ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Biotech Manager

Speakers

Dr Markus Fido
MFI Bio-Consulting, Austria

Dr Ulrike Herbrand
Charles River Laboratories, Germany

Dr Wolf Hagen Holtkamp
Paul-Ehrlich Institut, German Federal Agency for Vaccines and Biomedicines

Dr Henno van den Hooven
MSD, The Netherlands

Dr Michael Leiss
Roche Diagnostics, Germany

Dr Dietmar Reusch
Roche Diagnostics, Germany

Markus Roucka
VelaLabs, Austria

Protein Analytics

Evaluation, Implementation and Use of Suitable Technologies

Live Online Training on 13/14 April 2021

Highlights

- Regulatory Aspects
- Available Methods e.g. HPLC, MS, biophysical methods, immunochemical methods, (non-cellular) bioassays
- Qualification, Validation and Optimisation of Methods
- Host Cell Proteins
- Physicochemical Methods

Bringing Compliance and Science together

Objective

Biopharmaceutical processes and the specifics in the control of these processes are highly complex. Compared to the "classic" chemical pharmaceutical products and processes, they are frequently on a much higher level – as, for instance, in the case of proteins. In addition, the drug product alone possibly poses real challenges due to the restraints created by the nature of the protein.

Over the last years a huge variety of analytical methods – ranging from physicochemical tests to biological assays – have been established.

As the range of biopharmaceuticals is evolving, new tests have to be developed, validated, transferred, applied at the same time. And, last but not least, they have to be accepted by regulatory authorities.

In this Live Online Training, pros and cons of established and newly emerging assays will be discussed. Industry experts will share their in-depth knowledge and experiences. During workshops in small groups, you will deepen your knowledge about special methods and their validation issues.

The course has been designed to answer your individual questions concerning assays for the quality control of proteins. In addition you will benefit from information on bioassays and current hot topics like host cell proteins. Therefore, the number of participants is strictly limited.

Background

The number of biopharmaceutical products is increasing, in clinical phases as well as in the market. Due to their high complexity they show an excellent targeting ability. To ensure the quality and targeting ability, a profound analysis of the drug substance's quality is of utmost importance. This particularly applies to protein based products and in the production of recombinant proteins. However, it 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 thus a multi-disciplinary effort involving many professionals with diverse backgrounds.

Target Audience

This Live Online Training is of interest to those who are involved in

- Quality Control
- Quality Assurance
- Regulatory Affairs
- Research and Development

of proteins, processes and analytical assays in the biopharmaceutical industry.

Programme

Why do we Test? What must be Analysed?

- ICH guideline Q6B
- Composition of product (desired product, excipients, impurities, contaminants)
- Application of tests

Regulatory Aspects on Analytical Methods

- What do we expect from bioanalytical methods?
- Biopharmaceuticals - challenges for analytical methods
- Development of novel analytical methods (needs and challenges)
- Validation of analytical methods (LOQ)

Liquid Chromatography

- Reversed-phase high-performance liquid chromatography
- Size-exclusion chromatography
- Ion-exchange chromatography
- Applications for biopharmaceuticals

Controlling Host-Cell Impurities in Biopharmaceuticals

- Why HCP analytics?
- Means to analyze HCP and Limitations of Applied Methods
- Control strategy and Regulatory Expectations

ELISA, ECL Technologies

- ECL introduction using MesoScaleDiscovery device
- ELISA based setups for PK & immunogenicity
- ECL – optimizing immunogenicity assays
- Validation of PK and ADA screening assay

Mass Spectrometry

- Intact Mass Analysis - investigation of antibody heterogeneity
- LC/MS - investigation of primary structure and modifications
- Fundamentals of MALDI-MS
  MALDI-MS as a complementary technique to ESI-MS

Characterization of Biotherapeutic Proteins by Size-Exclusion Chromatography Coupled to Native Mass Spectrometry

- Status quo: Methods for therapeutic Protein Characterization
- Current Questions and Challenges
- Innovative Approaches and Methods
- Application and Examples

Bioassays

- Types of Assays for different molecules
- Mechanism of Action (MoA) reflecting assays
- Surrogate Approaches for tedious primary assays
- Biosimilarity assessment

Non-Cellular Assays (SPR, Lectin Binding)

- Orthogonal methods to Bioassays
- Prediction of potency with non-cellular assays (surrogate assays)
- Characterization of antibodies and its biosimilars
- Explanation of Surface Plasmon Resonance (SPR) technology and lectin array

