Highlights

- Importance of Dissolution Testing in Drug Development and for a Commercial Product
- In vivo Relevant Dissolution Testing
- Discriminatory Power of a Dissolution Method
- Regulatory Requirements (Pharmacopoeias, Required Data for Application of Marketing Authorisation)
- Country-specific Challenges: Japan, Korea, Taiwan, China etc.
- Automation of Dissolution Methods
- Mechanical Qualification and Performance Verification Testing (PVT)
- Development of Dissolution Methods
  - How to Set Specifications?
  - Analytical Validation
  - Practical Recommendations
- OOS Results in Dissolution Testing
- Dissolution Profile Comparison

Speakers

Dr Corinna Bode
Bayer

Dr Jan Joseph
Bayer

Dr Gerd Michael Maier
Boehringer Ingelheim

Dr Johanna Milsmann
Boehringer Ingelheim
Objective

This GMP Education Course on Dissolution Testing aims at providing delegates with a sound understanding of the principles and best practices in dissolution testing.

As Dissolution represents a very interdisciplinary topic, a broad variety of areas within the development and commercial phase will be discussed. You will get to know

- how to characterize formulations
- how to support formulation and process development
- how to evaluate the impact of formulation and process parameters changes
- how to control the quality (QC tool) of clinical trial supplies and the commercial product
- how to justify formulation/production changes (e.g., according to SUPAC, Biowaivers)
- how to predict in vivo performance

Due to the wide range of applications and the sensitivity of dissolution testing, sound method development and validation is of essential importance. Furthermore, also knowledge on dissolution apparatus qualification, dissolution specification setting, dissolution profile comparison and handling of OOS/OOE results will be trained and discussed.

Programme

Fundamentals of Dissolution Testing: From Physicochemistry to Bioavailability

- Mechanism and theories of solid dissolution (e.g. diffusion layer model)
- Intrinsic dissolution rate
- Sink conditions
- Kinetics of drug release
- Relationship between dissolution and bioavailability
- Quality control dissolution testing and in vivo predictive dissolution testing
- Biopharmaceutics Classification System
- Fraction of a dose absorbed classification system
- Hurdles and limitations of dissolution testing

Development of Dissolution Methods - The balancing Act between Quality Control and Clinically Relevance

- Method development for Immediate Release, Extended Release and Delayed Release Formulations
- Regulatory recommendations
- Dissolution apparatus and medium selection
- Use of surfactants
- Adequate discriminatory capability
- Standard Dissolution Test Conditions
- Evaluation of bio-relevance
- Dissolution methods for developing an IVIVE/C to gain regulatory flexibility

Dissolution Testing – Regulatory Requirements (Guidelines, Pharmacopoeias, etc.)

- Prerequisites of international and mostly harmonized pharmacopoeias (USP, EP, Pharm Jap)
- Miniaturization of dissolution tests
- General guidelines for dissolution testing
- Contents and differences in Chinese pharmacopoeia
- Validation of dissolution test methods
- Bioequivalence considerations
- Special in vitro bioequivalence applications in Japan
- Waiving dissolution tests by disintegration tests

**Setting Specifications for Dissolution Methods**

- How to set adequate dissolution specifications for various types of formulations:
- Requirements of different Pharmacopoeias and Guidelines
- Specifics and exceptions

**WORKSHOP I**

*How to Set Specifications: Sharing Information of the Learned Theories*

- Presentation of Case Studies and discussion of potential results
- Q&A Session

**Mechanical Calibration & Performance Verification Test (PVT)**

- Regulatory basis
- Fundamentals of instrument qualification
- Qualification and calibration of dissolution apparatuses
- Mechanical calibration
- USP Performance Verification Test (PVT)
- Deviations and OOC

**Case Study**

*Application of Dissolution Testing in Industrial Drug Product Development*

Discussion of various case studies occurring during product development

**Automation in Dissolution Testing**

- Why and when is automation valuable?
- Various types of dissolution systems
- New products on the market

**Dissolution Testing throughout the Drug Product Development Lifecycle: In vivo relevance and Bio-waivers**

- Use of dissolution testing during Drug Product development
- What is Biorelevance? Meaning and Misconceptions
- How to establish a link between dissolution and bioavailability
- The role of IVIVC
- Setting biorelevant dissolution specifications
- BCS based biowaivers
- Waivers based on proportional similarity
- Country specific regulatory differences
- Case studies

**OOS Results in Dissolution Testing (incl. OOE)**

- Regulatory aspects
- Dissolution methods having appropriate discriminatory power
- General OOS procedure for dissolution testing
- Defining and handling of OOS results including CAPA
- OOS evaluation for immediate release products
- OOS evaluation for capsules
- OOS evaluation for modified-release products
- OOT/OOE results: Evaluating stability effects by applying dissolution testing

**Analytical Validation of Dissolution Testing Methods**

- Pharmacopoeial and Regulatory Recommendations (e.g., ICH Q2 (R1), USP <1092>, RDC No. 166/2017)
- Validation characteristics:
  - Specificity, Linearity, Precision, Accuracy and Robustness
  - Validation of automated procedures
- Some practical recommendations for performing the validation and recommended acceptance criteria
- Dissolution method transfer

