ECA Academy
Your GMP/GDP Information Source

Speakers

Dr Thomas Fürst
Boehringer Ingelheim Pharma
Germany

Dr Wolfgang Grimm
Germany

Dr Cornelia Nopitsch-Mai
Quality Assessor, Germany

Dr Jordi Ruiz-Combalia
Audit GMP, Spain

Dr Thomas Uhlich
Bayer, Germany

Stability Testing for Drug Substances and Drug Products

Live Online Training on 03 December 2020

Highlights

- Current ICH and CHMP Guidelines for Stability Testing
- Stability Testing throughout Drug Development
- Stability Testing for Drug Substances
- Stability Testing for Drug Products
- Evaluation of Stability Results – Statistical Considerations

Live Q&A session after each presentation

Objectives

This Live Online Training is intended to provide information on different aspects of stability testing.

The event 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. Furthermore, stability testing for drug products and a risk based approach for stability testing covering different climatic zones are presented. In addition, the specific challenges of data evaluation will be addressed.

Background

Analytical methods that were not "stability-indicating" are frequently cited in FDA 483s and Warning Letters. This Live Online Training 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.

Target Audience

This Live Online Training 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.

During the Q&A sessions, 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 Markus Funk, CONCEPT HEIDELBERG

Programme

09.00 – 09.15 h
Introduction

09.15 – 10.45 h
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

10.45 – 11.00 h
Break

11.00 – 12.00 h
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

12.00 – 13.00 h
Break

13.00 – 14.00 h
Stability Testing for Drug Substances

- Stability protocols
- Stress testing
- Photostability testing
- Documentation

14.00 – 14.15 h
Break

14.15 – 15.15 h
Stability Testing for Drug Products

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

15.15 – 15.30 h
Break

15.30 – 16.30 h
Evaluation of Stability Results – Statistical Considerations

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

Q&A sessions after each presentation ensure interaction and that your questions are answered.

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 Live Online Training in detail and with which you document your training.

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 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 11S and collaborates with the APIC (Active Pharmaceutical Ingredients Committee) in the GMP Working Group.

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. 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.

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

_____

_____

_____

_____

CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49(0) 62 21/84 44 34

D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

☐ *Stability Testing for Drug Substances and Drug Products | Live Online Training on 03 December 2020*
and
☐ *Setting Specifications and Acceptance Criteria | Live Online Training on 02 December 2020*

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 2 weeks prior to the conference 10 %,
- Cancellation until 1 weeks prior to the conference 50 %
- Cancellation 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.

Date of the Live Online Training

Thursday, 03 December 2020, 09.00 – 16.30 h
All times mentioned are CET.

Technical Requirements

For our webinars, we use Cisco WebEx, one of the leading suppliers of online meetings.
At https://www.webex.com/test-meeting.html you can check if your system meets the necessary requirements for the participation at a WebEx meeting and at the same time install the necessary plug-in. Please just enter your name and email address for the test. If the installation is not possible because of your rights for the computer system, please contact your IT department.
WebEx is a standard nowadays and the necessary installation is fast and easy.

Fees (per delegate, plus VAT)

ECA Members EUR 890,-
APIC Members EUR 990,-
Non-ECA Members EUR 1,090,-
EU GMP Inspectorates EUR 545,-
The conference fee is payable in advance after receipt of invoice.

Would you like to save money?

If you book the Live Online Training "Stability Testing for Drug Substances and Drug Products" AND in addition the Live Online Training "Setting Specifications and Acceptance Criteria" (02 December 2020) the fees reduce as follows:

Setting Specifications AND Stability Testing
ECA Members € 1,380,-
APIC Members € 1,580,-
Non-ECA Members € 1,780,-
EU GMP Inspectorates € 890,-

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 will be made available to you prior to the Live Online Training as PDF files. 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
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

For questions regarding content please contact:
Dr Markus Funk (Operations Director) at
+49(0)62 21/84 44 40, or at
funk@concept-heidelberg.de

For questions regarding organisation etc. please contact:
Nicole Bach (Organisation Manager) at
+49(0)62 21/84 44 22 or at
bach@concept-heidelberg.de