20 YEARS ECA Academy Your GMP/GDP Information Source

Setting Specifications and Acceptance Criteria

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

Speakers:

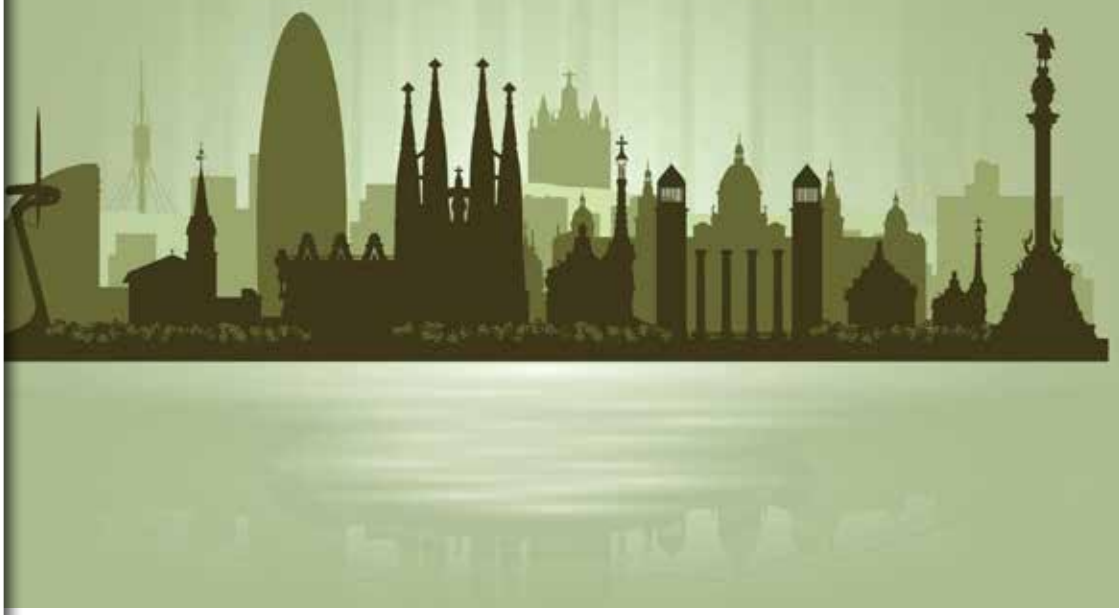
Dr Thomas Fürst
Boehringer Ingelheim Pharma, Germany

Dr Hiltrud Horn
Horn Pharmaceutical Consulting, Germany

Dr Cornelia Nopitsch-Mai
Bonn, Germany

Dr Bettina Pahlen
Quality x Pharma Consulting GmbH, Germany

Dr Thomas Uhlich
Bayer AG, Germany



27 – 28 November 2019, Barcelona, Spain

Highlights:

- Regulatory Requirements for Specifications (ICH Q6A)
- Regulatory Requirements for Specifications of Biotech Products/ Well-characterised Biologicals (ICH Q6B, etc.)
- Principles for Setting of Release and Shelf-life Specifications throughout Development
- Organic Impurities, Degradation Products and Genotoxic Impurities
- Rational Development and Justification of
  - API Specifications
  - Drug Products Specifications
  - Biological Drug Substances and Products focussing on Monoclonal Antibodies (mAbs)
- Specifications for Specific Drug Products
- Specifications for Excipients and Container Closure Systems (EU/US) including important aspects such as latest news on functionality testing (EP, USP) and GMP for excipients

This conference is recognised for the ECA GMP Certification Programme „Certified QC Manager“. Please find details at www.gmp-certification.eu

Setting Specifications and Acceptance Criteria

27-28 November 2019, Barcelona, Spain

Objectives

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.

Programme

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

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

Programme

Current Regulatory Requirements for Specifications of Biotech Products/ Well-characterised Biologicals (ICH Q6B and other Guidelines)

- Overview of regulatory requirements
- Characterization of product and establishing acceptance criteria
- Analytical aspects including method validation
- Setting up specifications – principles to consider
- New approaches: Design Space for a Biotechnological Product – ICH Q11 requirements

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

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 Specifications

- 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

Programme

Part III – Specific Considerations during Development and for Specfic 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
- Group work

Part V – Excipients and Container Closure Systems

Specifications for Excipients and Container Closure Systems (EU/US)

- Excipients in the CTD: What needs to be considered for setting specs in the CTD?
- Excipients: What is new and important for you (functionality testing, GMP for excipients)
- Packaging material: Which information should be included in the CTD?
- What needs to be considered in a global environment?
- What are the typical questions from Authorities?

Speakers

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 Hiltrud Horn, Horn Pharmaceutical Consulting, Germany
Dr Horn is managing director of HORN PHARMACEUTICAL CONSULTING with focus on CMC, GMP and Regulatory Affairs. She started in pharma industry in 1990 and held several managerial positions within Hoffmann-La Roche in Basel and Knoll (Abbott) with global responsibility within QC / QA / Regulatory Affairs / Project Management / Medical Writing.

Dr Cornelia Nopitsch-Mai, Quality Assessor, Germany
Dr Nopitsch-Mai is 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 GmbH, Alling, 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 AG, Drug Discovery, Pharmaceuticals, Berlin, 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. Since then, he has been working in Drug Discovery Pharmaceuticals at Bayer AG. He is heading a laboratory which is specialized in the development and validation of analytical methods as well as quality control and stability testing of pharmaceuticals in clinical development.

Social Event
Participants of the conference "Setting Specifications" are cordially invited to a guided sight-seeing tour of Barcelona followed by a dinner in a nice restaurant 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.

