



## 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

22/23 October 2024 | Barcelona, Spain



*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 event 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 conference 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.

## Moderator

Dr Thomas Fürst, Boehringer Ingelheim, Germany

## Programme

### Part I – Regulatory Requirements and Setting Specifications during the Development Phase

#### Basic Principles for Setting of Release and Shelf-Life Specifications

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- 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)

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- 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

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- 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

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- 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 Specifications

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- 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)

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- 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

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- 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

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- 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

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- 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)

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- 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

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- 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

## Social Event

Participants of the conference “Setting Specifications” are cordially invited to a dinner on the evening of the first conference day. This is an excellent opportunity to share your own views and experiences with colleagues from other companies in a relaxed and casual atmosphere.



# 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

Tuesday, 22 October 2024, 09.00 h - 18.00 h

(Registration and coffee 08.30 h - 09.00 h)

Wednesday, 23 October 2024, 08.30 h - 14.00 h

## Venue

Barceló Sants Hotel

Plaça dels Països Catalans, s/n

08014 Barcelona | Spain

Phone: +34 (93) 503 53 00

E-Mail: [sants@barcelo.com](mailto:sants@barcelo.com)

## 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 and includes dinner on the first day, lunch on both days and all refreshments. VAT is reclaimable.



### 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" (23-24 October 2024) the fees reduce as follows:

### Setting Specifications AND Stability Testing

ECA Members € 2,790

APIC Members € 2,890

Non-ECA Members € 2,990

EU GMP Inspectorates € 1,495

## Presentations/Certificate

The presentations for this event will be available for you to download and print before and after the event. Please note that no printed materials will be handed out on site and that there will not be any opportunity to print the presentations on site. After the event, you will automatically receive your certificate of participation.



### Important Information!

The presentations of this ECA Course will be available for download and your print-out 1 week before the conference.

Note: there will be no print-outs available during the conference.

## 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](http://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.

CONCEPT HEIDELBERG

P.O.Box 10 17 64 | 69007 Heidelberg, Germany

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[www.concept-heidelberg.de](http://www.concept-heidelberg.de)

For questions regarding content please contact:

Dr Markus Funk (Director Operations) at

+49 (0)62 21/84 44 40 or per e-mail at

[funk@concept-heidelberg.de](mailto:funk@concept-heidelberg.de)

For questions regarding organisation etc. please contact:

Ms Marion Grimm (Organisation Manager) at

+49 (0)62 21/84 44 18, or per e-mail at

[marion.grimm@concept-heidelberg.de](mailto:marion.grimm@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

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](http://www.gmp-certification.org)



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GERMANY

### Reservation Form (Please complete in full)

- Setting Specifications and Acceptance Criteria | 22 – 23 October 2024, Barcelona, Spain  
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 | 23 – 24 October 2024, Barcelona, Spain

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.

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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: [www.gmp-compliance.org/eca\\_privacy.html](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.



## Speakers



Dr Ulli Backofen  
Boehringer Ingelheim, Germany



Dr Heiko Brunner  
Hamburg, Germany



Dr Thomas Fürst  
Boehringer Ingelheim, Germany



Dr Josef Hofer  
EXDRA, Germany



Dr Cornelia Nopitsch-Mai  
Formerly Quality Assessor, Germany



Dr Thomas Uhlich  
Bayer, Germany

# Stability Testing for Drug Substances and Drug Products

23/24 October 2024 | Barcelona, Spain



## 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 event is intended to provide information on different aspects of stability testing. The conference will be opened by an overview of stability testing with a special focus on important changes in current revisions of ICH Guidelines. In the subsequent presentations, important aspects of stability testing for biologicals and throughout drug development are discussed. The second day commences with a lecture on stability testing for Drug Substances, followed by a talk on Drug Products and a risk based approach for stability testing covering different climatic zones. In the following presentation, the focus lies on to the various aspects of submitting stability data. The specific challenges of data evaluation and typical questions from authorities will also be addressed. 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 conference 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.

## Moderator

Dr Thomas Fürst, Boehringer Ingelheim, Germany

## Programme

### Current ICH and CHMP Guidelines for Stability Testing

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- Overview of Stability Guidelines
- Concepts of Stability testing
- Retest period and Shelf-life
- Post-marketing Stability Studies
- Future Activities

### Stability Testing for Biologicals

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- 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

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- 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

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- Stability protocols
- Stress testing
- Photostability testing
- Documentation

### Stability Testing for Drug Products

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

### Submitting Stability Data

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- 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

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- 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 and has worked since 1991 for various international pharmaceutical companies in the field of product development. Since 2008 he has been with HELM AG, where he worked in the areas of pharmaceutical development, project management and analytical development and quality control. Dr Brunner was head of quality control and 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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Please find more information at [www.gmp-certification.org](http://www.gmp-certification.org)

### Social Event

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  - Setting Specifications and Acceptance Criteria | 22/23 October 2024, Barcelona, Spain
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Title, first name, surname

Department

Company

Important: Please indicate your company's VAT ID Number

Purchase Order Number, if applicable

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## Date

Wednesday, 23 October 2024, 14.00 h - 18.15 h  
(Registration and coffee 13.30 h - 14.00 h)

Thursday, 24 October 2024, 08.30 h - 15.00 h

## Venue

Barceló Sants Hotel  
Plaça dels Paisos Catalans, s/n | 08014 Barcelona | Spain  
Phone: +34 (93) 503 53 00 | E-Mail: [sants@barcelo.com](mailto:sants@barcelo.com)

## Conference Fees (per delegate plus VAT)

Non-ECA Members € 1,890 | ECA Members € 1,690 |  
APIC Members € 1,790 | EU GMP Inspectorates € 945  
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### Stability Testing AND Setting Specifications

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## Conference language

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## Organisation and Contact

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Phone +49(0)62 21/84 44-0 | Fax +49(0)62 21/84 44 34  
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For questions regarding content please contact:

Dr Markus Funk (Director Operations) at  
+49 (0)62 21/84 44 40 or per e-mail at  
[funk@concept-heidelberg.de](mailto:funk@concept-heidelberg.de)

For questions regarding organisation etc. please contact:

Ms Marion Grimm (Organisation Manager) at  
+49 (0)62 21/84 44 18, or per e-mail at  
[marion.grimm@concept-heidelberg.de](mailto:marion.grimm@concept-heidelberg.de)