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

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69007 Heidelberg, Germany

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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
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Setting Specifications AND Stability Testing
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Accommodation
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Reservation should be made directly with the hotel. Early reservation is recommended.

Conference language
The official conference language will be English.

Organisation and Contact
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❑ **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

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WA/07062017

Post-Conference Session

Stability Studies to Support Shipping/Distribution of Pharmaceuticals and Biopharmaceuticals

1 December 2017, Vienna, Austria

Speaker:

DR RAPHAEL BAR
BR Consulting, Israel

Highlights:

- Stability programs and stress testing – a regulatory overview
- Qualification of shipment and temperature monitoring
- World climatic zones and Mean Kinetic Temperature
- Storage label statements in the EU and the US
- Studies at different temperatures and conditions
- Investigation and evaluation of excursions and responsibility issues

With Workshop on **Evaluation of a Temperature Excursion in a shipped drug product**

This post-Conference Session ideally complements the ECA education courses
"Setting Specifications" (28-29 November 2017 in Vienna, Austria)
and
"Stability Testing of Drug Substances and Drug Products"
(29-30 November 2017 in Vienna, Austria).

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

Post Conference Session "Stability Studies to Support Shipping/ Distribution of Pharmaceuticals and Biopharmaceuticals"

1 December 2017, Vienna, Austria

Objectives

This session will give a comprehensive overview of tools that a Qualified Person (QP), Quality Assurance personnel or a Product Manager/ Manufacturer should have in order to evaluate the impact of excursions from the storage label instructions on the disposition of distributed shipments of pharmaceutical/biopharmaceutical products.

Background

The formal stability studies of pharmaceuticals and biopharmaceuticals are a well established discipline and they are regularly conducted at precisely monitored conditions of temperature (within 2°C) and of humidity (within 5% RH) under cGMP. However, the inevitable processes of shipping and distributing medicines from the manufacturer to wholesaler to warehouses to the end user via air, ship or car exposes often the shipments to temperatures and humidity different from the label storage conditions. For instance, how would you handle a shipment that was exposed to a varying temperature up to 61°C in the airport for an accumulated duration of several days? How would you evaluate the quality of a refrigerated injectable that was exposed to near zero or freezing temperatures for a few hours? Would you release or reject such a shipment which may cost hundreds of thousands of dollars?

Shipping/Distribution of a medicine is considered a "mobile storage". However, a temperature excursion outside the label instructions may also be considered a 'trauma" inflicted on the medicine and this may impact the quality of the newly arrived shipments. But the big question remains: how would that 'trauma" affect the quality at the end of the declared shelf life of any pharmaceutical and of a biopharmaceutical in particular? Will the long-term impact lead to a "hidden OOS"?

This course will address these aspects. Finally, a workshop will demonstrate how the evaluation of an example of a temperature excursion may be approached

Programme

Overview of stability programs and Stress Testing– regulatory view (GMP and GDP)

- Long-term and accelerated storage conditions of new drug substances and products (EU, USA)
- Stability storage programs for generic drugs (EU, USA)
- Stress testing vs Forced Degradations
- Stressing factors
- GDP Guides (EU, WHO, USP Chapter <1079>)
- "Time-out-of-Storage" and "stability budget" concept

Overview of qualification of shipment of pharmaceuticals and Temperature Monitoring

- The four Qs: DQ, IQ, OQ and PQ
- Temperature monitoring in a shipment

World climatic zones and Mean Kinetic Temperature (MKT)

- Mean Kinetic Temperature (MKT) and relative humidity
- Interpretation of MKT
- MKT from temperature loggers
- Global climatic zones by ICH and WHO

Storage label statements (EU and USA)

- Linking storage instructions to formal stability studies
- Labeling statements for various pharmaceuticals (EMA guideline)
- USP controlled temperatures

Programme

Stability studies to support shipping/distribution of pharmaceuticals and biopharmaceuticals

- Studies at elevated extreme temperatures
- Studies at low extreme conditions
- When, how and what?
- Thermal Cyclic studies
- What attributes to test

Workshop
Evaluation of a Temperature Excursion in shipped refrigerated drug product

Investigation of excursions from storage label conditions

- Handling an excursion
- What stability data are required to investigate temperature excursions
- Responsibilities of manufacturer, distributor and QP

Evaluation of Temperature Excursions

- Estimation of degradation rates at the excursion temperature
- Estimation of degradation at the expected long-term shelf-life
- Estimation of a maximal "Time-out-of-Storage" of a drug

Speaker

DR RAPHAEL BAR, BR CONSULTING, ISRAEL
Raphael Bar is presently a pharmaceutical consultant for the Pharma and bio-Pharma industries. He is consulting various companies and provides development and analytical support to investigational, generic, new drugs as well as combination device-drug products and CMC project management. With a doctorate in Chemistry (1984), Dr. Bar joined (1995) Teva Pharmaceuticals and headed for three years the Analytical R&D Laboratory. He was involved in preparation of ANDA files. He then joined Pharmos where he managed the quality control and R&D laboratory till 2007.
As Senior Director of Analytical Development he was actively involved in preparation of CMC packages for clinical trial studies. From 2009 until June 2015, he was a member of the scientific advisory board of global PDA (USA).

This post-Conference Session ideally complements the ECA education courses "Setting Specifications" (28-29 November 2017 in Vienna, Austria) and "Stability Testing of Drug Substances and Drug Products" (29-30 November 2017 in Vienna, Austria).

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Date
Friday, 1 December 2017, 08.30 h - 16.00 h
(Registration and coffee 08.00 h - 08.30 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
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Fees (per delegate plus VAT)
ECA Members € 690
APIC Members € 790
Non-ECA Members € 890
EU GMP Inspectorates € 445
The conference fee is payable in advance after receipt of invoice and includes conference documentation, all refreshments. VAT is reclaimable.

Would you like to save money?
If you book the post-Conference Session "Stability Studies to Support Shipping/Distribution of Pharmaceuticals and Biopharmaceuticals" AND in addition the conference

- Stability Testing in Drug Substances and Drug Products (29-30 November 2017) AND the conference
- Setting Specifications (28-29 November 2017)

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Stability Testing for Drug Substances and Drug Products AND post-Conference Session
ECA Members € 1,980
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