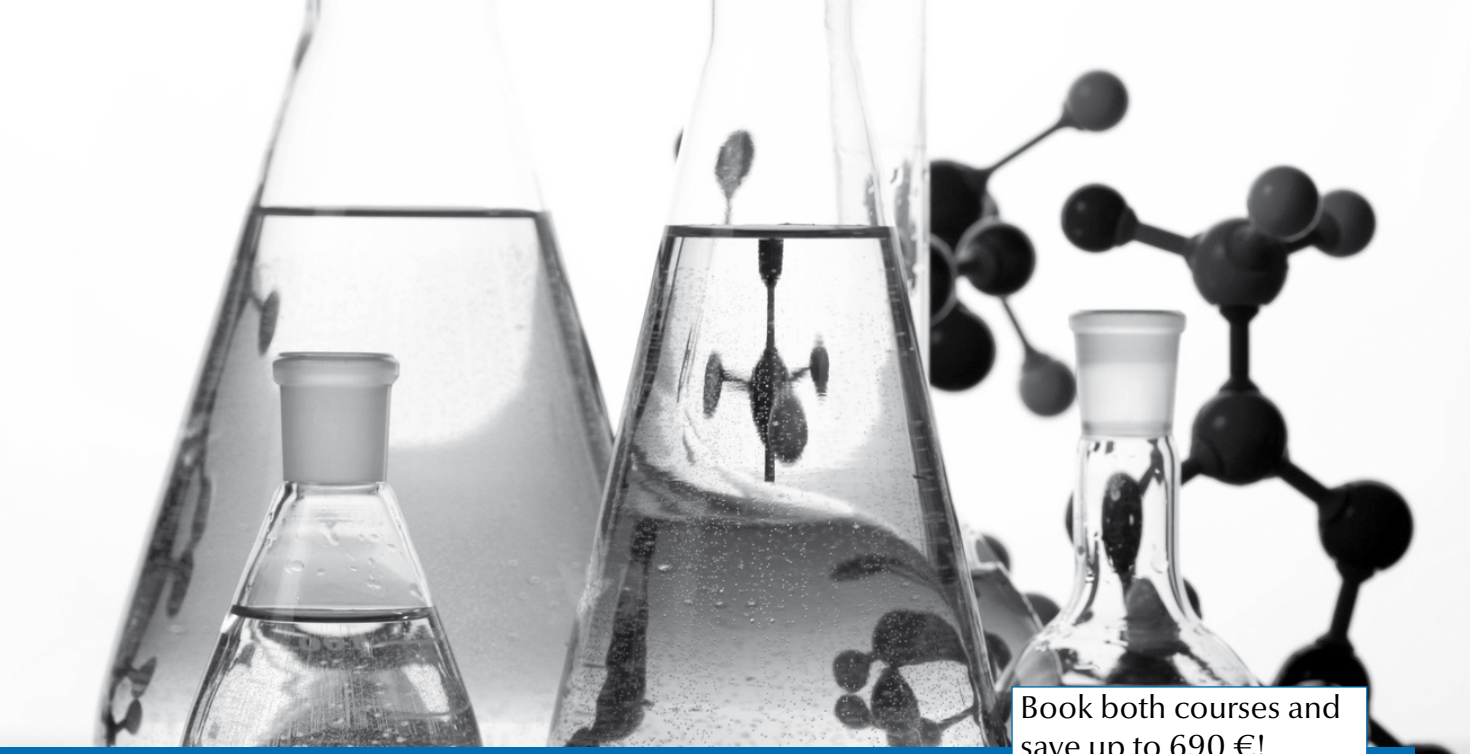

Book both courses and save up to 690 €!

