Speakers from Authorities:

DR STEFAN CHRISTIANS
Paul Ehrlich Institut,
Germany

DR ABIGAIL MORAN
MHRA, London, UK

Industry Speakers:

DR SVEN OLIVER ARNDT
Merck, Germany

DR CHRISTOPHER BURGESS
Burgess Analytical
Consultancy, UK

DR JUERGEN DÖNNECKE
Boehringer Ingelheim,
Germany

DR THOMAS FÜRST
Boehringer Ingelheim
Pharma, Germany

DR WOLFGANG GRIMM
Germany

DR BETTINA PAHLEN
Quality x Pharma
Consulting, Germany

DR JORDI RUIZ-COMBALIA
Bioiberica, Spain

DR THOMAS UHLICH
Bayer Schering Pharma,
Germany

Two European Conferences

Setting Specifications and Stability Testing

5 – 6 October 2011, Frankfurt/Main, Germany

Setting Specifications and Acceptance Criteria

6 – 7 October 2011, Frankfurt/Main, Germany

Stability Testing for Drug Substances and Drug Products

ECA
European Compliance Academy

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 KGaA, Germany
Sven Oliver Arndt joined Merck KGaA, Germany in 2000. Currently, he holds the position of a Principal Research Scientist in the Analytical Development department. His current interests and responsibilities include analytical development as well as quality control of biological entities from pre-clinical stages to commercialization.

DR CHRISTOPHER BURGESS, Burgess Analytical Consultancy, Barnard Castle, UK
Dr Burgess is a Chartered Chemist and has more than 36 years experience in the pharmaceutical industry primarily with Glaxo in Quality Assurance and Analytical R&D. He is a "Qualified Person" and a member of the European QP Association advisory board. He has been appointed to the United States Pharmacopoeia's Council of Experts 2010 to 2015 and is a visiting professor of the University of Strathclyde's School of Pharmacy and Biomedical Sciences (SIPBS). In addition, he is the chairman of the ECA Analytical Quality Control Group and a member of the Executive committee of European Compliance Academy.

DR JUERGEN DÖNNECKE, Boehringer Ingelheim GmbH, Germany
Since 2002 Dr Dönnecke is working in the Corporate Department Drug Regulatory Affairs of Boehringer Ingelheim with the focus on CMC documentation for registered and new drug products.

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 Aug 2007 Dr Fürst joined Boehringer Ingelheim where he is working as senior principle scientist in the development department as a CMC expert.

DR STEFAN CHRISTIANS, Paul Ehrlich Institut, Germany
Dr Christians works at the Paul-Ehrlich-Institut, the Federal Agency for Sera and Vaccines in Germany. As deputy head of the section Immunochemistry he is responsible for the physicochemical testing of biological drug products for batch release. He is also involved in the quality assessment of immunoglobulins, immunosera, and monoclonal antibodies

DR WOLFGANG GRIMM, Biberach, Germany
At Boehringer Ingelheim, Dr Grimm 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 he FDA as an advisor for the climatic zone concept.

DR ABIGAIL MORAN, MHRA, London, UK
Dr Abigail Moran joined the MHRA as a pharmaceutical assessor in 2004, where she worked in the therapeutic areas of cardiovascular disease and anti-infectives before moving to the team working in the areas of malignant disease, immunosuppression and musculoskeletal disease in 2006. Her current role is Deputy Manager and Pharmaceutical Assessor in Product Lifecycle Assessment Team (PLAT) 6, Medicines and Healthcare products Regulatory Agency (MHRA).

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 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, Bioiberica S.A., Barcelona, 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 Schering Pharma AG, Berlin, Germany
Thomas Uhlich is a chemist and has been working in Global Drug Discovery at Bayer Schering Pharma AG for several years. He is heading a laboratory group which is specialized in the development and validation of analytical methods as well as the stability testing of pharmaceuticals in clinical development.

Setting Specifications

Setting Specifications and Acceptance Criteria – How to Achieve Regulatory Compliance for APIs, Biological Substances and Drug Products
5 - 6 October 2011, Frankfurt, Germany

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**.

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. And genotoxic impurities and strategies for the control of **genotoxic impurities** 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 CHRISTOPHER BURGESS, Burgess Analytical Consultancy, UK

General Part I

Current Regulatory Requirements for Specifications (ICHQ6A)

- 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 ABIGAIL MORAN, MHRA, London, UK

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

- Overview of regulatory requirements
- Characterization of product
- Analytical considerations
- Setting up specifications and acceptance criteria
- Adjustment of specifications during pharmaceutical development

DR BETTINA PAHLEN, Quality x Pharma Consulting, Germany

Setting Specifications during Development Phase

- 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 Schering Pharma AG, Germany

Part II – Drug Substance

Parallel Session (Lectures and Workshops)

