



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

- 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 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.



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.



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Social Event

At the end of the first course day, participants of the conference “Stability Testing” are cordially invited to a social event. This is an excellent opportunity to share your own views and experiences with colleagues from other companies in a relaxed and casual atmosphere.



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- Stability Testing for Drug Substances and Drug Products | 23/24 October 2024, Barcelona, Spain
 - 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

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- 1. We are happy to welcome a substitute colleague at any time.
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 - Cancellation until 4 weeks prior to the conference 10 %
 - Cancellation until 3 weeks prior to the conference 25 %
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Important: This is a binding registration and above fees are due in case of cancellation. German law shall apply. Court of jurisdiction is Heidelberg.

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German law shall apply. Court of jurisdiction is Heidelberg.

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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

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 the second day and all refreshments. VAT is reclaimable.



Would you like to save money?

If you book the conference "Setting Specifications" (22-23 October) AND in addition the conference "Stability Testing for Drug Substances and Drug Products" (23-24 October 2024) 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

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.

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.

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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