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# Stability Testing for Drug Substances and Drug Products

## Speakers:



**Dr Thomas Füst**  
SANOFI, Germany



**Dr Wolfgang Grimm**  
Germany



**Dr Hiltrud Horn**  
Horn Pharmaceu-  
tical Consulting,  
Germany



**Dr Cornelia  
Nopitsch-Mai**  
Bonn, Germany



**Dr Jordi  
Ruiz-Combalia**  
Audit GMP, Spain



**Dr Thomas Uhlich**  
Bayer AG, Germany



**29 – 30 November 2018, Barcelona, Spain**

## 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



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# Stability Testing for Drug Substances and Drug Products

29 – 30 November 2018, Barcelona, Spain

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## 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 IIS 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

Thursday, 29 November 2018,  
14.00 h - 18.15 h  
(Registration and coffee  
13.30 h - 14.00 h)  
Friday, 30 November 2018,  
09.00 h - 15.15 h

### Venue

Barceló Sants Hotel  
Plaça dels Països Catalans, s/n  
08014 Barcelona, Spain  
Phone +34 (93) 503 53 00  
Fax +34 (93) 490 60 45  
sants@barcelo.com

### 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 the second day and all refreshments. VAT is reclaimable.

### Would you like to save money?

If you book the conference "Setting Specifications" AND in addition the conference "Stability Testing in Drug Substances and Drug Products" (29-30 November 2018) the fees reduce as follows:

ECA Members € 2,380  
APIC Members € 2,580  
Non-ECA Members € 2,780  
EU GMP Inspectorates € 1,390

### 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 event. 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.

Ms Nicole Bach phone +49 (0) 62 21/84 44 22, bach@concept-heidelberg.de, the responsible Organisation Manager, is happy to help you with any questions concerning reservation, hotel, etc.

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  
Fax +49 (0) 6221/84 44 34

69007 Heidelberg  
Germany

Reservation Form (Please complete in full)

 +49 6221 84 44 34

- Stability Testing for Drug Substances and Drug Products**, 29-30 November 2018, Barcelona, Spain
- Setting Specifications**, 28-29 November 2018, 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

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Company

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Department

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Important: Please indicate your company's VAT ID Number

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Purchase Order Number, if applicable

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Street / P.O. Box

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Zip Code

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Country

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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 %
  - until 1 week 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 HEIDELBERG will 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](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.