ECA ACADEMY

Speakers:

Dr Thomas Fürst
Boehringer Ingelheim Pharma, Germany

Dr Hiltrud Horn
Horn Pharmaceutical Consulting, Germany

Dr Bettina Pahlen
Quality x Pharma Consulting GmbH, Germany

Dr Wilhelm Schlumbohm
Berlin, Germany

Dr Thomas Uhlich
Bayer Pharma, Germany

Setting Specifications and Acceptance Criteria

10 - 11 November 2015, Berlin, Germany

Highlights:

- Regulatory Requirements for Specifications (ICH Q6A)
- Regulatory Requirements for Specifications of Biotech Products/Well-characterised Biologicals (ICH Q6B, etc.)
- Principles for Setting of Release and Shelf-life Specifications throughout Development
- Organic Impurities, Degradation Products and Genotoxic Impurities
- Rational Development and Justification of
  - API Specifications
  - Drug Products Specifications
  - Biological Drug Substances and Products
- Specifications for Specific Drug Products
- Specifications for Excipients and Container Closure Systems (EU/US)

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

Setting Specifications and Acceptance Criteria

10 - 11 November 2015, Berlin, Germany

Objectives

This event covers all aspects of specifications for Active Pharmaceutical Ingredients (APIs = Drug Substances), biological substances and pharmaceutical drug products from an **analytical and a registration perspective.**

In the workshops the participants will elaborate specifications

- for drug substance and drug product based on different case studies,
- specifications of biotechnological drug substances / drug products – general part
- specifications of biotechnological drug substances / drug products – related to the impurity profiles

These example specifications will be useful "take home messages" which will help the participants to define or to evaluate specifications in their daily work.

Background

In the development of new pharmaceutical products it is a great challenge to establish meaningful and reasonable specifications, which are scientifically sound and appropriate for APIs (chemical and biological drug substances), excipients and drug products. According to ICH Guideline Q6A, a specification is defined as a list of tests, references to analytical procedures, and appropriate acceptance criteria, which are numerical limits, ranges, or other criteria for the tests described.

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.

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.

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, Boehringer Ingelheim Pharma GmbH & Co. KG, Germany

Programme

Part I –
Regulatory Requirements and Setting Specifcations during the Development Phase

Current Regulatory Requirements for Setting Specifications (ICH Q6A)

- Regulatory overview
- Impact of pharmacopoeial provisions
- Setting specifications for active substances and finished products
- Justification of specifications
- Changes/variations

DR WILHELM SCHLUMBOHM, Berlin, Germany

Part I – Regulatory Requirements and Setting Specifcations during the Development Phase

Current Regulatory Requirements for Specifications of Biotech Products/ Well-characterised Biologicals (ICH Q6B and other Guidelines)

- Overview of regulatory requirements
- Characterization of product and establishing acceptance criteria
- Analytical aspects including method validation
- Setting up specifications – principles to consider
- New approaches: Design Space for a Biotechnological Product – ICH Q11 requirements

DR BETTINA PAHLEN, Quality x Pharma Consulting GmbH, Germany

Basic Principles for Setting of Release and Shelf-life Specifications

- Some basic statistics: Distribution and Variation
- Variation and specifications
- Changes over time and shelf life specification
- Process Capability
- Control strategy
- QbD or not to be

DR THOMAS FÜRST, Boehringer Ingelheim Pharma KG, Germany

Organic Impurities and Degradation Products with Special Emphasis on Genotoxic Impurities

- What do the guidelines tell us
- Impurity identification and profiling
- Impurity tracking
- Toxicological qualification
- Genotoxic impurities
- Control of genotoxic impurities

DR THOMAS FÜRST, Boehringer Ingelheim Pharma KG, Germany

Part II – Chemical APIs and Biopharmaceutical Drug Development Parallel Session A (Lectures and Workshops)

CHEMICAL APIs
Group I:
APIs Manufactured by Chemical Synthesis

Lecture and Workshop Rational Development and Justification of API Specifications

- In this workshop participants will elaborate specifications comprising typical tests for APIs.
- Assay, organic impurities and degradation products, water, residual solvents, heavy metals, particle size distribution, polymorphs, genotoxic impurities etc.

DR THOMAS FÜRST,
Boehringer Ingelheim Pharma KG,
Germany

BIOLOGICALS
Group II:
Drug Substances / Drug Products Manufactured by Biotechnological Processes – Part 1

Lecture and Workshop Setting Specifications during Biopharmaceutical Drug Development

- General overview of manufacturing processes for biopharmaceuticals
- Analytical testing scope for biopharmaceuticals
- How to set specifications: principles to consider
- Setting specifications: The phase-dependent approach
- Group Work

DR BETTINA PAHLEN,
Quality x Pharma Consulting GmbH,
Germany

Part III – Specific Considerations during Development and for Specfic Dosage Forms

Setting Specifications throughout Drug Development

- Specifications throughout development
- Specifications in Pharmacopoeias
- Stability of the manufacturing process
- Specifications for comparator products

DR THOMAS UHLICH, Bayer Pharma AG, Germany

Specifications for Specific Drug Products – What is the Difference to Standard Formulations

- Specific aspects required for special drug products, e.g.
- Gastro-intestinal therapeutic systems (GITS) or osmotic-controlled release oral delivery systems (OROS)
- Transdermal patches
- Orally inhaled and nasal drug products (OINDPs)

DR THOMAS UHLICH, Bayer Pharma AG, Germany

Part IV – Drug Products and Biological Impurities
Parallel Session B (Lectures and Workshops)

DRUG PRODUCTS
Group I:
Drug Products Containing APIs (manufactured by chemical synthesis)

Lecture and Workshop
Rational Development and Justification of Drug Products Specifications

- In this workshop participants will elaborate specifications comprising typical tests for different types of drug products: e.g. assay, purity, content uniformity, dissolution, fill volume, endotoxines, sterility etc.