Group I: APIs Manufactured by Chemical Synthesis

Lecture: Rational Development and Justification for Acceptance Criteria for Impurities

- Impurities in APIs
- Impurity profile
- Identification / qualification of impurities
- Impurity limits based on method capability and stability results
- ICH Guidelines Q3A, Q3B
- Related substances / degradation products
- Residual solvents
- Catalysts
- Limit of detection / limit of quantification
- Genotoxic impurities

DR THOMAS FÜRST, Boehringer Ingelheim Pharma KG, Germany

Workshop: Specifications for APIs: Evaluating Organic Impurities
Topics: Area normalization; high-low method; external standard; reporting limits and LOD; case studies
Moderator: DR THOMAS FÜRST,Boehringer Ingelheim Pharma KG, Germany

Group II: APIs Manufactured by Biotechnological Processes

Lecture: Impurities in Biological APIs

- Regulatory requirements
- Definitions of impurities
- Impurities in biological APIs
- Product-related impurities
- Process-related impurities
- Contaminants
- Identification of possible degradation products

DR BETTINA PAHLEN, Quality x Pharma Consulting , Germany

Workshop: Impurities in Biological APIs
Topics: Development of impurity specifications for a monoclonal antibody as an example: from pre-clinical phase to phase III
Moderator: DR BETTINA PAHLEN,Quality x Pharma Consulting, Germany

Genotoxic Impurities

- What is genotoxicity
- The story that triggered it all
- Guidelines
- What is the real risk
- Sources of genotoxic impurities
- Strategies for the control of genotoxic impurities

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

Specifications in Stability Testing

- Components of a stability specification
- Types of specification and related acceptance criteria
- Differences between product and API specifications
- Impact of analytical method changes on stability testing
- Combining data to generate rational specifications
- Changing specifications from early development to full production

DR CHRISTOPHER BURGESS, Burgess Analytical Consultancy, UK

Part III - Drug Product

Parallel Session (Lectures and Workshops)

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

Lecture: Rational Development and Justification of Acceptance Criteria for the Assay of the API in Drug Products

- Drug product assay development
- Coping with change through the development life cycle
- Can the European requirement of 95-105% always be achieved ?
- How many repetitions (repeated determinations) are commonly used?
- Statistical considerations in setting pharmacopoeial specifications

DR CHRISTOPHER BURGESS, Burgess Analytical Consultancy, UK

Workshop: Specifications for Drug Products containing chemically manufactured APIs
Moderator: DR CHRISTOPHER BURGESS, Burgess Analytical Consultancy, UK

Group II:
Biopharmaceutical Products

Lecture: Development of Analytical Methods and Setting of Rational Specifications for Biotechnological Products

- Definition of a drug product specification
- Assay development for biotechnological drug products
- How to set specifications: The phase-dependent approach

DR SVEN OLIVER ARNDT, Merck KGaA, Germany

Workshop: Specifications for Biopharmaceutical Drug Products
Moderator: DR SVEN OLIVER ARNDT, Merck KGaA, Germany

Part IV -
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 ABIGAIL MORAN, MHRA, London, UK

Social Event

Participants of the Conference "Setting Specifications" are cordially invited to a guided sight-seeing tour of Frankfurt 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 Thursday 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

6 - 7 October 2011, Frankfurt, Germany

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 CHRISTOPHER BURGESS, Burgess Analytical Consultancy, UK

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 ABIGAIL MORAN, MHRA, London, UK

Stability Testing throughout Drug Development

- Must the development stability programme meet ICH Q1A?
- Stability testing from research to product launch – evolution of a project
- mpatibility with excipients
- R&D Clinical Stability Protocol
- Stability of Comparators

DR THOMAS UHLICH, Bayer Schering Pharma AG, Germany

Stability Testing for Drug Substances

- Stability protocols
- Stress testing
- Photostability testing
- Low stability products
- Documentation, Stability Report
- Packaging considerations

DR JORDI RUIZ-COMBALIA, Bioiberica, Spain

Stability Testing for Drug Products

- Regulatory requirements
- Evaluating development stability data
- Excipients compatibility studies
- ICH Q1F withdrawn and now?
- Stress testing for zone III and IV countries
- Labelling requirements

DR WOLFGANG GRIMM, Germany

Post-marketing Stability Testing

- Purpose of post-marketing stability studies
- Fixed interval and selected date methods; cluster approach
- Impact of major changes
- Experiences with the regulatory authorities

DR JUERGEN DÖNNECKE, Boehringer Ingelheim GmbH, Germany

Evaluation of Stability Results – Statistical Considerations

- The stability testing process
- Regulatory guidance
- Trend analysis in stability testing
- FDA ANOVA method for shelf life prediction (long term stability)
- Pooling of data

