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
MFi Bio-Consulting, Austria

Dr Ulrike Herbrand
Charles River Laboratories, Germany

Dr Michael Leiss
Roche, Germany

Bioassays and Bioanalytics

Live Online Training on 25/26 October 2022

Stability Testing for Biological/Biotechnological Drug Substances and Drug Products

Live Online Training on 27 October 2022

Highlights

Bioassays and Bioanalytics

- GMP and GLP Regulatory 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 Live Online Training Courses and save up to 400 €!

Objective

The Live Online Training 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. Case studies 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

Case Studies on Special Bioassays for Biopharmaceuticals and Biosimilars

- ADCC/CDC
- RBA mAb

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 Live Online Training 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

Study Design, Impurities and Stability Specifications

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
MFi Bio-Consulting GmbH, Austria

Markus Fido has started his own consulting business in 2020. Before that he was CEO and Founder of Vela Laboratories, were he was 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 postdoctoral 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 of the Live Online Training

Bioassays and Bioanalytics
Tuesday, 25 October 2022, 09.00 – 17.30 h CEST
Wednesday, 26 October 2022, 09.00 – 17.30 h CEST

Stability Testing for Biological/Biotechnological Drug Substances and Drug Products
Thursday, 27 October 2022, 08.30 – 17.00 h CEST

Technical Requirements

We use WebEx Events for our live online training courses and webinars. At https://www.gmp-compliance.org/training/online-training-technical-information you will find all the information you need to participate in our trainings and you can check if your system meets the necessary requirements to participate. If the installation of browser extensions is not possible due to your rights in the IT system, please contact your IT department. WebEx is a standard nowadays and the necessary installation is fast and easy.

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 fee is payable in advance after receipt of invoice.

Stability Testing for Biological/Biotechnological Drug Substances and Drug Products
ECA Members € 990
APIC Members € 1,040
Non-ECA Members € 1,090
EU GMP Inspectorates € 545
The fee is payable in advance after receipt of invoice.

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 € 2,280
APIC members € 2,380
Non-ECA Members € 2,480
EU GMP Inspectorates € 1,440
The fee is payable in advance after receipt of invoice.

Registration

Via the attached reservation form, by e-mail or by fax message. Or you register online at www.gmp-compliance.org.

Presentations/Certificate

The presentations will be made available to you prior to the Live Online Training as PDF files. After the event, you will automatically receive your certificate of participation.

Conference language

The official conference language will be English.

Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this event.

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Ordering Recordings

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This Live Online Training is recognized for the GMP/GDP Certification Scheme

Building on your education the ECA GMP/GDP certification programmes provide you with the appropriate supplement to acquire this qualification. This training course is the first element for your additional certification. Simply choose any three courses within the programme according to your professional interest. Your certificate is then valid for two years. To renew it, you can pick any training from the ECA courses and conferences list within that two-years period – allowing you to broaden your knowledge in GMP and GDP compliance. Please find more information at www.gmp-certification.org.


ECA Academy

We hereby confirm that

Mr John Smith

has completed the following ECA GMP Certification Programme

ECA Certified Quality Control Manager

[to be renewed by February 2022]

Statement of Continuous Education

We also confirm the participation in the following training courses and conferences recognised for the ECA GMP Certification Programme

Analytical Instrument Qualification
Leachables and Extractables Testing and Assessment
Validation of Analytical Test Procedures and Measurement Uncertainty

Heidelberg, January 2020

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Reservation Form (Please complete in full)

☐ Bioassays and Bioanalytics, Live Online Training on 25/26 October 2022
☐ Stability Testing for Biological/Biotechnological Drug Substances and Drug Products, Live Online Training on 27 October 2022

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.
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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.

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