ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Quality Control Manager

Speakers

Dr Ulli Backofen
Boehringer Ingelheim, Germany

Dr Thomas Fürst
Boehringer Ingelheim, Germany

Dr Josef Hofer
EXDRA, Germany

Dr Cornelia Nopitsch-Mai
Formerly Quality Assessor, Germany

Dr Bettina Pahlen
Quality x Pharma Consulting, Germany

Dr Thomas Uhlich
Bayer, Germany

Setting Specifications and Acceptance Criteria

Live Online Training on 11/12 November 2025

How to Achieve Regulatory Compliance for APIs, Biological Substances and Drug Products

Highlights

- Principles for Setting of Release and Shelf-life Specifications throughout Development
- Regulatory Requirements for Specifications (ICH Q6A)
- Specifications of Biopharmaceuticals
- Organic Impurities, Degradation Products and Genotoxic Impurities
- Rational Development and Justification of
  - API Specifications
  - Drug Products Specifications
  - Biological Drug Substances and Products
- Specifications for Specific Drug Products
- Setting Specifications in the CTD

Objective

This Live Online Training covers all aspects of specifications for Active Pharmaceutical Ingredients (APIs = Drug Substances), biological substances and pharmaceutical drug products from an **analytical and a registration perspective**.

In the workshops the participants will elaborate specifications

- for drug substance and drug product based on different case studies
- specifications of biotechnological drug substances/drug products – general part
- specifications of biotechnological drug substances/drug products – related to the impurity profiles

These example specifications will be useful "take home messages" which will help the participants to define or to evaluate specifications in their daily work.

Background

In the development of new pharmaceutical products it is a great challenge to establish meaningful and reasonable specifications, which are scientifically sound and appropriate for APIs (chemical and biological drug substances), excipients and drug products. According to ICH Guideline Q6A, a specification is defined as a list of tests, references to analytical procedures, and appropriate acceptance criteria, which are numerical limits, ranges, or other criteria for the tests described. Learn about latest news and **important aspects** of **excipients**, such as **functionality testing** (EP and USP) as well as **what GMP-level is requested** for excipients. Concentrate on the essentials for packaging material including important information to be included in the CTD.

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.

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. Furthermore, **genotoxic impurities** and strategies for their control will be presented and **QbD (Quality by Design)** will also be discussed.

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

Part I – Regulatory Requirements and Setting Specifcations during the Development Phase

Basic Principles for Setting of Release and Shelf-Life Specifications

- Some basic statistics: Distribution and Variation
- Variation and specifications
- Changes over time and shelf-life specification
- Process Capability
- Control strategy
- QbD or not to be

Current Regulatory Requirements for Setting Specifications (ICH Q6A)

- Regulatory overview
- Impact of pharmacopoeial provisions
- Setting specifications for active substances and finished products
- Justification of specifications
- Changes/variations
- Introduction to the requirements of risk assessment with focus on setting specifications for heavy metals
- How authorities will proceed in respect of submitting the required documentation for approved marketed products

Specifications of Biopharmaceuticals

- Overview of regulatory requirements
- Critical Quality attributes and Control Strategy
- Differences between NCEs and NBEs
- Considerations for Drug Substance and Drug Product
- Specifications during early and late stage development
- Acceptance criteria at release and for shelf-life

Organic Impurities and Degradation Products with Special Emphasis on Genotoxic Impurities

- What do the guidelines tell us
- Impurity identification and profiling
- Impurity tracking
- Toxicological qualification
- Genotoxic impurities
- Control of genotoxic impurities

Part II – Chemical APIs and Biopharmaceutical Drug Development

Parallel Session A (Lectures and Workshops)

CHEMICAL APIs
Group I: APIs Manufactured by Chemical Synthesis

Lecture and Workshop Rational Development and Justification of API Specfications

- In this workshop participants will elaborate specifications comprising typical tests for APIs:
- Assay, organic impurities and degradation products, water, residual solvents, heavy metals, particle size distribution, polymorphs, genotoxic impurities etc.

