ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Quality Control Manager

Speakers

Dr Jörg Engelbergs
Paul Ehrlich Institute, Germany

Rainer Fedra
VelaLabs, Austria

Dr Markus Fido
Vela Labs, Austria

Dr Ulrike Herbrand
Charles River Laboratories, Germany

Dr Michael Leiss
Roche

Bioassays and Bioanalytics

20/21 October 2020 | Hamburg, Germany

Stability Testing for Biological/Biotechnological Drug Substances and Drug Products

22 October 2020 | Hamburg, Germany

Highlights

Bioassays and Bioanalytics

- 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

Book both courses and save 590 €!

Objective

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

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

Objective

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 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, Vienna, 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.

Dates

Bioassays and Bioanalytics

Tuesday 20 October 2020, 09.30 – 18.00 h
(Registration and coffee 09.00 – 09.30 h)
Wednesday, 21 October 2020, 08.30 – 17.30 h

Stability Testing for Biological/Biotechnological Drug Substances and Drug Products

Thursday 22 October 2020, 08.30 – 17.00 h
(Registration and coffee 08.00 – 08.30 h)

Venue of both courses

Barceló Hotel Hamburg
Ferdinandstrasse 15
20095 Hamburg, Germany
Phone +49(0)40 22 63 62 0
Email hamburg@barcelo.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“ imultaneously, the fee reduces as follows:
ECA Members € 2,180
APIC members € 2,280
Non-ECA Members € 2,380
EU GMP Inspectorates € 1,190
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 hotel. You will receive a room reservation form/POG when you have registered for the course. 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.

Certificate of Participation

Shortly after the event, you will receive your certificate of participation by email.

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:
Mr Axel H. Schroeder (Operations Director) at
+49(0)62 21/84 44 10, or at
schroeder@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 at
strohwald@concept-heidelberg.de

Social Event

In the evening of the 20 October, 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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CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49 (0) 62 21/84 44 34

D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

☐ Bioassays and Bioanalytics, 20/21 October, Hamburg, Germany
☐ Stability Testing for Biological/Biotechnical Drug Substances and Drug Products, 22 October, Hamburg, Germany

Title, first name, surname

Department Company

Important: Please indicate your company's VAT ID Number Purchase Order Number, if applicable

City ZIP Code Country

Phone / Fax

E-Mail (Please fill in)

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 %,
- Cancellation until 1 weeks prior to the conference 50 %
- Cancellation 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 HEIDELBERGwill 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)! (As of January 2012).
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 me information in relation with 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.