- Bioassays and Bioanalytics
- Stability Testing

Bioassays and Bioanalytics
27-28 March 2012, Copenhagen, Denmark

Stability Testing for Biological/Biotechnological Drug Substances and Drug Products
29 March 2012, Copenhagen, Denmark

SPEAKERS:

Markus Fido
Vela Laboratories, Austria

Siegfried Giess
Paul Ehrlich Institute, Germany

Ana T. Menendez
Menendez bio-Consultants LLC, UK

Andreas Nechansky
Vela Laboratories, Austria

ECA
EUROPEAN COMPLIANCE ACADEMY

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

Bioassays and Bioanalytics

27-28 March 2012, Copenhagen, Denmark

Objectives

The course includes a general discussion of GMP, GLP and GCLP principles and how they apply to potency Bioassay, limit tests, pharmacokinetics, pharmacodynamics and immunogenicity. Furthermore you will learn the principles of phase specific validation as they relate to potency Bioassays and limits tests. We will outline the industry guidelines on PK assays with an emphasis on the accuracy and precision expectations for biopharmaceuticals, including Incurred Sample Reanalysis. The immunogenicity section helps the participants understand important regulatory expectations by a systematic evaluation of critical portions of the EMA guidance. In addition you become acquainted with the specific challenges of transferring Bioassays between laboratories and and you get a checklist to identify and overcome the hurdles in the process. Workshops on writing validation protocols provide hands-on experience to cover these pivotal documents. You will also hear case studies that add relevance to the lecture materials and provide a launch point for class discussion.

Background

The number of biopharmaceutical products is increasing in the clinic and in the market. Their excellent targeting ability is the result of a high complexity that cannot be measured by analytical tests alone. Therefore, the development process of all biopharmaceutical products requires non-analytical tests to fully evaluate their functionality and safety. Biopharmaceutical development is a multi-disciplinary effort that involves many professionals with diverse backgrounds. This course will help team members without the appropriate technical background by clarifying the timelines, requirements and significance of Bioassays based testing. The types of methods that will be addressed are cell-based assays, immunoassays and molecular assays.

Target Audience

- Manufacturing process professionals
- QA/QC staff and regulatory personnel
- Clinical staff, pharmacologists and toxicologists
- Project Managers & outsourcing personnel
- Analytical chemists and biochemists

Moderators

Ana Menendez, Axel Schroeder

Social Event

On 27 March 2012, you are cordially invited to a social event. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

Programme

Introduction to Bioassays and Bioanalytical Methods
- What is a potency assay?
- Product analytics versus Bioanalytics (preclinical & clinical approach)
- Why do we need bioassays?
- Characterisation of Biopharmaceuticals & Biosimilars

GMP and GLP Overview and Expectations
- Key regulatory guidelines and industry white papers
- Life cycle of biopharmaceuticals
- Risk assessment

Strategic Selection of Potency Method
- Feasibility
- Preparing the Cell Bank
- Optimization Parameters

Development – Standards and Controls
- Standards and controls
- Eliminating edge and hook effects
- Setting system suitability criteria

GMP pre-Validation of Potency Bioassays
- Parallelism: Similarity versus Hypothesis Testing
- Defining and improving intermediate precision
- Process Controls

GMP Validation Protocol of Potency Bioassays
- Setting Realistic Sample Specs for Validation
- Phase Specific Validation
- Validation Report

Development of Immunoassays for GLP Bioanalytics
- PK and immunogenicity
- DOE versus OFAT

Workshops Session
- Validation Protocol Workshop for Potency Bioassays
- Validation Protocol Workshop for PK/PD and Immunogenicity Assays

GLP Validation of Immunoassays for GLP Bioanalytics
- Critical parameters: accuracy, sensitivity & precision
- Population cut-point and confirmatory assays
- Stability of positive controls in biological matrix
- Incurred Sample Re-Analysis

Strategies and techniques to improve assays
- Improve accuracy and repeatability
- Avoid common technical errors

Method Transfer
- How to transfer a method?
- Transfer tools during product development
- Donor and Acceptor
- Investigation, calculation and comparison of method parameters

Stability Testing for Biological/Biotechnological Drug Substances and Drug Products

29 March 2012, Copenhagen, Denmark

Objectives

During this course you will get to know the relevant aspects of stability testing for biological and biotechnological drug substances and drug products. You will learn about