DR THOMAS FÜRST,
Boehringer Ingelheim Pharma KG, Germany
DR THOMAS UHLICH,
Bayer Pharma AG, Germany

BIOLOGICALS
Group II:
Drug Substances / Drug Products Manufactured by Biotechnological Processes – Part 2

Lecture and Workshop
Impurities in Biological Drug Substances and Drug Products

- Impurities from chemical synthesis versus biotechnological process
- Definition of impurities: product-related impurities, process-related impurities, contaminants and identification of possible degradation products
- How to deal with impurities in biological drug substances and drug products
- Analytical techniques and other aspects
- Group work

DR BETTINA PAHLEN,
Quality x Pharma Consulting GmbH, Germany

Part V – Excipients and Container Closure Systems

Specifications for Excipients and Container Closure Systems (EU/US)

- Excipients in the CTD: What needs to be considered for setting specs in the CTD?
- Packaging material: Which information should be included in the CTD?
- What needs to be considered in a global environment?
- What are the typical questions?

DR HILTRUD HORN, Horn Pharmaceutical Consulting, Germany

Speakers

Dr Thomas Fürst, Boehringer-Ingelheim Pharma KG, Biberach, Germany
Dr Fürst joined Schering in 1987 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 August 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 Boehringer Ingelheim.

Dr Hiltrud Horn, Horn Pharmaceutical Consulting, Germany
From 1990 to 1997, she was employed by Hoffmann-La Roche in Quality Control/Quality Assurance. From 1997 to 1999, she dealt with medical writing in the ‚International Drug Regulatory Affaires and Project Management' department of the same company. In 1999, she joined Knoll AG as head of the departments ‚Regulatory Compliance and CMC Documentation' and ‚Dossier Production and Compliance' for international drug registration. In 2002, she started at Cap Gemini Ernst & Young, where she was the responsible consultant for questions concerning biotechnology and life sciences.

Dr Bettina Pahlen, Quality x Pharma Consulting GmbH, Alling, Germany
Bettina Pahlen, PhD, studied pharmacy at the University of Muenster, Germany, graduated in pharmaceutical chemistry and performed post-docs in USA and Germany. During the last 20 years she worked at university, authority and in different areas of the pharmaceutical industry (R&D, manufacturing, quality control, quality assurance). Since July 2007, she has been working as a consultant in the pharmaceutical industry focussing on GMP Quality Assurance aspects.

Dr Wilhelm Schlumbohm, Berlin, Germany
Dr Schlumbohm worked more than 20 years with German drug licensing authorities in the field of assessment of the CMC parts of new drug applications. He works as expert for for the Certification Procedure of the European Pharmacopoeia.

Dr Thomas Uhlich, Bayer Pharma AG, 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 Global Drug Discovery at Bayer Pharma AG. He is heading a laboratory which is specialized in the development and validation of analytical methods as well as the stability testing of pharmaceuticals in clinical development.

Social Event
Participants of the conference "Setting Specifications" are cordially invited to a guided sight-seeing tour of Berlin followed by a dinner in a nice restaurant on the evening of the first conference day. This is an excellent opportunity to share your own views and experiences with colleagues from other companies in a relaxed and casual 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
Tuesday, 10 November 2015,
09.00 h - 18.00 h
(Registration and coffee 08.30 h - 09.00 h)
Wednesday, 11 November 2015,
08.30 h - 14.00 h

Venue
Hotel Steigenberger Kanzleramt Berlin
Ella-Trebe-Straße 5
10557 Berlin, Germany
Phone +43 (0)30 74 07 43 0
Fax +43 (0) 30 74 07 43 999

Conference fees (per delegate plus VAT)
ECA Members € 1,490
APIC Members € 1,590
Non-ECA Members € 1,690
EU GMP Inspectorates € 845

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 conference "Setting Specifications" AND the conference "Stability Testing" simultaneously, the fee for each conference reduces as follows:
Non-ECA Members € 1,290
ECA Members € 1,090
APIC Members € 1,190
EU GMP Inspectorates € 645

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 Günter Brendelberger, phone +49(0)62 21/84 44 40, brendelberger@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:

_____

_____

_____

_____

_____

CONCEPT HEIDELBERG
P.O. Box 10 17 64
Fax +49 (0) 6221/84 44 34

69007 Heidelberg
Germany

Reservation Form (Please complete in full)

❑ **Setting Specifications and Acceptance Criteria**
10 – 11 November 2015, Berlin, Germany
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

❑ **Stability Testing for Drug Substances and Drug Products**
11 – 12 November 2015, Berlin, Germany

□ Mr □ Ms

_____
Title, first name, surname

_____
Company

_____
Department

_____
Important: Please indicate your company's VAT ID Number **Purchase Order Number, if applicable**

_____
Street / P.O. Box

_____
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 %,
- 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).

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/versl/27052015