Bioassays and Bioanalytics
17/18 September 2019, Copenhagen, Denmark

Stability Testing for Biological/Biotechnological Drug Substances and Drug Products
19 September 2019, Copenhagen, Denmark

SPEAKERS:

Dr Jörg Engelbergs
Paul-Ehrlich-Institut, German Federal Agency for Vaccines and Biomedicines

Rainer Fedra
VelaLabs, Austria

Dr Markus Fido
VelaLabs, Austria

Dr Ulrike Herbrand
Charles River Laboratories, Germany

Dr Michael Leiss
Roche Diagnostics, Germany

GMP and GLP Overview and Expectations
Development Potency Assays
GMP Validation
Development of Immunoassays
Optimizing Strategies
DOE
Statistics & Trending
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 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

Moderator

Dr Markus Fido

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

GMP & G(C)(L)P Guidelines (EMA & FDA)
- Overview and Interpretation

Development of Bioactivity / Potency Assays – selecting methods and types of assays
- Assay Types
- Feasibility
- Preparing the Cell Bank
- Optimization Parameters
- Replacement methods for primary assays
- Readouts

Development of Immunoassays for GCLP Bioanalytics
- Standards and controls
- Eliminating edge and hook effects
- Setting system suitability criteria

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

Statistical Analyses & Trending

Development of clinical assays (PK/PD/ADA)

GMP Validation of Bioactivity (Potency) Assays
- Guidelines and Requirements
- Validation Parameters
- Setting Realistic Sample Specs for Validation
- Phase Specific Validation
- Validation Report

DOE
- DOE versus OFAT

Workshops Session

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

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

Bioassays and Bioanalytics
17/18 September 2019, 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
- Biologials and relevant guidelines
- Specific differences between chemical entities and biologials
- 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

Dr Jörg Engelbergs, Paul-Ehrlich-Institut, German Federal Agency for Vaccines and Biomedicines
Jörg studied biology at the university of Düsseldorf and Duisburg-Essen. After his PhD he worked in different positions at the German Cancer Center before he joined the PEI in 2006 as Scientific-Regulatory Expert Biomedicines (Quality, Non-Clinic, Pers. Medicines - Biomarker/CDx)

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, were 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 Ulrike Herbrand, Charles River Biopharmaceutical Services GmbH, Biosafety & Bioassays Services, Germany
Ulrike Herbrand joined Charles River Laboratories in 2007. She is Scientific Director Global in vitro Bioassays and Supervisor for Bioassay Research & Development at Charles River Laboratories’ site in Erkrath, Germany. 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. She is an expert in mechanism of action-reflecting bioassays for protein therapeutics, specifically monoclonal antibodies.

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.
Date

**Bioassays and Bioanalytics**
Tuesday, 17 September 2019, 09.30 – 18.00 h  
(Registration and coffee 09.00 – 09.30 h)

**Stability Testing for Biological/Biotechnological Drug Substances and Drug Products**
Thursday, 19 September 2019, 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)

**Bioassays and Bioanalytics**
ECA Members € 1,590  
APIC Members € 1,690  
Non-ECA Members € 1,790  
EU GMP Inspectorates € 895  
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 € 890  
APIC Members € 940  
Non-ECA Members € 990  
EU GMP Inspectorates € 495  
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 „Bioassays and Bioanalytics“ AND „Stability Testing for Biological/Biotechnological Drug Substances and Drug Products“ simultaneously, the fee reduces as follows:  
ECA Members € 2,080  
APIC members € 2,180  
Non-ECA Members € 2,280  
EU GMP Inspectorates € 1,140  
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/POG 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
ECA has entrusted Concept Heidelberg with the organisation of this event.

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

For questions regarding content please contact:  
Bioassays and Bioanalytics:  
Mr Axel Schroeder (Operations Director) at +49-62 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. please contact:  
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 September 17, 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.
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:
   - until 2 weeks prior to the conference 10%,
   - until 1 week 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. In these cases, 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.

Terms of payment: Payable without deductions within 10 days after receipt of invoice.

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)!

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 information related to 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.