**WORKSHOP II**

*Analytical Validation of Dissolution Methods*

Putting theory to work (case studies):

- Develop validation protocol for validation of dissolution methods for solid oral dosage forms
- Pitfalls in performing the experiments

**Dissolution Profile Comparison; Approaches and Issues**

- Importance of dissolution profile comparisons during drug product development and for a commercial product
- Regulatory requirements concerning dissolution profile comparison
- Different approaches to compare dissolution profiles: Model dependent and independent approaches
- Examples

**Conference Exhibition**

Leading suppliers of Dissolution apparatus and Dissolution systems are invited to exhibit their products. Please contact Mr. Niklaus Thiel for further information on the opportunity to exhibit at the conference:

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Dr Corinna Bode  
Bayer AG, Elberfeld, Germany
Dr Corinna Bode is a pharmacist by training and received her PhD in pharmaceutical technology from the Université de Lille, France. Her doctoral thesis focused on biodegradable implants (both pre-formed and in situ-forming) and the underlying mechanisms for drug release and degradation. She joined Bayer in 2020 and is heading a dissolution lab within the Drug Product Development department.

Dr Jan Joseph  
Bayer AG, Berlin, Germany
Dr Jan Joseph is a pharmacist by training and obtained his PhD in Pharmaceutical and Medicinal Chemistry from Freie Universität Berlin, where he was heading a unit of the departments core facility for chromatography and mass spectrometry focusing on (bio-)pharmaceutical analyses for three years. In 2020 he joined Bayer’s Analytical Development department within Chemical and Pharmaceutical Development and is currently heading a dissolution lab within the Drug Product Development department.

Dr Gerd Michael Maier  
Boehringer Ingelheim Pharma GmbH & Co. KG, Biberach, Germany
Dr Gerd-Michael Maier is a chemist by training and did his PhD graduation in bioinorganic chemistry at the University of Konstanz. He joined Boehringer Ingelheim in 1997 where he started in the Drug Regulatory Affairs department and worked as a regulatory affairs manager. After three years as team leader Regulations & Training in the Quality Systems group Gerd-Michael joined the department of Drug Discovery Support in research leading a CMC lab for almost 10 years. Since 2014 he holds the position of a dissolution lab head within the Analytical Development Department at Boehringer Ingelheim, Biberach, Germany.

Dr Johanna Milsmann  
Boehringer Ingelheim Pharma GmbH & Co. KG, Biberach, Germany
Dr Johanna Milsmann joined the Analytical Development Department at Boehringer Ingelheim in Biberach, Germany, as a Postdoc in 2018. Currently, she is heading a dissolution laboratory at Boehringer Ingelheim in Biberach, which is responsible for the development and validation of QC dissolution methods. In addition, she is leading all biorelevant dissolution activities as well as oversees all dissolution activities concerning novel formulations such as long acting injectables. Prior joining Boehringer Ingelheim she was a Postdoc at Abbvie in Ludwigshafen, Germany, focusing on discriminative dissolution setups for ASD formulations. Johanna studied Food Science and Technology and received her PhD from the University of Kiel.
Date
Wednesday, 27 June 2024, 9.00 h – 18.00 h
(Registration and coffee 8.30 – 9.00 h)
Thursday, 28 June 2024, 8.30 h – 15.30 h

Venue
Barceló Hotel Hamburg
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hamburg@barcelo.com

Fees (per delegate, plus VAT)
ECA Members € 1,690
APIC Members € 1,790
Non-ECA Members € 1,890
EU GMP Inspectorates € 945

The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on both days and all refreshments. VAT is reclaimable.

Accommodation
CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form/POG when you have registered for the course. Reservation should be made directly with the hotel. Early reservation is recommended.

Registration
Via the attached reservation form, by e-mail or by fax message.
Or you register online at www.gmp-compliance.org.

Conference language
The official conference language will be English.

Organisation and Contact
ECA has entrusted Concept Heidelberg with the organisation of this event.

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For questions regarding reservation, hotel, organisation etc. please contact:
Mr Niklaus Thiel (Organisation Manager) at +49(0)62 21/84 44 43, or at thiel@concept-heidelberg.de

Social Event
At the end of the first course day you are cordially invited to a social event. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

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Internationally Acknowledged Certificate from ECA Academy

The EU GMP Guide requires: “…All personnel should be aware of the principles of Good Manufacturing Practice that affect them and receive initial and continuing training,…”. This is why you receive an acknowledged participant certificate, which lists the contents of the seminar in detail and with which you document your training.

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1. We are happy to welcome a substitute colleague at any time.
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   - Cancellation until 4 weeks prior to the conference 10%,
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   - Cancellation within 2 weeks prior to the conference 100%.

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Terms of payment: Payable without deductions within 10 days after receipt of invoice.

Important: This is a binding registration and above fees are due in case of cancellation or non-appearance. If you cannot take part, you have to inform us in writing. The cancellation fee will then be calculated according to the point of time at which we receive your message.

In case you do not appear at the event without having informed us, you will have to pay the full registration fee, even if you have not made the payment yet. Only after we have received your payment, you are entitled to participate in the conference (receipt of payment will not be confirmed)! (As of July 2022).

German law shall apply. Court of jurisdiction is Heidelberg.

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