Stability Testing for Drug Substances and Drug Products

28/29 November 2019, Barcelona, Spain

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

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
**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
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.

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 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 IIIS 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.

Participants of the conference “Stability Testing” are cordially invited to dinner. This is an excellent opportunity to share your own views and experiences with colleagues from other companies in a relaxed and casual atmosphere.
Reservation Form (Please complete in full)

- Stability Testing for Drug Substances and Drug Products, 28/29 November 2019, Barcelona, Spain
- Setting Specifications, 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

- Mr  
- Ms

Title, first name, surname

Company

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Important: Please indicate your company’s VAT ID Number

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Reserve a room at the Barceló Sants Hotel

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 fees (per delegate plus VAT)

- ECA Members € 1,590
- APIC Members € 1,690
- Non-ECA Members € 1,790
- EU GMP Inspectors € 895

The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on the second day and all refreshments. VAT is reclaimable.

If the conference must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. CONCEPT HEIDELBERG will not be responsible for discount airline penalties or other costs incurred due to a cancellation.

Terms of payment:
- Payable without deductions within 1 week after receipt of invoice.
- Payable without deductions within 10 days after receipt of invoice.

Important: This is a binding registration and the responsible Organisation Manager, Ms Nicole Bach, will help you with any technical questions as regards content.

If you have to cancel entirely we must charge the following processing fees: Cancellation within 1 week prior to the conference 100 %, within 2 weeks prior to the conference 50 %, within 4 weeks prior to the conference 20 %, within 6 weeks prior to the conference 10 %, within 8 weeks prior to the conference 5 %.

If you cannot attend the conference you have to inform us in writing. The cancellation fee will then be calculated according to the point of time at which we receive your message.

In case you do not appear at the event without having informed us, you will have to pay the full registration fees, 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 January 2012).

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 purposes 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.

Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this event.

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bach@concept-heidelberg.de, the responsible Organisation Manager, is happy to help you with any questions concerning reservation, hotel, etc.