- the basic requirements of stability testing and stability study design from the supervisory authority's view
- the peculiarities of stability indicating analytical methods
- optimising strategies regarding packaging and storage of biological/biotechnological material
- how to submit stability data for a marketing authorisation dossier according to the new Guideline on Quality Documentation

Background

The active components in biotechnological/biological products are typically proteins and/or polypeptides. They have distinguishing characteristics to which consideration should be given in any well-defined testing program designed to confirm their stability during the intended storage period. The products are particularly sensitive to environmental factors such as temperature changes, oxidation, light, ionic content, and shear. In order to ensure maintenance of biological activity and to avoid degradation, stringent conditions for their storage are usually necessary.

The evaluation of stability may necessitate complex analytical methodologies. Appropriate physicochemical, biochemical and immunochemical methods for the analysis of the molecular entity and the quantitative detection of degradation products should also be part of the stability program.

In order to get the approval to conduct a clinical trial data have to be presented on the biological, chemical and pharmaceutical quality of Investigational Medicinal Product (IMP). In the new Guideline on the Requirements for Quality Documentation Concerning Biological Investigational Medicinal Products in Clinical Trials particular provisions are laid down on how to document stability and other quality related data within the CTD structure.

Target Audience

- Manufacturing process professionals
- QA/QC staff and regulatory personnel
- Clinical staff, pharmacologists and toxicologists
- Project Managers & outsourcing personnel
- Analytical chemists and biochemists

Programme

Stability Testing of Biological and Biotechnological Drug Substances and Drug Products

- Biologicals and relevant guidelines
- Specific differences between chemical entities and biologicals
- Stability-indicating profile of Monoclonal Antibodies and Immunoglobulins
- Storage conditions
- Impact of changes on stability
- Submitting stability data within the CTD-structure

Stability studies and shelf-life determination, starting activities and study report

- Prerequisites for performing a stab study
- Concepts for study design and reporting
- Start, study performance and study closing
- Regulatory aspects during product development
- Objectives for a final stab study report

Stability-indicating analytical methods for biotechnological/biological products

- Selection of appropriate, sensitive methods
- Analysis of stressed samples
- Statistical interpretation of shifts and drifts

Workshop I:
Study Design, Impurities and Stability Specifications

Workshop II:
Potency assays

Optimising Packaging and Storage Conditions for biotech products

Stability requirements of the new Guideline on Quality Documentation Concerning Biological Investigational Medicinal Products in Clinical Trials

- Control of excipients
- Specifications, batch analysis
- Stability data
- Shelf-life determination
- Post approval extension
- Substantial amendments

Speakers

Dr Markus Fido

Vela, Austria

Markus Fido is CEO and Founder of Vela Laboratories, were he is responsible for Finance & Controlling Regulatory Affairs & Quality Operations. Before that he was Head Quality Control at Igeneon / Aphton Biopharma AG where he was in charge for all QC aspects of pre-clinical and clinical projects such as stability studies, specifications, method validation, and product release. Prior he was working as a Group Leader of Immunology and Product Development at Biomin GmbH, Head Biochemical Control at Baxter AG and Head Quality Operations at Octapharma GmbH. His focus is GMP/GCP concerns during the development of Biopharmaceuticals, Biosimilars and Biologics. He holds a Ph.D. in biochemistry and molecular microbiology from the Technical University in Graz (Austria).

Dr Siegfried Giess

Paul Ehrlich Institute, Germany

Siegfried Giess is deputy head of the Department of Immunology and head of the Immunochemistry-Section. He is engaged in testing activities of the OMCL-network and involved in the quality assessment of immunoglobulins, immunsera and monoclonal antibodies. Furthermore is nominated expert of the CHMP at the European Medicines Agency (EMA), member of the Working Party Monoclonal Antibodies of the EP Commission and belongs to the USP Monoclonal Antibodies Expert Panel. He is member of the Heads of Medicines Agencies Working Group on Product Testing and member of the BWP Drafting Group for the "Guideline on the Requirements for Quality Documentation concerning Biological Investigational Medicinal Products in Clinical trials"

