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
Vela Labs, Austria

Protein Analytics

Evaluation, Implementation and Use of Suitable Technologies

06/07 June 2023 | Neuss/Düsseldorf, Germany

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 course, 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.

We recommend early registration.

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. In addition, the relevant guidelines for analytical methods are also subject to repeated updates in order to follow the state of the art in science and technology (ICH Q2 (R2), ICH Q14, ICH Q6b and more).

Target Audience

This course 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 Workshop Sessions with Case Studies and Practical Examples:

1. **Immunochemical Methods**
   Dr Markus Fido
2. **Spectroscopic Analysis and Chromatography**
   Dr Dietmar Reusch, Dr Michael Leiss, Henno van den Hooven
3. **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.

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, Vela Laboratories, 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. After eight years as Head of Laboratory & department leader of assay development his current position is now COO and Business development.

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GERMANY

Reservation Form (Please complete in full)

Protein Analytics, 06/07 June 2023, Neuss/Düsseldorf, Germany

Please choose TWO workshops:
☐ *Immunochemical Methods*
☐ *Spectroscopic Analysis and Chromatography*
☐ *Cellular Assays*

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 4 weeks prior to the conference 10 %,
- Cancellation until 3 weeks prior to the conference 25 %,
- Cancellation until 2 weeks prior to the conference 50 %,
- Cancellation within 2 weeks prior to the conference 100 %.

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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.

Date
Tuesday, 06 June 2023, 09.00 – 18.00 h
(Registration and coffee 08.30 -09.00 h)
Wednesday, 07 June 2023, 08.30 – 16.30 h

Venue
Crowne Plaza Congress Centrum Düsseldorf / Neuss
Rheinallee 1
41460 Neuss, Germany
Phone +49 (0) 2131 77 00
Email emailus.neu02@gchhotelgroup.com

Fees (per delegate, plus VAT)
ECA Members € 1,690
APIC Members € 1,790
Non-ECA Members € 1,890
EU GMP Inspectorates € 945
The fee is payable in advance after receipt of invoice and includes dinner on the first day, lunch on both days and all refreshments. VAT is reclaimable.

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.

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.

Presentations / Certificate
The presentations for this event will be available for you to download and print before and after the event. Please note that no printed materials will be handed out on site and that there will not be any opportunity to print the presentations on site. After the event, you will automatically receive your certificate of participation.

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.
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