- **Incl. Laboratory Visit at Vela Labs - Bringing Compliance and Science together**

Protein Analytics

Evaluation, Implementation and Use of Suitable Technologies

24 – 26 March 2015, Vienna Austria

SPEAKERS:

Rainer Fedra
Vela Labs
Dr Markus Fido
Vela Labs
Dr Ulrike Herbrand
Charles River Laboratories
Klaus Hajszan
Vela Labs
Dr Silke Huber
BSL Bioservices
Henno van den Hooven
MSD
Iris Koller
Vela Labs
Dr Michael Leiss
Roche, Diagnostics
Dietmar Reusch
Roche Diagnostics
Markus Roucka
Vela Labs
Dr Olaf Stamm
Charles River Laboratories

PROGRAMME:

- Qualification and Validation of Methods
- Available Methods – from Immunochemical to Cellular Assays
- Data Evaluation and Statistics
- Optimising and Speeding Analytics

ECA ACADEMY

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 methodss, 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

Validation of Protein Analytical Technologies
- Definitions of validation parameters
- Method validation as a lifecycle approach:
  - actual validation
  - transfers
  - maintenance

Analytical Methods for the Analysis of Excipients in formulations of Monoclonal Antibodies
- Status quo: methods for Release
- Current Questions and Challenges
- Innovative Approaches and Methods
- Application and Examples

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

Spectroscopic Analysis
- Application of UV spectroscopy for concentration measurements
- Application of UV and fluorescence spectroscopy for structural studies
- Industry examples

ELISA, ECL-Technologies
- ELISA setups for immunogenicity
- ECL introduction and ELISA comparison
- ECL – optimizing immunogenicity assays

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

The devil in the detail – HCP assay performance by design Considerations for the choice of a suitable antigen including regulatory and practical requirements
- Optimization of the immunization process by cascade/subtractive approaches
- Qualification of antigen and antisera as reagents for a GMP compliant assay development
- Targeted enhancement of coverage by combining tools from proteomics, protein synthesis and immunization

Non-Cellular assays (Biacore, Receptor-binding)

- Characterization of antibodies with non-cellular assays
- Explanation of Surface Plasmon Resonance (SPR) technology and alternatives
- Cost-effective procedures while maintaining and increasing the accuracy and sensitivity
- Guidelines for ligand binding assays

GLP Validation of Immunoassays for GLP Bioanalytics

- Ligand binding assay: ELISA formats and detection mechanisms
- Development and optimization: Setting acceptance criteria
- Relevant guidelines
- Validation procedure

Workshop Sessions :

- Immunochemical Methods
- Spectroscopic Analysis
- Chromatography
- Cellular Assays

Curve fitting and relative potency

- Curve fitting
- Regression models (linear, 4-PL, 5-PL)
- Relative potency evaluation

Bioassays

- Characterization of antibodies with non-cellular assays
- Explanation of Surface Plasmon Resonance (SPR) technology and alternatives
- Cost-effective procedures while maintaining and increasing the accuracy and sensitivity
- Guidelines for ligand binding 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, osmolality

Glycoanalysis

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

Moderators

Axel H. Schroeder, Concept Heidelberg
Dr. Markus Fido, VelaLabs, Vienna

Site Visit at Vela labs

VelaLabs is a world-wide acting, GMP-certified contract laboratory that offers in-depth analytical characterisation services for proteins (Biopharmaceuticals, Biologics and Biosimilars).
Combining a focused, customer - orientated approach, a highly motivated team and a broad expertise in analytical development and quality control, VelaLabs is dedicated to support the customer's needs from research activities to clinical phases and up to product commercialization.
Vela Laboratories offers analytical test methods for medicinal agents in the preclinical and clinical development phase. The analytic portfolio is based on the ICH-guidelines (International Conference for Harmonisation) and covers non-cellular and cellular methods. The service offer is completed by advisory support for submission-relevant clinical studies and drug product release.
The important quality assuring tool of Vela is the GMP certification which represents the highest quality standard in the pharmaceutical industry.

Image: Vela Labs

Please Note: Vela Labs reserves the right that participants from direct competitors could not participate at the site visit. In this case we will inform you latest 14 days after your registration.

Speakers

Rainer Fedra, Vela Labs, 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, Dept. Assay Development.

Dr Markus Fido, Vela Labs, 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 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.

Klaus Hajszan, VelaLabs, Austria
Klaus Hajszan is Head of Quality Control at Vela Laboratories and responsoble for planning, controlling and statistical analysis of method validation and for the coordination of analytical method transfer.

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.

Dr Henno van den Hooven, MSD, The Netherlands
At present, Henno van den Hooven is heading Analytical Project Management 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 Silke Huber, BSL Bioservice, Germany
Silke Huber studied nutritional science at the Technical University Munich followed by a PhD degree in the field of immunology at the LMU Munich. In 2011 she started her career at BSL as Study Director Immunoanalytics. Since 2013, she is the Head of the section immunoanalytics at BSL.