Easy Registration

Reservation Form:
CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg, Germany

Reservation Form:
+ 49 6221 84 44 34

e-mail:
info@concept-heidelberg.de

Internet:
www.gmp-compliance.org

Date
Wednesday, 27 November 2019,
09.00 h - 18.00 h
(Registration and coffee
08.30 h - 09.00 h)
Thursday, 28 November 2019,
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
sants@barcelo.com

Conference fees (per delegate plus VAT)
ECA Members € 1,590
APIC Members € 1,690
Non-ECA Members € 1,790
EU GMP Inspectorates € 895
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

Would you like to save money?
If you book the conference "Setting Specifications" AND in addition the conference "Stability Testing in Drug Substances and Drug Products" (28/29 November 2019) the fees reduce as follows:

Setting Specifications AND Stability Testing
ECA Members € 2,380
APIC Members € 2,580
Non-ECA Members € 2,780
EU GMP Inspectorates € 1,390

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 event. Reservation should be made directly with the hotel. Early reservation is recommended.

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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Ms Nicole Bach
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the responsible Organisation Manager,
is happy to help you with any questions concerning reservation, hotel, etc.

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Germany

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Reservation Form (Please complete in full)

❑ **Setting Specifications and Acceptance Criteria**
27/28 November 2019, 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**
28/29 November 2019, Barcelona, Spain

□ Mr □ Ms

_____
Title, first name, surname

_____
Company

_____
Department

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

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City Zip Code

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Country

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General terms and conditions
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2. If you have to cancel entirely we must charge the following processing fees: Cancellation
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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 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.

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Stability Testing for Drug Substances and Drug Products

Speakers:

Dr Thomas Fürst
Boehringer Ingelheim Pharma, Germany

Dr Wolfgang Grimm
Germany

Dr Hiltrud Horn
Horn Pharmaceutical Consulting, Germany

Dr Cornelia Nopitsch-Mai
Bonn, Germany

Dr Jordi Ruiz-Combalia
Audit GMP, Spain

Dr Thomas Uhlich
Bayer AG, Germany

28/29 November 2019, Barcelona, Spain

Highlights:

- Stability testing from early development to product launch
- Stability testing strategies for Drug Products
- Essential hints for writing the stability part in the CTD
- Stability Studies after approval (EU/US)
- Evaluation of stability results – Statistical Considerations

This conference is recognised for the ECA GMP Certification Programme „Certified QC Manager".
Please find details at www.gmp-certification.eu

Stability Testing for Drug Substances and Drug Products

28/29 November 2019, Barcelona, Spain

Objectives

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, practical aspects of stability testing for drug substances and throughout drug development are discussed.

The second day commences with a lecture on stability testing for Drug Products and a risk based approach for stability testing covering different climatic zones. In the following talks special consideration is given to the various aspects of post-marketing stability testing procedures. The specific challenges of data evaluation and the structure of the Common Technical Document (CTD) will then be addressed

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

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, SANOFI, Germany

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 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

Programme

Submitting Stability Data – The CTD Structure

- Drug substance stability
- Drug product stability
- Storage recommendations/labelling
- Essential hints for writing the stability part in the CTD

Evaluation of Stability Results – Statistical Considerations

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

Post-marketing Stability Testing

- Stability studies after approval (EU/US)
- Changes with impact on stability
- Examples

Speakers

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 Wolfgang Grimm, Biberach, Germany
Dr Grimm was responsible for the analytical development and stability testing at Boehringer Ingelheim Pharma KG in Biberach. He wrote 35 papers and 4 books on Stability Testing and Analytical Development. He has been invited for lectures and workshops in Europe, USA, Japan, Brazil, South Africa, Thailand, Taiwan and Turkey. He has participated in the working party of the ICH Stability Guideline as a representative of the European Pharmaceutical Industry. He has been invited by the FDA as an advisor for the climatic zone concept.

Dr Hiltrud Horn, Horn Pharmaceutical Consulting, Germany
Dr Horn is managing director of HORN PHARMACEUTICAL CONSULTING with focus on CMC, GMP and Regulatory Affairs. She started in pharma industry in 1990 and held several managerial positions within Hoffmann-La Roche in Basel and Knoll (Abbott) with global responsibility within QC / QA / Regulatory Affairs / Project Management / Medical Writing.

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Dr Jordi Ruiz-Combalia, Audit GMP, Spain
Dr Ruiz-Combalia has 30 years experience in the Active Pharmaceutical Ingredient Industry, where he has had different responsibilities. In his current position he has been working as R&D Director. Since 1992, he is a member of the Organic Chemistry Expert Group of the Real Farmacopea Española. Since 1994, he is member of the Groups of Experts of the European Pharmacopoeia, currently chairman of Group 11S and collaborates with the APIC (Active Pharmaceutical Ingredients Committee) in the GMP Working Group.

Dr Thomas Uhlich, Bayer AG, Drug Discovery, Pharmaceuticals, Berlin, 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. Since then, he has been working in Drug Discovery Pharmaceuticals at Bayer AG. He is heading a laboratory which is specialized in the development and validation of analytical methods as well as quality control and stability testing of pharmaceuticals in clinical development.

Social Event

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Friday, 29 November 2019,
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Venue
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The responsible Operations Director
Dr Gerhard Becker,
phone +49(0)62 21/84 44 65,
becker@concept-heidelberg.de
will help you with any technical questions as regards content.

Ms Nicole Bach
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28/29 November 2019, Barcelona, Spain

❑ **Setting Specifications,** 27/28 November 2019, Barcelona, Spain
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□ Mr □ Ms

Title, first name, surname

Company

Department

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

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