeation experiments under harsh conditions in different formats including 96 well plates. Alternative novel devices to study dissolution / permeation simultaneously in more detail (e.g. Permealoop ™) and alternative analytical tools are developed. These efforts are directed towards animal-free drug development by improved IVIVCs.

Dr. Kai Lindenstruth

Dr. Kai Lindenstruth studied pharmacy and received his doctoral degree in pharmaceutical technology on dosage forms for peptide drugs. He then worked for F. Hoffmann-La Roche, where he lead a research and development laboratory for oral dosage forms. As pharmaceutical project manager, Kai Lindenstruth was also responsible for the global coordination of formulation activities for clinical studies. He then worked for the law firm Hertin & Partner and BASF SE in the area of intellectual property. Kai Lindenstruth is a patent attorney and now works for Roche Diabetes Care GmbH in Mannheim. His main scientific interests are in the area of modern excipients, sustained-release dosage forms and innovative systems for drug delivery.



APV basics

The APV basics series covers pharmaceutical-technological topics in various specialist areas such as pharmaceutical technology, processing, production of liquid and solid dosage forms, biopharmaceuticals, and packaging.

The APV basics series is equally suitable for practitioners who would like to learn more about the theoretical background, as well as for those with theoretical training who are looking for means to implement their knowledge, as well as for newcomers to the field of dosage forms, in terms of development and production. The APV basics series addresses employees from the areas of development, analytics, production and approval.

Objectives

Tablets are the most frequently used dosage form because, in addition to being inexpensive to produce, their advantages include precise dosing, generally good stability and shelf life, and easy ingestion by the patient. In order to realize these advantages in practice, all parameters that are crucial for the successful production of tablets must be precisely coordinated.

The aim of the course is to provide participants with in-depth basic knowledge and to work out important basic principles, both in seminars and with practical exercises. In addition to an overview of the different types of tablets, this course covers the selection of suitable excipients depending on the physicochemical properties of the active ingredient. But it's not just these active ingredient properties that need to be taken into account, because the selection of tablet ingredients also plays an important role in terms of high throughput and avoiding problems. The tableting process itself and the associated compression processes are therefore also focus areas of this course.

Finally, as part of the practical training, small groups work on modern tablet machines under experienced guidance: the tableting process is illustrated using practical examples, the choice of suitable process parameters is explained and the respective processes are monitored and explained in detail. The participants themselves have the opportunity to follow the tabletting and monitor the process via the machine software. The focus is on solving problems and optimizing throughput, which is illustrated by selecting the components of the formulation on the one hand and adjusting the settings on the tablet machine on the other.

At the end of the course, the participants will have acquired basic knowledge about tableting and will be able to independently recognize and evaluate the criteria relevant to tablet production.

Please note that for competitive reasons, individual participants may be excluded from the company tour.

This seminar is limited to 24 participants!

Programme

Wednesday, 06 November 2024, 12:00 - 18:00 h

Welcome and Introduction of Participants
Prof. Dr. Annette Bauer-Brandl, University of Southern Denmark, DK-Odense
Dr. Kai Lindenstruth, Roche Diabetes Care GmbH, D-Mannheim
Dr. Jan Henrik Finke, TU Braunschweig, D-Braunschweig
Dr. Friederike Gütter, Korsch AG, D-Berlin

Basics on Tablets
- Overview of tablet types with regard to function site of application and release
- Properties and quality requirements
- Testing of tablets
- General aspects of tablet production
- Comparison of tablets produced on single punch and rotary presses

Prof. Dr. Annette Bauer-Brandl

Development of Tablet Formulations
- Determination of a development strategy taking into account the area of application (clinical formulation/market formulation)
- Influence of the active pharmaceutical ingredient on tablet properties
- Selection of excipients
- Example formulations for immediate release and modified release tablets

Dr. Kai Lindenstruth

Basics on Tablet Presses
- Types of tablet presses, their applications and special features
- Physical processes taking into account pressure holding times and effect on porosity
- Trouble-shooting, e.g. with regard to the lubrication problem
- Compaction simulators and the prediction of compressibility and compactibility

Prof. Dr. Annette Bauer-Brandl

Practical Training in Groups – Part 1 / Part 2 / Part 3 / Part 4

Practical Training in Groups – Part 1
- Experiments on a rotary press
- Identification of process parameter limits for a rotary presses
- Effects of machine settings on tablet properties
- Use of development software to optimize compression conditions

Facility Tour at Company Korsch – Part 2

Networking dinner

Programme

Thursday, 07 November 2043, 08:00 - 16:00 Uhr

Process Parameters during Tableting and their Monitoring
- Tablet press set-up and options for measuring process parameters (real-time)
- Online measurement of tablet properties
- Control circuits for single punch and rotary presses for R&D and production machines
- Force measurement sensorics

Dr. Friederike Gütter

Excipients at a Glance
- Properties and areas of application
- Characterization of excipients and excipient blends
- Behavior of excipients during tablet production
- Influence of excipients on stability and storage of tablets

Dr. Kai Lindenstruth

Practical Training in Groups– Part 3
- Experiments on a single punch press
- Use of different excipients and investigation tabletability
- Use of development software to optimize compression conditions
- Characterization of the tablets obtained and identification of parameters for good or poor tabletability/tablet properties

Practical Training in Groups– Part 4
- Demonstration of the development and production of multilayer tablets
- Presentation of the technical requirements for a tablet press for the production of multilayer tablets
- Machine setting options and process monitoring

Scale Transfer – from Compaction Simulator to Rotary Press Production
- Use of compaction simulators
- Differences to rotary presses
- Opportunities and challenges of transferability of results
- Other approaches to scale transfer

Dr. Jan Henrik Finke

Evaluation/conclusion/final discussion

Programme subject to changes.

Seminaranmeldung by E-Mail apv@apv-mainz.de

MAKING SCIENCE WORK

Veranstaltungsort

KORSCH AG
Breitenbachstr. 1
13509 Berlin
Germany

Date

Course no.: 6996
from 06 November 2024 12:00 h
to 07 November 2024 16:00 h

Registration fee

Industry	1690	EUR
Authority/University	845	EUR
Students*	250	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
E-mail: apv@apv-mainz.de
Web: www.apv-mainz.de

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

Hotelreservation

Hotel am Borsigturm
Am Borsigturm 1
13507 Berlin
Phone: 0049 30 430 360 00
E-mail: info@hab.berlin

We have blocked a contingent on the special rate of **121.00 € incl. breakfast and VAT. Reservation code: APV.** The rate is available until 08 October 2024.

APV basics - Practical training: Tableting, 06 - 07 November 2024, Berlin, Course no.: 6996

Registration
As soon as you have found a seminar of your interest, it is very easy to register for it via 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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