- Bioassays and Bioanalytics
11-12 September 2018, Copenhagen, Denmark

- Stability Testing for Biological/Biotechnological Drug Substances and Drug Products
13 September 2018, Copenhagen, Denmark

SPEAKERS:

Rainer Fedra
VelaLabs, Austria

Markus Fido
VelaLabs, Austria

Siegfried Giess
form. Paul Ehrlich Institute, Germany

Ulrike Herbrand
Charles River Laboratories, Germany

Michael Leiss
Roche Diagnostics, Germany

Dr Manuela Leitner
AGES, Austria

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Bioassays and Bioanalytics

- GMP and GLP Overview and Expectations
- Development Potency Assays
- GMP Validation
- Development of Immunoassays
- Optimising Strategies
- Method Transfer

Stability Testing for Biological/Biotechnological Drug Substances and Drug Products

- Expectations of the Regulatory Authorities on Stability Data
- Stability-indicating analytical methods
- Stability studies and shelf-life determination
- Optimising storage conditions
- Degradation of Polysorbate
- Submitting Stability Data within the CTD-Structure - the new Guideline on Quality Documentation Concerning Biological Investigational Medicinal Products in Clinical Trials

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

The course includes a general discussion of GMP, GLP, and GCLP principles and how they apply to potency assays, limits 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 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

Markus Fido, Axel Schroeder

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

Regulatory Expectations and Requirements on Bioassays and Bioanalytical Methods
- Introduction and general aspects
- Bioassays and methods – expected data
- Guidance documents

Development I - Selecting Methods and Types of Assays
- Assay types
- Feasibility
- Preparing the cell bank
- Optimization parameters
- Replacement methods for primary assays
- Readouts

Development II – focus on clinical assays (PK/PD/ADA)
- Standards and controls
- Eliminating edge and hook effects
- Setting system suitability criteria

GMP Pre-Validation of Bioactivity (Potency) Assays
- Choice of statistical models
- Defining and improving intermediate precision
- Process controls

GMP Validation Protocol of Bioactivity (Potency) Assays
- Guidelines and requirements
- Validation parameters
- Setting realistic sample specs for validation
- Phase specific validation
- Validation report

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

GCLP Validation of Immunoassays with Focus on Bioanalytics
- Critical parameters: accuracy, sensitivity & precision
- Population cut-point and confirmatory assays
- Stability of positive controls in biological matrix
- Incurred sample re-analysis

Workshops Session

1. Validation Protocol Workshop for Bioactivity (Potency) Bioassays
2. Validation Protocol Workshop for PK/PD and Immunogenicity Assays

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
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
- Biologics and relevant guidelines
- Specific differences between chemical entities and biologics
- 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 Studies beyond Lot Stability
- Selection of appropriate, sensitive methods
- Analysis of stressed samples
- Statistical interpretation of shifts and drifts
- Acceptance limits

Workshop I:
Study Design, Impurities and Stability Specifications

Workshop II:
Potency Assays

Degradation of Polysorbate
- Mechanisms of Polysorbate degradation
- Consequences of Polysorbate degradation
- Analytical tool box for degradation assessment

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

Rainer Fedra, VelaLabs, Austria
Rainer started his career in the Quality Control Labs of Boehringer Ingelheim Vienna, during his studies of pharmaceutical biotechnology at the IMC Krems. He joined Vela laboratories in 2011. His current position is Deputy Head Laboratory, Head Assay Development.

Dr Markus Fido, VelaLabs, Austria
Markus Fido is CEO and Founder of Vela Laboratories, where he is responsible for Finance & Controlling, Regulatory Affairs & Quality Operations. Before that he was Head Quality Control at Igeneon / Aphton Biopharma AG, Group Leader of Immunology and Product Development at Biomin GmbH, Head Biochemical Control at Baxter AG and Head Quality Operations at Octapharma GmbH.

