20 YEARS ECA Academy Your GMP/GDP Information Source

Protein Analytics

Evaluation, Implementation and Use of Suitable Technologies

Bringing Compliance and Science together

SPEAKERS:

Dr Markus Fido
Vela Labs, Austria

Dr Norbert Handler
RD&C, Austria

Dr Ulrike Herbrand
Charles River Laboratories, Germany

Dr Henno van den Hooven
The Netherlands

Dr Michael Leiss
Roche Diagnostics, Germany

Dr Dietmar Reusch
Roche Diagnostics, Germany

Markus Roucka
Vela Labs, Austria

28-29 May 2019, Munich, Germany

PROGRAMME:

- Regulatory Aspects
- Available Methods e.g. HPLC, MS, Biophysical Methods, Immunochemical Methods, (Non-Cellular) Bioassays
- Qualification, Validation and Optimisation of Methods
- Host Cell Proteins
- Biochemical Methods

This education course is recognised for the ECA GMP Certification Programme „Certified Biotech Manager“.
Please find details at www.gmp-certification.eu

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Objectives

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.

Target Group

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
- Analytical Methods for Biological Activity
- Challenges in Impurity Analytics
- Unwanted Immunogenicity
- Biosimilars
- General Authority Expectations

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 eterogeneity
- 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 their 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

Workshop Sessions:

- Immunochemical Methods
- Spectroscopic Analysis
- Chromatography
- Cellular Assays

Physicochemical Methods

- Relevant physico-chemical methods – like CD, fluorescence, IR spectroscopy, AUC, SEC-MALLS, DLS, DSC, microflow imaging, etc.
- Compendial release tests like appearance, clarity, colour, pH, extractable volume, content uniformity, particulate matter by laser obscuration spectroscopy, osmolarity

Speakers

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 / Apthon Biopharma AG where he was in charge for all QC aspects of pre-clinical and clinical projects such as stability studies, specifications, method validation, and product release. Prior he was working as a Group Leader of Immunology and Product Development at Biomin GmbH, Head Biochemical Control at Baxter AG and Head Quality Operations at Octapharma GmbH. His focus is GMP/GCLP concerns during the development of Biopharmaceuticals, Biosimilars and Biologics. He holds a Ph.D. in Biochemistry and Molecular Microbiology from the Technical University in Graz (Austria).

Dr Norbert Handler, RD&C Research, Development & Consulting GmbH, Austria
Norbert Handler is pharmacist by training and holds a PhD in Medicinal Chemistry. After several years in academia and pharmaceutical industry he was co-founder of the experts office RD&C GmbH in 2014, where he currently holds the position of a managing director. He is involved in several pharmaceutical projects providing scientific and regulatory advice with a specific focus on CMC, stability and impurities. Additionally, he was appointed as general authorized and certified expert for pharmaceutical chemistry at the trade court in Vienna.

Dr Ulrike Herbrand, Charles River Laboratories, Germany
Ulrike Herbrand joined Charles River Biopharmaceutical Services in 2007 and works as a scientific officer in the Biosafety & Bioassay Services department. 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.

Dr Henno van den Hooven, The Netherlands
Henno van den Hooven obtained his PhD degree in 1995 in the field of biophysical chemistry at the University of Nijmegen, The Netherlands. He did post-doctoral work in the field of biochemistry at the Dutch Institute for Dairy Research (NIZO), and at the Wageningen University, The Netherlands. 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.

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
After his study of chemistry, he was engaged at TÜV Stuttgart as specialist of environmental safety. He 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. His responsibilities are the characterization and comparability of all large molecules in development and production including mass spectrometry and glycoanalysis for release and high throughput.

Markus Roucka, Vela LabsOeca-t, Austria.
Markus started his career in the biotechnical laboratories of Biomin GmbH, Austria as R&D assistant for new product developments. He was responsible for fermentation and QC processes of the products. After more than four years he studied medical and pharmaceutical biotechnology at the University of Applied Science IMC Krems. For his Master thesis Markus went to the Netherlands and studied the effect of the TRIAL in combination with Bortezomib on NSCLC. 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.

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.

Easy Registration

Reservation Form:
CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg
Germany

Reservation Form:
+ 49 6221 84 44 34

e-mail:
info@concept-heidelberg.de

Internet:
www.gmp-compliance.org

If the bill-to-address deviates from the specifications on the right, please fill out here:

Reservation Form (Please complete in full)

+ 49 6221 84 44 34

Protein Analytics, 28-29 May 2019, Munich, Germany
Each participant will have the opportunity to take part in **TWO** workshops.

☐	Immunochemical Methods
☐	Spectroscopic Analysis
☐	Chromatography
☐	Cellular Assays

☐ Mr. ☐ Ms.

Title, first name, surname

Company Department

Important: Please indicate your company's VAT ID Number **P.O. Number (if applicable)**

Street/P.O. Box

City Zip Code Country

Phone/Fax E-Mail (please fill in)

CONCEPT HEIDELBERG
P.O. Box 101764
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D-69007 Heidelberg
GERMANY

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 %,
- until 1 weeks prior to the conference 50 %
- within 1 week 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, 28 May 2019, 09.00 – 18.00 h
(Registration and coffee 08.30 -09.00 h)
Wednesday, 29 May 2019, 08.30 – 16.30 h

Venue

Holiday Inn Munich - City Centre
Hochstraße 3
81669 Munich, Germany
Phone +49 (0)89 - 4803 0
postoffice@muchb.holidayinn.com

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 and includes conference documentation, dinner on the first day, lunch on both 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 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

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Mr Ronny Strohwald (Organisation Manager) at +49-62 21 / 84 44 51, or per e-mail at strohwald@concept-heidelberg.de.