ECA Academy
Your GMP/GDP Information Source

Speakers

Dr Ulli Backofen
Boehringer Ingelheim Pharma
Germany

Dr Thomas Fürst
Boehringer Ingelheim Pharma
Germany

Dr Cornelia Nopitsch-Mai
Quality Assessor, Germany

Dr Thomas Uhlich
Bayer, Germany

Setting Specifications and Acceptance Criteria

Live Online Training on 02 December 2020

Highlights

- Basic Principles for Setting of Release and Shelf-Life Specifications
- Regulatory Requirements for Specifications (ICH Q6A)
- Specifications of Biopharmaceuticals
- Rational Development and Justification of API Specifications
- Principles for Setting of Release and Shelf-life Specifications throughout Development
- Rational Development and Justification of Drug Product Specifications
- Specifications for Specific Drug Products

Live Q&A session after each presentation

Objectives

This Live Online Training covers different aspects of specifications for Active Pharmaceutical Ingredients (APIs = Drug Substances), biological substances and pharmaceutical drug products from an analytical and regulatory perspective. The examples presented 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 Live Online Training will thus address how to set impurity limits for related substances and degradation products based on method capability and stability results.

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 – 09.45 h
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

09.45 – 10.45 h
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
- Introduction to the requirements of risk assessment with focus on setting specifications for heavy metals
- How authorities will proceed in respect of submitting the required documentation for approved marketed products

10.45 – 11.00 h
Break

11.00 – 11.45 h
Specifications of Biopharmaceuticals

- Overview of regulatory requirements
- Critical Quality attributes and Control Strategy
- Differences between NCEs and NBEs
- Considerations for Drug Substance and Drug Product
- Specifications during early and late stage development
- Acceptance criteria at release and for shelf life

11.45 – 12.30 h and 13.15 – 13.45 h
Rational Development and Justification of API Specifications (Part 1 and Part 2)

- Impurity identification and profiling
- Impurity tracking
- Classification of impurities
- Thresholds for Drug Substance
- Assay, organic impurities and degradation products, water, residual solvents, heavy metals, particle size distribution, polymorphs, genotoxic impurities etc.

12.30 – 13.15 h
Break

13.45 – 14.45 h
Setting Specifications throughout Drug Development

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

14.45 – 15.00 h
Break

15.00 – 15.45 h and 16.00 – 16.30 h
Rational Development and Justification of Drug Product Specifications (Part 1 and Part 2)

- Specification types
- Regulatory limits and limits based on data
- Typical tests for different types of drug products, e.g. assay, purity, content uniformity, dissolution, fill volume, endotoxines, sterility etc.

15.45 – 16.00 h
Break

16.30 – 17.15 h
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)

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.


CERTIFICATE

Speakers

Dr Ulli Backofen
Boehringer Ingelheim, Germany
Dr Backofen started his career as postdoc in pharmaceutical industry in 2001. In 2003 he became head of analytical laboratory (NCE) at Boehringer Ingelheim. From 2010 to 2018 he worked as R&D project leader and was responsible for various NCE and NBE projects. In 2018 he was appointed director and Head of Quality Control in the department Analytical Development Biologicals at Boehringer Ingelheim in Biberach.

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 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.

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Reservation Form (Please complete in full)

☐ *Setting Specifications and Acceptance Criteria | Live Online Training on 02 December 2020*
and
☐ *Stability Testing for Drug Substances and Drug Products | Live Online Training on 03 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.
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Terms of payment: Payable without deductions within 10 days after receipt of invoice.
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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

Wednesday, 02 December 2020, 09.00 – 17.15 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 "Setting Specifications and Acceptance Criteria" AND in addition the Live Online Training "Stability Testing for Drug Substances and Drug Products" (03 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.

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CF/16092020