Dr Ana T. Menendez

Menendez bio-Consultants LLC - President

Dr Menendez obtained her Ph.D. in Microbiology/Immunology in 1995 from NY Medical College. She has over 25 years of experience in biopharmaceutical method development and validation and implemented several laboratories to verify the functionality, purity and safety of biotechnology products. Her skills include cellular and immunological methods used in potency, residual testing, bioanalytical testing and immunogenicity. During her career, she hold different positions at Wyeth, Bristol Myers Squibb and Catalent. Since 2011 she leads Menendez Bio-Consultants to continue applying her expertise to the development of biological products.

Dr Andreas Nechansky

Vela Laboratories, Austria

Andreas graduated in 1997 ('Molecular Genetics') from the University of Vienna and did his post-doctorial work at the Novartis Research Institute in Vienna and The Scripps Research Institute in La Jolla, USA. He held the position of Head of Analytical Development at Igeneon/Aphton Biopharma where he was responsible for the method establishment and qualification. He is Founder/COO of Vela Laboratories and responsible for analytical operations. His extensive experience covers the field of antibody/protein characterization, the underlying immunology and the regulatory requirements.

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@gmp-compliance.org

Internet:
www.gmp-compliance.org

Date

Bioassays and Bioanalytics
Tuesday, 27 March 2012 09.30 – 18.00 h
(Registration and coffee 09.00 – 09.30 h)
Wednesday, 28 March 2012, 08.30 – 17.30 h

Stability Testing for Biological/Biotechnological Drug Substances and Drug Products
Thursday 29 March 2012, 08.30 – 17.00 h
(Registration and coffee 08.30 – 09.00 h)

Venue of both courses

Radisson BLU Scandinavia Hotel
Amager Boulevard 70
2300 Copenhagen S
Denmark
Phone +45 33 96 50 00 or 00800 3333 3333
Fax +45 33 96 55 55

Fees

Bioassays and Bioanalytics
ECA Members € 1,490.- per delegate plus VAT
APIC Members € 1,590.- per delegate plus VAT
(does not include ECA Membership)
Non-ECA Members € 1,690.- per delegate plus VAT
EU GMP Inspectorates € 845.- 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.

Stability Testing for Biological/Biotechnological Drug Substances and Drug Products
ECA Members € 790.- per delegate plus VAT
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(does not include ECA Membership)
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EU GMP Inspectorates € 445.- per delegate plus VAT
The conference fee is payable in advance after receipt of invoice and includes conference documentation, lunch and all refreshments. VAT is reclaimable.

Would you like to save money?
If you book „Bioassayss and Bioanalytics" AND „Stability Testing for Biological/Biotechnological Drug Substances and Drug Products" simultaneously, the fee reduces as follows:
ECA Members € 1,790.- per delegate plus VAT
APIC members € 1,890,- per delegate plus VAT (does not include ECA membership)
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EU GMP Inspectorates € 995.- per delegate plus VAT
The fee is payable in advance after receipt of invoice and includes conference documentation, social event and dinner on the first day, lunch on all 3 days and all refreshments. VAT is reclaimable.

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 event. Please use this form for your room reservation or be sure to mention "VA 7305 ECA Course" to receive the specially negotiated rate (single room DKK 1.445 per night, plus DKK 185 for breakfast) for the duration of your stay. Reservation should be made directly with the hotel not later than 27 February 2012. Early reservation is recommended.

Registration

Via the attached reservation form, by e-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 ++49-62 21/84 44-0
Fax ++49-62 21/84 44 34
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Stability Testing for Biological/Biotechnological Drug Substances and Drug Products:
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For questions regarding reservation, hotel, organisation etc.:
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☐ **Bioassays and Bioanalytics,** 27 – 28 March 2012, Copenhagen, Denmark

☐ **Stability Testing for Biological/Biotechnical Drug Substances and Drug Products,** 29 March 2012, Copenhagen, Denmark

☐ Mr ☐ Ms

Title, first name, surname

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