DR CHRISTOPHER BURGESS, Burgess Analytical Consultancy, UK

Submitting Stability Data – The CTD-Structure

- Overview of the stability documentation
- Consequences of the CTD format
- Structure of the reports
- Stability data relevant links and references in Module 3.2
- Post-approval stability protocol and commitment
- Stability related one-time studies for drug product

DR JUERGEN DÖNNECKE, Boehringer Ingelheim GmbH, Germany

Stability Testing of Biological and Biotechnological Products

- Biologicals and relevant guidelines
- Specific differences between chemical entities and biologicals
- Stability indicating parameters in monoclonal antibodies and polyclonal immunoglobulins
- Test methods to assess the stability of biological drug products
- Storage conditions
- Impact of changes on stability

DR STEFAN CHRISTIANS, Paul Ehrlich Institut, Germany

Social Event

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

What Is ECA?

The European Compliance Academy (ECA) is an independent educational organisation chaired by a Scientific Advisory Board with members of the pharmaceutical industry and regulatory authorities. The ECA will provide 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.

How Do You Become a Member of ECA?

By participating in one of the European Compliance Conferences or Courses, you will automatically become a member of ECA for two years - free of charge. More information about ECA can be obtained on the Website **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 organised by ECA in co-operation with CONCEPT HEIDELBERG.

The GMP Guideline Manager Software with a large number of guidelines, e.g. EC Directives, FDA Guidelines, ICH Guidelines, will be forwarded to you when you are using your membership for a conference registration.

About CONCEPT HEIDELBERG

Founded in 1978, CONCEPT HEIDELBERG is the leading organiser of seminars on pharmaceutical production, quality control, quality assurance and GMP in Europe. This year more than 240 events will be organised by CONCEPT HEIDELBERG. ECA has entrusted CONCEPT HEIDELBERG with the organisation of its events.

Easy Registration

Reservation Form:
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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, 5 October 2011, 09.00 h - 18.00 h
(Registration and coffee 08.30 h - 09.00 h)
Thursday, 6 October 2011, 08.30 h - 14.00 h

Conference fees
ECA Members EUR 1,290.- per delegate plus VAT
APIC Members EUR 1,390.- per delegate plus VAT
Non-ECA Members EUR 1,490.- per delegate plus VAT
EU GMP Inspectorates EUR 745.- per delegate plus VAT
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, 6 October 2011, 14.00 h - 18.30 h
(Registration and coffee 13.30 h - 14.00 h)
Friday, 7 October 2011, 09.00 h– 17.00 h

Conference fees
ECA Members EUR 1,290.- per delegate plus VAT
APIC Members EUR 1,390.- per delegate plus VAT
Non-ECA Members EUR 1,490.- per delegate plus VAT
EU GMP Inspectorates EUR 745.- per delegate plus VAT
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 „Setting Specifications" AND „Stability Testing" simultaneously, the fee for **EACH** conference reduces as follows:
ECA Members EUR 1,161.- per delegate plus VAT
APIC Members EUR 1,225.- per delegate plus VAT
Non-ECA Members EUR 1,290.- per delegate plus VAT
EU GMP Inspectorates EUR 645.- per delegate plus VAT

Venue of both conferences
Welcome Hotel Frankfurt
Leonardo-da-Vinci-Allee 2
60486 Frankfurt, Germany
Phone: + 49 (0) 69 770 670 0
Fax: + 49 (0) 69 770 670 444

Accommodation
CONCEPT has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form when you have registered for the conference. Please use this form for your room reservation or be sure to mention booking code ECA 6974 to receive the specially negotiated rate for the duration of your stay. Reservation should be made directly with the hotel not later than 5 September 2011. 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, Fax +49 (0) 62 21/84 44 34
info@concept-heidelberg.de, www.concept-heidelberg.de

The responsible operations directors
Dr Günter Brendelberger, phone +49(0)62 21/84 44 40, brendelberger@concept-heidelberg.de (**Setting Specifications),** and Dr Gerhard Becker, phone +49(0)62 21/84 44 65, becker@concept-heidelberg.de **(Stability Testing)** will help you with any technical questions as regards content.
Ms Susanne Ludwig, phone +49 (0) 62 21 / 84 44 44, ludwig@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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Reservation Form (Please complete in full)

☐ **Setting Specifications**, 5 - 6 October 2011, Frankfurt, Germany
Please tick ONE group in each Parallel Session
Parallel Session I
☐ Group I: APIs Manufactured by Chemical Synthesis
☐ Group II: APIs Manufactured by Biotechnological Processes
Parallel Session II
☐ Group I: Drug Products Containing APIs (manufactured by chemical synthesis)
☐ Group II: Biopharmaceutical Products
☐ **Stability Testing for Drug Substances and Drug Products,** 6 - 7 October 2011, Frankfurt, Germany

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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:
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- until 2 weeks prior to the conference 10 %,
- until 1 weeks prior to the conference 50 %
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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)!

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