Iris Koller, VelaLabs, Head Quality ControlVienna, Austria
Iris studied Biochemistry and Biotechnology with a focus on active substances. In 2009 she joined VelaLabs and became 2012 Senior Officer Quality Control. Since April 2014, she is Head of the Quality Control department at Vela Labs

Dr. Michael Leiss, Roche Diagnostics, Germany
Michael Leiss studied biochemistry at the University Regensburg. After a stay at the University of Hong Kong with the DAAD, he gained his doctorate at the MPI. 2012, he joined Roche and is currently Project manager at the site in Penzberg.

Dietmar Reusch, Roche Diagnostics, Germany
Since 1988 Dietmar Reusch 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 Laboratories, Austria.
Markus started his career in the biotechnical laboratories of Biomin, Austria, followed with the study of pharmaceutical biotechnology at the IMC Krems. He joined Vela laboratories 2008. His current position is Head of Laboratory, Dept. Assay Development.

Dr Olaf Stamm, Charles River Bioservices, Germany
Dr Stamm joined Charles River (formerly NewLab) in 2003 and became responsible for the business development activities in Europe, Asia and the US. Prior to joining Charles River/NewLab he worked for Eurofins Scientific running their microbiological GMP testing laboratories in Switzerland.

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

Date

Tuesday, 24 March 2015, 09.00 – 1 8.00 h
(Registration and coffee 08.30 – 09.00 h)
Wednesday, 25 March 2015, 08.30 – 18.30 h
Thursday, 26 March 2015, 09.00 – 16.30

Venue

Austria Trend Hotel Bosei
Gutheil Schoder Gasse 7b
1100 Vienna, Austria
Phone +43/1/661 06-0
Fax +43/1/661 06-1122

Fees (per delegate plus VAT)

ECA Members € 1,990
APIC Members € 2,090
Non-ECA Members € 2,190
EU GMP Inspectorates € 1,095
The fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on all 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 when you have registered for the event. Please use this form for your room reservation to receive the specially negotiated rate for the duration of your stay. 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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P.O. Box 10 17 64
69007 Heidelberg, Germany
Phone +49 (0) 62 21/84 44-0
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www.concept-heidelberg.de

For questions regarding content:
Mr Axel Schroeder (Operations Director) at
+49-62 21 / 84 44 10, or per e-mail at
schroeder@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc.:
Ms Marion Weidemaier (Organisation Manager) at
+49-62 21 / 84 44 46, or per e-mail at
weidemaier@concept-heidelberg.de.

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Social Event

On 24 March 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.

GMP Certification Programme

This course is recognised within the GMP Certification Programme for the module "ECA Certified QA Manager". By attending selected seminars, the participant can acquire an additional certificate. We offer the following certification modules:

- ECA Certified Validation Manager
- ECA Certified QA Manager
- ECA Certified API Production Manager
- ECA Certified Quality Control Manager
- ECA Certified Technical Operations Manager
- ECA Certified Computer Validation Manager
- ECA Certified Regulatory Affairs Manager
- ECA Certified Microbiological Laboratory Manager
- ECA Certified Sterile Production Manager
- ECA Certified Biotech Manager
- ECA Certified Pharmaceutical Development Manager
- ECA Certified GMP Auditor
- ECA Certified GDP Compliance Manager

On the internet at www.gmp-compliance.org you will find a text explaining which seminars are recognised for which certificates. Or you send an e-mail to info@gmp-compliance.org or a fax to +49-6221-84 44 64 with the request for information about the GMP Certification Programme. We will then send you our brochure on the topic.

Special offer with Lufthansa – up to 20% discounted travel for all ECA Events Attendees

As an ECA course or conference attendee, you will receive **up to 20% discounted travel fares** (according to availability). And as Lufthansa German Airlines offers a comprehensive global route network linking major cities around the world you will most likely be able to benefit from these special prices and conditions.
And this is how it works: Once you registered for a course or conference you will receive a link together with your registration confirmation. Opening that link will take you to the Mobility Partner Program website where you can enter a code in the "Access to Event Booking" area you will also receive. This will take you into an online booking platform* that will automatically calculate the discount offered or provide you with an even better offer if another promotional fare is available.

We look forward to welcoming you at one of our next events – and we already wish you a pleasant flight!

*Please note: You may have to enable pop-ups on the Mobility Partner Program website – other-wise the booking platform window will not open.

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

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

Reservation Form (Please complete in full)

+ 49 6221 84 44 34

Protein Analytics, 24 – 26 March 2015, Vienna Austria
Each participant will have the opportunity to take part in **THREE** 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)

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 %.

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 HEIDELBERG will 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)

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.