ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Quality Control Manager

Speakers

Dr Corinna Bode
Bayer

Dr Jan Joseph
Bayer

Dr Gerd Michael Maier
Boehringer Ingelheim

Dr Johanna Milsmann
Boehringer Ingelheim

Dissolution Testing

Development/Quality Control and *in vivo* Relevance

Live Online Training on 23/24 June 2026

Image: ERWEKA GmbH, Germany

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
- Automation of Dissolution Methods
- Mechanical Qualification and Performance Verification Testing (PVT)
- Development of Dissolution Methods
- OOS Results in Dissolution Testing
- Dissolution Profile Comparison

Objective

This Live Online Training 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 support drug product stability testing
- 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.

Background

The dissolution test is a key test parameter for assessing the performance of solid and semi-solid dosage forms in both drug development and quality control. In these fields it is used to assure batch-to-batch quality as well as providing process control information as part of the approach to Process Validation.

Dissolution testing is usually connected to *in vivo* performance because the API must be released from the formulation in the gastro intestinal tract (GIT) before *in vivo* absorption can occur. Therefore, dissolution testing is generally employed during drug product development and optimization. A dissolution test should therefore have adequate discriminatory power to detect relevant drug product changes.

Where dissolution testing data can be shown to be correlated to *in vivo* performance, clinical trials may be avoided by *in vitro* dissolution studies under certain circumstances, thereby reducing development time and costs.

There are many dissolution guidance and associated guidelines (e.g. FDA, EMA and the Pharmacopoeias) dealing with Scale-up and Post-Approval Changes, Bioequivalence studies, Waiver of *in vivo* Bioavailability and Bioequivalence Studies. Additionally, there are some country-specific dissolution requirements which are very challenging for global pharmaceutical companies.

This GMP Education Course will, therefore, cover the following topics:

- physicochemical and biopharmaceutical foundations
- dissolution method development,
- validation of the dissolution methodology
- approaches for setting specifications
- OOS and OOE Results in dissolution testing
- statistical methods for comparing dissolution profiles
- approaches for substitution of BE-studies (biowaiver) and
- approaches to establish *in vitro in vivo* correlations (IVIVC)
- country-specific dissolution requirements and challenges

In addition, the expectations of the European Medicines Agency (EMA) and of the pharmacopoeias (Ph.Eur. 2.9.3 and USP Chapters <711> and <1092>) including USP Reference Standard Tablets and Mechanical calibration for the dissolution apparatus qualification will be discussed.

The objective of this course is to cover all aspects of dissolution testing with a focus on practical examples. Two **online-workshops** are also part of the course in order to encourage the exchange of experience and to allow interactive and in depth discussions of the subject.

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 pharmacopeias (USP, EP, Pharm Jap)
- Miniaturization of dissolution tests
- General guidelines for dissolution testing
- Contents and differences in Chinese pharmacopeia
- 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 (including 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

Speakers

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 Dicovery 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 of the Live Online Training

Tuesday, 23 June 2026, 9.00 h - 17.15 h
Wednesday, 24 June 2026, 9.00 h - 17.15 h
All times mentioned are CEST.

Technical Requirements

We use Webex for our live online training courses and webinars. At www.gmp-compliance.org/training/online-training-technical-information you will find all the information you need to participate in our events and you can check if your system meets the necessary requirements to participate. If the installation of browser extensions is not possible due to your rights in the IT system, please contact your IT department. Webex is a standard nowadays and the necessary installation is fast and easy.

Fees (per delegate, plus VAT)

ECA Members € 1,890
APIC Members € 1,990
Non-ECA Members € 2,090
EU GMP Inspectorates € 1,045
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.

Registration

Via the attached reservation form, by e-mail or by fax – or search and register directly at www.gmp-compliance.org under the number 22491.

Presentations/Certificate

The presentations will be made available to you prior to the Live Online Training as PDF files. After the event, you will automatically receive your certificate of participation.

Conference language

The official conference language will be English.

Organisation and Contact

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

CONCEPT HEIDELBERG
P.O.Box 10 17 64
69007 Heidelberg, Germany
Phone: +49 (0) 6221/84 44 0
Fax: +49 (0) 6221/84 44 34
info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content please contact:
Dr Markus Funk (Operations Director) at
+49 (0) 6221/84 44 40, or at
funk@concept-heidelberg.de

For questions regarding organisation etc. please contact:
Ms Manuela Luckhaupt (Organisation Manager) at
+49 (0) 6221/84 44 66, or at
luckhaupt@concept-heidelberg.de

Your Benefits

Internationally Acknowledged Certificate from ECA Academy


CERTIFICATE

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.

****

This Training Course is recognized for the GMP/GDP Certification Scheme „Certified Quality Control Manager"

Building on your education the ECA GMP/GDP certification programmes provide you with the appropriate supplement to acquire this qualification. This training course is the first element for your additional certification. Simply choose any three courses within the programme according to your professional interest. Your certificate is then valid for two years. To renew it, you can pick any training from the ECA courses and conferences list within that two-years period – allowing you to broaden your knowledge in GMP and GDP compliance. Please find more information at www.gmp-certification.org

NEWS

Stay informed with the GMP Newsletters from ECA

The ECA offers various free of charge GMP newsletters for which you can subscribe to according to your needs.

To subscribe, simply scan the QR code on the right or visit www.gmp-compliance.org/gmp-newsletter

You cannot attend the Live Event?

We also offer many of the training courses and conferences as recordings. This means that you can watch the videos of the event „on demand" – whenever it suits you – on our web server. It is quite uncomplicated and doesn't require any software – you simply watch the video on your browser. You can find all recorded events at www.gmp-compliance.org/recordings.

If the bill-to-address deviates from the specifications on the right, please fill out here:

_____

_____

_____

_____

CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49 (0) 62 21/84 44 34

D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

Dissolution Testing | Live Online Training on 23/24 June 2026

Title, first name, surname

Department Company

Important: Please indicate your company's VAT ID Number Purchase Order Number, if applicable

City ZIP Code Country

Phone / Fax

E-Mail (Please fill in)

General terms and conditions
If you cannot attend the conference you have two options:
1. We are happy to welcome a substitute colleague at any time.
2. If you have to cancel entirely we must charge the following processing fees:
- Cancellation until 4 weeks prior to the conference 10 %,
- Cancellation until 3 weeks prior to the conference 25 %,
- Cancellation until 2 weeks prior to the conference 50 %
- Cancellation within 2 weeks prior to the conference 100 %.

CONCEPT HEIDELBERG reserves the right to change the materials, instructors, or speakers without notice or to cancel an event.
If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. CONCEPT HEIDELBERG will not be responsible for discount airfare penalties or other costs incurred due to a cancellation. **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.

Privacy Policy: By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at http://www.gmp-compliance.org/eca_privacy.html). I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.