ECA Academy
Your GMP/GDP Information Source

Stability Testing for Drug Substances and Drug Products

Speakers:

Dr Thomas Fürst
SANOFI, 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

29 – 30 November 2017, Vienna, Austria

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

29 – 30 November 2017, Vienna, Austria

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, SANOFI, Biberach, Germany
Dr Fürst joined Schering in 1997 working in a production facility for oral dosage forms. Later he joined the analytical development department. His responsibilities were method development and validation of analytical methods. In 2006 Dr Fürst was appointed head of the Pharmaceutical Development Services group of Bayer Schering Pharma AG in Berlin. In Aug 2007 Dr Fürst joined Boehringer Ingelheim as a CMC expert. At present he is a project leader in the development department for consumer healthcare products at SANOFI.

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 Hiltrud Horn is managing director of HORN Pharmaceutical Consulting with focus on CMC, GMP and Regulatory Affairs (EU and US). She started in pharma industry in 1990 and held several managerial positions within Hoffmann-La Roche in Basel and Knoll (now Abbott) in Ludwigshafen with global responsibility within QC/QA/Regulatory Affairs/Project Management/Medical Writing. She was consultant for the biotech and life science industry at Cap Gemini Ernst & Young prior to starting her own business more than 13 years ago. She is pharmacist with a Ph.D. and holds a Diploma in Pharmaceutical Medicine (Basel). Furthermore, she is specialised pharmacist for pharmaceutical analytics and for drug information.

Dr Cornelia Nopitsch-Mai, Quality assessor, Germany
Dr Cornelia Nopitsch-Mai studied pharmacy at the Free University Berlin and graduated in pharmaceutical biology. She 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 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

On 29 November you are cordially invited to a dinner. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed 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, 29 November 2017,
14.00 h - 18.15 h
(Registration and coffee 13.30 h - 14.00 h)
Thursday, 30 November 2017,
09.00 h - 15.15 h

Venue
Austria Trend Hotel
Park Royal Palace Vienna
Schlossallee 8
1140 Vienna, Austria
Phone +43/1/89110 9 200
Fax +43/1/891 109 050
email Park.royal.palace@austria-trend.at

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 conferences "Stability Testing" AND "Setting Specifications" (28-29 November 2017) AND/OR the Post-Conference Session "Stability Studies to support shipping/distribution of pharmaceuticals and biopharmaceuticals" (1 December 2017) simultaneously the fees reduce as follows:

Stability Testing AND post-Conference Session
ECA Members € 1,980
APIC Members € 2,180
Non-ECA Members € 2,380
EU GMP Inspectorates € 1,190

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

Setting Specifications AND Stability Testing AND post-Conference Session
ECA Members € 2,970
APIC Members € 3,270
Non-ECA Members € 3,570
EU GMP Inspectorates € 1,785

Accommodation
CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form when you have registered for the event. Please use this form for your room reservation to receive the specially negotiated rate for the duration of your stay.
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.
CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg, Germany
Phone +49 (0) 62 21/84 44-0
Fax +49 (0) 62 21/84 44 34
info@concept-heidelberg.de
www.concept-heidelberg.de

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.

Mr Niklaus Thiel
phone +49 (0) 62 21/84 44 43,
thiel@concept-heidelberg.de,
the responsible Organisation Manager,
is happy to help you with any questions concerning reservation, hotel, etc.

Reservation Form (Please complete in full)

+49 6221 84 44 34

❑ **Stability Testing for Drug Substances and Drug Products,**
29-30 November 2017, Vienna, Austria
❑ Post-Conference Session **Stability studies to support shipping/distribution of Pharmaceuticals and Biopharmaceuticals,** 1 December 2017, Vienna, Austria
❑ **Setting Specifications,** 28-29 November 2017, Vienna, Austria
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

If the bill-to-address deviates from the specification to the right, please fill out here:

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P.O. Box 10 17 64
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69007 Heidelberg
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Department

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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 2 weeks prior to the conference 10 %,
- until 1 weeks prior to the conference 50 %
- within 1 week prior to the conference 100 %.

CONCEPT HEIDELBERG reserves the right to change the materials, instructors, or speakers without notice or to cancel an event.

If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. CONCEPT HEIDELBERGwill not be responsible for discount airfare penalties or other costs incurred due to a cancellation.
Terms of payment: Payable without deductions within 10 days after receipt of invoice.
Important: This is a binding registration and above fees are due in case of cancellation or non-appearance. If you cannot take part, 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 fee, 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 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.

WA/07062017