ECA
ACADEMY

Speakers from Authorities:

DR SIEGFRIED GIESS
Paul Ehrlich Institut, Germany

DR CORNELIA NOPITSCH-MAI
Federal Institute for Drugs and Medical Devices (BfArM), Germany

Industry Speakers:

DR SVEN OLIVER ARNDT
Merck, Germany

DR THOMAS FÜRST
Boehringer Ingelheim Pharma, Germany

DR WOLFGANG GRIMM
Germany

DR HILTRUD HORN
Horn Pharmaceutical Consulting, Germany

DR BETTINA PAHLEN
Quality x Pharma Consulting, Germany

DR JORDI RUIZ-COMBALIA
Audit GMP, Spain

DR THOMAS UHLICH
Bayer Pharma, Germany

Two European Conferences

Setting Specifications and Stability Testing

20 – 21 November 2013,
Barcelona, Spain
Setting Specifications and Acceptance Criteria

21 – 22 November 2013,
Barcelona, Spain
Stability Testing for Drug Substances and Drug Products

Book both conferences for 1,290,- each and save € 400,-!

These conferences are recognised for the ECA GMP Certification Programme „Certified Quality Control Manager". Please find details at www.gmp-certification.eu

Speakers of both conferences

DR SVEN OLIVER ARNDT,
Merck, Germany

Dr Arndt graduated as Biochemist from the University of Hannover and from the German Cancer Research Center, Heidelberg. Dr Arndt joined Merck KGaA, Germany in 2000. Currently, he is working as plant manager's assistant within Operation Chemicals. Prior to this, he was heading a group of laboratories in the department of "Analytical Development Biotech Products", being responsible for physico-chemical characterization, analytical development and QC analytics of new biological entities (NBEs).

DR THOMAS FÜRST,
Boehringer Ingelheim Pharma KG, 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 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 Boehringer Ingelheim.

DR SIEGFRIED GIESS,
Paul Ehrlich Institut, Germany

Dr Giess studied chemistry at the Johann Wolfgang Goethe-University in Frankfurt and received his PhD at the Institute for Biochemistry. In his present position he works at the Paul-Ehrlich-Institut, the Federal Agency for Sera and Vaccines in Germany, as head of the Immunochemistry Section. He is responsible for chemical, physico-chemical and biochemical analysis of biological drug products and engaged in the testing activities of the OMCL Network. Dr Giess is involved in the quality assessment of immunoglobulins, immunsera and monoclonal antibodies. He is member of the Working Party Monoclonal Antibodies of the EP Commission and belongs to the USP Monoclonal Expert Panel.

DR WOLFGANG GRIMM,
Germany

Dr Grimm graduated as an Organic Chemist from the Technical University in Darmstadt. Then he joined the Max-Planck Institute for Experimental Medicine in Göttingen followed by the University of Illinois in Urbana, USA. Back in Germany he joined the Boehringer Ingelheim Pharma KG in Biberach. There he was responsible for the analytical development and stability testing. 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. 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 Affairs 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 CORNELIA NOPITSCH-MAI,
Federal Institute for Drugs and Medical Devices (BfArM), Bonn, 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.

DR BETTINA PAHLEN,
Quality x Pharma Consulting GmbH, 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 15 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 JORDI RUIZ-COMBALIA,
AUDIT GMP, Barcelona, Spain

Dr Ruiz Combalia has more than 40 years experience in API Industry, where he has had different responsibilities. He started as R&D Director, then he moved to Quality positions. Between 1992 and 2006 he has collaborated with the Organic Chemistry Expert Group of the Real Farmacopea Espanola. Since 1994, and up to 2007 he has been member of Group of the Experts 11, Chair of the CRB Working Party, and member of the Spanish Delegation to the European Pharmacopoeia Commission. He was one of the starting members of BPCC, actually APIC. He left Bioiberica in 2012 and works now with AUDIT GMP, Barcelona.

DR THOMAS UHLICH,
Bayer Pharma AG, Germany

Thomas Uhlich is a chemist and has been working in Global Drug Discovery at Bayer Pharma AG for several years. 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.

Setting Specifications

20-21 November 2013, Barcelona, Spain

Objectives

This Conference 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 Group

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.