Glycoanalysis

- Glycosylation of protein
- Why glycoanalysis?
- Principles of glycoanalysis
- Separation based methods
- MS based methods
- Comparison of methods for glycoanalysis

Interactive Session with Case Studies and Practical Examples:

- Immunochemical Methods
  Dr Markus Fido
- Spectroscopic Analysis and Chromatography
  Dr Dietmar Reusch & Dr Michael Leiss & Henno van den Hooven
- Cellular Assays
  Markus Roucka & Dr Ulrike Herbrand

Additional Methods for Protein Characterization

- Relevant Physico-chemical Methods – like CD, fluorescence, IR spectroscopy, AUC, SEC-MALLS, DLS, DSC, microflow imaging, etc. and biophysical methods

Moderators

Dr Markus Fido MFI Bio-Consulting, Austria
Axel H. Schroeder, Concept Heidelberg

Speakers

Dr Markus Fido, MFI Bio-Consulting, Austria

Markus Fido holds a doctorate in biochemistry & cell biology. He has worked in quality and product development at Octapharma, Baxter and Igeneon. He then founded Vela Laboratories which he led as CEO for many years. In 2019/2020 he was responsible for the international Pharma Business Development of the Tentamus Group. In May 2020 he founded his new company MFI Bio Consulting GmbH.

Dr Ulrike Herbrand, Charles River Laboratories, 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 is an expert in mechanism of action-reflecting bioassays for protein therapeutics, specifically monoclonal antibodies.

Dr Wolf Hagen Holtkamp, PEI, German Federal Institute for Vaccines and Biomedicines

Wolf Hagen Holtkamp studied Biochemistry at the Private Universität Witten-Herdecke. He worked as scientist at the University Witten Herdecke and the Max-Planck-Institute for biophysical Chemisty. 2017 he joined the Paul-Ehrlich-Institute as Laboratory Head product testing of immunological medicinal products and batch release control.

Dr Henno van den Hooven, MSD, The Netherlands

Henno van den Hooven obtained his PhD degree in 1995 in the field of biophysical chemistry at the University of Nijmegen. Until 2017 he was at MSD in Oss, the Netherlands. The responsibilities are mainly for late stage development and cover the field of analytical development of protein drugs. Since 2020 he is working again for MSD as Product Lead Biotech Technical Operations.

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 Dietmar Reusch, Roche Diagnostics, Germany

Dietmar gained his PhD at the Free University of Amsterdam with "Glycosylation analysis of therapeutic antibodies". Since 1988 he is working at Roche Diagnostics. At present Dietmar is heading the Characterisation Analytics department at the Roche facility in Penzberg, Germany.

Markus Roucka, VelaLabs GmbH, Austria

Markus started his career in the biotechnical laboratories of Biomin GmbH. Later he studied medical and pharmaceutical biotechnology at the University of Applied Science IMC Krems. He joined VelaLabs in 2008. Since than he had many stages starting from Head Laboratory to COO. His current position is Managing Director where he is responsible for Customer relations and Business development.

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Reservation Form (Please complete in full)

Protein Analytics, Live Online Training on 13/14 April 2021

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)

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If you cannot attend the conference you have two options:
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German law shall apply. Court of jurisdiction is Heidelberg.

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Date of the Live Online Training

Tuesday, 13 April 2021, 09.00 – 18.00 h CEST
Wednesday, 14 April 2021, 08.30 – 17.00 h CEST

Technical Requirements

For our Live Online Training Courses and Webinars, we use Cisco WebEx, one of the leading suppliers of online meetings. At http://www.webex.com/test-meeting.html you can check if your system meets the necessary requirements for the participation at a WebEx meeting and at the same time install the necessary plug-in. Please just enter your name and email address for the test. If the installation is not possible because of your rights for the computer system, please contact your IT department. WebEx is a standard nowadays and the necessary installation is fast and easy.

Fees (per delegate, plus VAT)

ECA Members € 1,690
APIC Members € 1,790
Non-ECA Members € 1,890
EU GMP Inspectorates € 945

The conference 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.

Internationally Acknowledged Certificate from ECA Academy

The EU GMP Guide requires: „... All personnel should be aware of the principles of Good Manufacturing Practice that affect them and receive initial and continuing training,...." This is why you receive an acknowledged participant certificate, which lists the contents of the seminar in detail and with which you document your training.

Organisation and Contact

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

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