Dr Siegfried Giess, formerly Paul Ehrlich Institute, Germany
Dr Giess worked at the Paul-Ehrlich-Institut, the Federal Institute for Vaccines and Biomedicines in Germany. He was deputy head of the Department of Immunology and head of the Immunochemistry Section. He was engaged in testing activities of the OMCL-Network and involved in the quality assessment of immunoglobulins, immunsera and monoclonal antibodies. Dr Giess was nominated expert of the CHMP at the European Medicines Agency (EMA) and was member of the Working Party Monoclonal Antibodies of the EP Commission and chair of the CAP Advisory Group at EDQM. Between 2010 and 2015 he belonged to the USP Monoclonal Antibodies Expert Panel.

Ulrike Herbrand, Charles River Biopharmaceutical Services GmbH, Biosafety & Bioassays Services, Germany
Ulrike Herbrand joined Charles River Biopharmaceutical Services in 2007 and works as a scientific officer in the Biosafety & Bioassay Services department. She gained a PhD in biological sciences during her time at the Max-Planck-Institute for Molecular Physiology in Dortmund (Germany) and worked five years at post-doctoral positions at medical research centers in the field of cancer research.

Dr Michael Leiss, Roche Diagnostics, Germany
Michael Leiss studied biochemistry at the University Regensburg and gained his doctorate at the Max Planck Institute of Biochemistry in Munich. He joined Roche in 2009, where he currently holds a position as lab manager, being responsible for biologics batch release testing and analytical method development.

Dr Manuela Leitner, AGES, Austria
Manuela Leitner started her career in the pharmaceutical industry as drug safety officer at Wyeth Whitehall Export GmbH, responsible for Austria and Eastern European countries. In 2006 she joined AGES, responsible for batch release testing at the OMCL (Official Medicines Control Laboratory). Her current position is quality assessor of biological and biotechnology derived products, with focus on recombinant proteins, biosimilars and plasma derived medicinal products at the Austrian Agency for Health and Food Safety (AGES).
Bioassays and Bioanalytics
Tuesday, 11 September 2018, 09.30 – 18.00 h
(Registration and coffee 09.00 – 09.30 h)

Stability Testing for Biological/Biotechnological Drug Substances and Drug Products
Thursday, 13 September 2018, 08.30 – 17.00 h
(Registration and coffee 08.00 – 08.30 h)

Venue of both courses
Radisson BLU Scandinavia Hotel
Amager Boulevard 70
2300 Copenhagen S, Denmark
Phone +45 33 96 50 00
Fax +45 33 96 55 00
email scandinavia.meetings.events@radissonblu.com

Fees (per delegate plus VAT)

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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 „Bioassays and Bioanalytics“ AND „Stability Testing for Biological/Biotechnological Drug Substances and Drug Products“ simultaneously, the fee reduces as follows:

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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 HEIDELBERG has reserved a limited number of rooms in the conference hotels. You will receive a room reservation form/FOG when you have registered for the event. Reservation should be made directly with the hotel. 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
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For questions regarding content: Bioassays and Bioanalytics
Mr. Axel Schroeder (Operations Director) at +49(0)62 21/84 44 10, or per e-mail at schroeder@concept-heidelberg.de.

Stability Testing for Biological/Biotechnological Drug Substances and Drug Products
Dr. Gerhard Becker (Operations Director) at +49(0)62 21/84 44 65, or per e-mail at becker@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc.: Mr. Ronny Strohwald (Organisation Manager) at +49(0)62 21/84 44 51, or per e-mail at strohwald@concept-heidelberg.de.

Social Event
In the evening of the first course day, 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.
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Reservation Form (Please complete in full)

☐ Bioassays and Bioanalytics,
11-12 September 2018, Copenhagen, Denmark

☐ Stability Testing for Biological/Biotechnical Drug Substances and Drug Products,
13 September 2018, Copenhagen, Denmark

Mr  ☐ Ms

Title, first name, surname

Company  Department

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German law shall apply. Court of jurisdiction is Heidelberg.

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