ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Quality Control Manager

Speakers

Dr Ulli Backofen
Boehringer Ingelheim, Germany

Dr Heiko Brunner
Hamburg, Germany

Dr Thomas Fürst
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Dr Josef Hofer
EXDRA, Germany

Dr Cornelia Nopitsch-Mai
Formerly Quality Assessor, Germany

Dr Thomas Uhlich
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Stability Testing for Drug Substances and Drug Products

Live Online Training on 12/13 November 2025

Highlights

- Stability Testing from Early Development to Product Launch
- Guidelines for Stability Testing
- Stability Testing for
  - Biologicals
  - Drug Substances
  - Drug Products
- Submitting Stability Data
- Evaluation of Stability Results – Statistical Considerations

Objective

This Live Online Training is intended to provide information on different aspects of stability testing. The course will be opened by an overview of stability testing with a special focus on the ICH Guidelines. In the subsequent presentations, important aspects of stability testing for biologicals and throughout drug development are discussed. Another lecture focuses on stability testing for Drug Substances, followed by a talk on Drug Products. In a further presentation, the focus lies on to the various aspects of submitting stability data. Finally, statistical considerations will be covered in another lecture.

Background

Analytical methods that were not "stability-indicating" are frequently cited in FDA 483s and Warning Letters. This conference will thus address how to set impurity limits for related substances and degradation products based on method capability and stability results.

The analytical result, which will be compared to the specification, is affected by the variability of the measurement itself and depends also on the sampling process and on the variability of the manufacturing process of the tested product itself. This makes statistical considerations essential and consideration of the associated measurement uncertainties vital when setting or complying with specifications.

Finally, specifications for the API (drug substance), excipient(s) and the drug product are part of the quality section of the marketing authorisation application which has to be submitted to the competent authority.

Target Audience

This Live Online Training is of particular interest to specialists from QA, QC and Regulatory Affairs departments of the API and pharmaceutical industry and CROs as well as to members of the EU inspectorates and authorities. Participants have the opportunity to exchange their experiences they gained with the different aspects of 'specifications' with the experts from the API and pharmaceutical industry as well as with members of competent authorities.

Programme

Current ICH and CHMP Guidelines for Stability Testing

- Overview of Stability Guidelines
- Concepts of Stability Testing
- Retest period and shelf-life
- Post-marketing Stability Studies
- Future Activities

Stability Testing for Biologicals

- Overview of regulatory requirements
- Types of stability studies for Biopharmaceuticals
- Practical aspects of stability studies with Biopharmaceuticals
- Degradation pathways
- Setting shelf life during early and late stage development

Stability Testing throughout Drug Development

- Must the development stability programme meet ICH Q1A?
- Stability testing from early development to product launch
- Clinical stability for comparators
- Site specific stability

Stability Testing for Drug Substances

- Stability protocols
- Stress testing
- Photostability testing
- Documentation

Stability Testing for Drug Products

- Strategy of Stability Testing
- Performance of new Drug Products
- Related Finished Products with existing substances
- Follow-up Stability Testing

Submitting Stability Data

- Regulatory Strategy Stability
- Drug Substance and Drug Product Stability Data and Evaluation
- Storage recommendations/labelling/SmPC
- Stability studies, commitments post approval
- Typical questions from authorities and answers

Evaluation of Stability Results – Statistical Considerations

- Sample number and replication
- Trend analysis
- Outliers
- Pooling of batch data
- Shelf-life prediction

Dr Ulli Backofen
Boehringer Ingelheim, Germany

Dr Backofen started his career as postdoc in pharmaceutical industry in 2001. In 2003 he became head of analytical laboratory (NCE) at Boehringer Ingelheim. From 2010 to 2018 he worked as R&D project leader and was responsible for various NCE and NBE projects. In 2018 he was appointed director and Head of Quality Control in the department Analytical Development Biologicals at Boehringer Ingelheim in Biberach.

Dr Heiko Brunner
Hamburg, Germany

Dr Brunner is a chemist who started his career in the pharmaceutical industry in 1991. He worked for various originator companies in the field of early and late phase product development. In 2008, he transitioned to the generic industry. In addition to holding leadership roles in product development, he also took on key positions in project management and served as Head of Quality Control and acted as a lead GMP auditor.

Dr Thomas Fürst
Boehringer Ingelheim, Germany

Dr Fürst joined Schering in 1997 working in a production facility for oral dosage forms. In 2007 he joined Boehringer Ingelheim as a CMC expert. From 2013 – 2018 he was head of development of Consumer Healthcare at Boehringer (from 2017 SANOFI). Since 2018 Dr Fürst is again with Boehringer as head of laboratory of the development department.

Dr Josef Hofer
EXDRA GmbH, Germany

Dr Josef Hofer is Managing Director of EXDRA GmbH (Excellence in Drug Regulatory Affairs.). Working for and in international pharmaceutical industry since 1980. Dr Hofer holds a lectureship at the University in Bonn for Drug Regulatory Affairs.

Dr Cornelia Nopitsch-Mai
Formerly Quality Assessor, Germany

Dr Nopitsch-Mai was scientist at the Federal Institute for Drugs and Medical Devices in the assessment of the quality part of the dossier since 1991. Since 2000 she was assessor for the Certification Procedure (EDQM) in Strasbourg. She was member of the Technical Advisory Board (EDQM) from 2001 until 2010; in that time she was chairperson from 2005 until 2010. From 2007 until 2011 she was a member of the EMA Quality Working Party.

Dr Thomas Uhlich
Bayer, Germany

Thomas Uhlich studied chemistry at Humboldt University Berlin and joined the Analytical Development function of Schering AG in 1998 after postdoctoral fellowships in the USA and Germany. Starting in 2006, he was heading a development laboratory of Bayer Pharmaceuticals. This laboratory was specialized in the development and validation of analytical methods as well as quality control and stability testing of pharmaceuticals in clinical development. Currently, he is working as a CMC Project Lead for drug development.

This Training Course is recognized for the GMP/GDP Certification Scheme

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.
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GERMANY

Reservation Form (Please complete in full)

☐ Stability Testing for Drug Substances and Drug Products | Live Online Training on 12/13 November 2025

☐ Setting Specifications and Acceptance Criteria | Live Online Training on 11/12 November 2025

Please tick ONE group for the Parallel Sessions:

☐ *Group I: APIs Manufactured by Chemical Synthesis / Drug Products Containing Chemical APIs*

☐ *Group II: Drug Substances/Drug Products Manufactured by Biotechnological Processes*

Title, first name, surname

Department | Company

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

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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 %.

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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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Date of the Live Online Training

Wednesday, 12 November 2025, 14.00 – 17.00 h CET
Thursday, 13 November 2025, 09.00 – 16.30 h CET

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.

Conference Fees (per delegate plus VAT)

Non-ECA Members € 1,890
ECA Members € 1,690
APIC Members € 1,790
EU GMP Inspectorates € 945
The conference fee is payable in advance after receipt of invoice.

Would you like to save money?

If you book the conference "Setting Specifications" (11/12 November 2025) AND in addition the conference "Stability Testing for Drug Substances and Drug Products" (12/13 November 2025) the fees reduce as follows:

Stability Testing AND Setting Specifications

ECA Members € 2,790
APIC Members € 2,890
Non-ECA Members € 2,990
EU GMP Inspectorates € 1,495

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 22028 or 22027 (for Stability Testing + Setting Specifications). To avoid incorrect information, please give us the exact address and full name of the participant.

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
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