Chairman

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 Specifications (ICH Q6A)

- How to set specifications for impurities in API
- How to set specifications for impurities in the finished product
- Cases
- Deficiencies which arise during assessment
- Changes / Variations
- Basic knowledge of QbD

DR CORNELIA NOPITSCH-MAI, Federal Institute for Drugs and Medical Devices (BfArM), Germany

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 Biotechnologial Product – new ICH Q11 requirements

DR BETTINA PAHLEN, Quality x Pharma Consulting, 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 Empasis 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 SVEN OLIVER ARNDT,
Merck, 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
- Too wide versus too narrow: Precision and Accuracy of analytical methods

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.
- Orally inhaled and nasal drug products (OINDPs)
- Transdermal patches
- Gastro-intestinal therapeutic systems (GITS) or osmotic-controlled release oral delivery systems (OROS)

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 Product 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

REGULATORY COMPLIANCE

Dossier Requirements for Setting Specifications

- Dossier requirements for the first submission
- Definition of Specification of drug substances and drug products
- Justification of Specifications of drug substances and drug products
- Preparing rationales for setting specifications in a justification document
- Specifications and justification for excipients
- Special requirements for excipients of human and animal origin
- Are pharmacopoeial testing criteria sufficient
- Specifications for container closure system

DR CORNELIA NOPITSCH-MAI, Federal Institute for Drugs and Medical Devices (BfArM), Germany

Social Event

Participants of the Conference "Setting Specifications" are cordially invited to a guided sight-seeing tour of Barcelona followed by a dinner in a nice restaurant on the evening of the first conference day.

Participants of the conference "Stability Testing" are also invited to dinner on Tuesday evening.

These are excellent opportunities to share your own views and experiences with colleagues from other companies in a relaxed and casual atmosphere.

Stability Testing for Drug Substances and Drug Products

21-22 November 2013, Barcelona, Spain

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. The conference is rounded off by a presentation on stability testing of biological and biotechnological products.

Chairman

DR THOMAS FÜRST, Boehringer Ingelheim Pharma GmbH & Co. KG, Germany

Programme

Current ICH and CHMP Guidelines for Stability

- The ICH process
- An overview of stability guidelines (ICH, CPMP, FDA and others)
- ICH Q1D – bracketing and matrixing for reduced stability testing
- Reduction strategies, experimental design
- ICH Q1E – data evaluation
- Packaging materials
- Recent changes
- Future activities

Dr CORNELIA NOPITSCH-MAI, Federal Institute for Drugs and Medical Devices (BfArM), Germany

Stability Testing throughout Drug Development

- Must the development stability programme meet ICH Q1A?
- Stability testing from early development to product launch
- Stability for comparators used in clinical trials
- Site specific stability

DR THOMAS UHLICH, Bayer Pharma AG, Germany

Stability Testing for Drug Substances

- Stress testing
- Formal stability studies
- Photostability testing
- Packaging and documentation

DR JORDI RUIZ-COMBALIA, Audit GMP, Spain

Stability Testing for Drug Products

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

DR WOLFGANG GRIMM, Germany

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

DR HILTRUD HORN, Germany

Evaluation of Stability Results – Statistical Considerations

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

DR THOMAS FÜRST, Boehringer Ingelheim Pharma GmbH & Co. KG, Germany

Post-marketing Stability Testing

- Stability Studies after Approval (EU/US)
- Specifics for US
- Changes with Impact on Stability
- Examples

DR HILTRUD HORN, Germany

Stability Testing of Biological and Biotechnological Products

- Differences between chemical entities and biologicals
- Relevant guidelines
- Stability indicating profile of monoclonal antibodies and immunoglobulins
- Storage conditions
- Impact of changes an stability
- Stability requirements for biological IMPs in clinical trials

DR SIEGFRIED GIESS, Paul Ehrlich Institut, Germany

Social Event

Participants of the conference "Stability Testing" are cordially invited to a dinner on Tuesday evening. This is an excellent opportunity to share your own views and experiences with colleagues from other companies in a relaxed and casual atmosphere.

Lufthansa is Mobility Partner for all ECA Events

Lufthansa Mobility Partner

As an ECA course or conference attendee, you will receive **up to 20% discounted travel fares** (according to availability). And as Lufthansa German Airlines offers a comprehensive global route network linking major cities around the world you will most likely be able to benefit from these special prices and conditions. And this is how it works: Once you registered for a course or conference you will receive a link together with your registration confirmation. Opening that link will take you to the Mobility Partner Program website where you can enter a code in the "Access to Event Booking" area you will also receive. This will take you into an online booking platform* that will automatically calculate the discount offered or provide you with an even better offer if another promotional fare is available.
We look forward to welcoming at one of our next events – and we already wish you a pleasant flight!