BIOLOGICALS
Group II: Drug Substances/Drug Products Manufactured by Biotechnological Processes – Part 1

Lecture and Workshop Setting Specifications in early Biopharmaceutical Drug Development (with a special focus on Monoclonal Antibodies)

- General overview of manufacturing processes for biopharmaceuticals and process control
- Analytical testing scope for biopharmaceuticals
- How to set specifications: principles to consider and justification
- Group Work

Part III – Specific Considerations during Development and for Specific Dosage Forms

Setting Specifications throughout Drug Development

- Specifications throughout development
- Specifications in Pharmacopoeias
- Stability of the manufacturing process
- Specifications for comparator products

Specifications for Specific Drug Products – What is the Difference to Standard Formulations

- Specific aspects required for special drug products, e.g.
- Gastro-intestinal therapeutic systems (GITS) or osmotic-controlled release oral delivery systems (OROS)
- Transdermal patches
- Orally inhaled and nasal drug products (OINDPs)

Part IV – Drug Products and Biological Impurities

Parallel Session B (Lectures and Workshops)

DRUG PRODUCTS
Group I: Drug Products Containing APIs (manufactured by chemical synthesis)

Lecture and Workshop Rational Development and Justification of Drug Products Specifications

- In this workshop participants will elaborate specifications comprising typical tests for different types of drug products, e.g. assay, purity, content uniformity, dissolution, fill volume, endotoxines, sterility etc.

BIOLOGICALS
Group II: Drug Substances/Drug Products Manufactured by Biotechnological Processes – Part 2

Lecture and Workshop Impurities in Biological Drug Substances and Drug Products (with a special focus on Monoclonal Antibodies)

- Impurities from chemical synthesis versus biotechnological process
- Definition of impurities and their classification: product-related impurities, process-related impurities, contaminants and identification of possible degradation products
- How to deal with impurities in biological drug substances and drug products
- Analytical techniques and other aspects

Part V – Common Technical Document (CTD)

Setting Specifications in the CTD

- Total Control Strategy and Regulatory background
- Drug Substances, Excipients and Drug Products
- Packaging materials
- Which information should be included in the CTD
- Typical questions from authorities and answers

Speakers

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 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 is 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 Bettina Pahlen
Quality x Pharma Consulting, Germany

Bettina Pahlen, PhD, studied pharmacy at the University of Muenster, Germany, graduated in pharmaceutical chemistry and performed post-docs in USA and Germany. During the last 15 years she worked at university, authority and in different areas of the pharmaceutical industry (R&D, manufacturing, quality control, quality assurance). Since July 2007, she has been working as a consultant in the pharmaceutical industry focussing on GxP Quality Assurance aspects.

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.

Date of the Live Online Training

Tuesday, 11 November 2025, 09.00 – 18.00 h CET
Wednesday, 12 November 2025, 08.30 – 13.00 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
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The conference fee is payable in advance after receipt of invoice.

Would you like to save money?

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

Setting Specifications AND Stability Testing

ECA Members € 2,790
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EU GMP Inspectorates € 1,495

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.

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 22026 or 22027 (for Stability Testing + Setting Specifications). To avoid incorrect information, please give us the exact address and full name of the participant.

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 organisation etc. please contact:
Ms Nicole Bach (Organisation Manager) at
+49 (0)62 21/84 44 22, or per e-mail at
nicole.bach@concept-heidelberg.de

Your Benefits:

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.

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

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D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

☐ 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*

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

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
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2. If you have to cancel entirely we must charge the following processing fees:
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- 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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EXDRA, Germany

Dr Cornelia Nopitsch-Mai
Formerly Quality Assessor, Germany

Dr Thomas Uhlich
Bayer, Germany

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.

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D-69007 Heidelberg
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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:

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Title, first name, surname

Department | Company

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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

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info@concept-heidelberg.de | www.concept-heidelberg.de

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funk@concept-heidelberg.de

For questions regarding organisation etc. please contact:
Ms Nicole Bach (Organisation Manager) at
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nicole.bach@concept-heidelberg.de