*Please note: You may have to enable pop-ups on the Mobility Partner Program website – otherwise the booking platform window will not open.

What are The ECA Foundation and the ECA Academy?

The European Compliance Academy Foundation (ECA Foundation) is an independent professional organisation chaired by a Scientific Advisory Board with members from the pharmaceutical industry and regulatory authorities. The ECA Foundation's goal is to support to the Pharmaceutical Industry and Regulators to promote the move towards a harmonised set of GMP and regulatory guidelines by providing information and interpretation of new or updated guidances. The ECA Academy offers professional basic and advanced education (training) programmes. All services offered by the ECA Academy and with regard to ECA Academy Memberships are solely managed by Concept Heidelberg (a leading European training and information services provider). The ECA Foundation is conceptual sponsor of the ECA Academy.

How Do You Become a Member of ECA?

By participating in one of the ECA Academy Conferences or Courses you will automatically become a ECA Academy Individual Member for two years - free of charge. More information about ECA Academy can be obtained on the Website http://www.gmp-compliance.org

What Are the Benefits of ECA?

During the membership, you enjoy a EUR 200,- discount on the regular participation fee of any European Conference or Course presented by the ECA Academy. In addition you will receive the GMP Guideline Manager Software with a large number of guidelines, e.g. EC Directives, FDA Guidelines, ICH Guidelines.

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

Conference „Setting Specifications"

Date
Wednesday, 20 November 2013, 09.00 h - 18.00 h
(Registration and coffee 08.30 h - 09.00 h)
Thursday, 21 November 2013, 08.30 h - 14.00 h

Conference fees
ECA Members € 1,290.-*
APIC Members € 1,390.-*
Non-ECA Members € 1,490.-*
EU GMP Inspectorates € 745.-*
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.

Conference „Stability Testing"

Date
Thursday, 21 November 2013, 14.00 h - 18.30 h
(Registration and coffee 13.30 h - 14.00 h)
Friday, 22 November 2013, 09.00 h– 17.00 h

Conference fees
ECA Members € 1,290.-*
APIC Members € 1,390.-*
Non-ECA Members € 1,490.-*
EU GMP Inspectorates € 745.-*
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.

* per delegate plus VAT

Would you like to save money?
If you book „Setting Specifications" AND „Stability Testing" simultaneously, the fee for **EACH** conference reduces as follows:
ECA Members € 1,090,-*
APIC Members € 1,190.-*
Non-ECA Members € 1,290.-*
EU GMP Inspectorates € 645.-*

Venue of both conferences
Nh Constanza
C/Deu I Mata, 66 -69
08029 Barcelona, Spain
Phone +34 93 281 1500
Fax +34 93 281 1525

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.

Registration
Via attached reservation form, by mail or by fax message. Or you register online at **www.gmp-compliance.org.**

Conference language
The official conference language will be English.

Organisation and Contact
CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg, Germany
Phone +49 (0) 62 21/84 44-0
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will help you with any technical questions as regards content.

Ms Marion Weidemaier
phone +49 (0) 62 21 / 84 44 46,
weidemaier@concept-heidelberg.de,
the responsible organisation manager,
is happy to help you with any questions concerning reservation, hotel, etc.

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69007 Heidelberg
Germany

Reservation Form (Please complete in full)

☐ **Setting Specifications**,
20-21 November 2013, Barcelona, Spain
Please tick ONE group in each Parallel Session:
Parallel Session I
☐ Group I: APIs Manufactured by Chemical Synthesis
☐ Group II: Drug Substances Drug Products Manufactured by Biotechnological Processes – Part 1
Parallel Session II
☐ Group I: Drug Products Containing APIs (manufactured by chemical synthesis)
☐ Group II: Drug Substances/Drug Products Manufactured by Biotechnological Processes – Part 2

☐ **Stability Testing for Drug Substances and Drug Products,**
21-22 November 2013, Barcelona, Spain

☐ Mr ☐ Ms

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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 **Purchase Order Number, if applicable**

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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 HEIDELBERG will not be responsible for discount airfare penalties or other costs incurred due to a cancellation.
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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)