ECA Certified Biotech Manager Course*

New:
Participate in two Workshops

Protein Analytical Technologies

Bringing Compliance and Science Together

23 – 24 March 2011, Vienna, Austria

SPEAKERS:

Dr Markus Fido
Vela Laboratories, Austria

Ron Hamelinck (BSc)
MSD, The Netherlands

Dr Andreas Nechansky
Vela Laboratories, Austria

Dietmar Reusch
Roche Diagnostics, Germany

Markus Roucka
Vela Laboratories, Austria

Dr Harald Wegele
Roche Diagnostics, Germany

PROGRAMME:

- Why do we test? What must be analyzed?
- Spectroscopic Analysis
- Electrophoresis / Capillary Electrophoresis
- Liquid Chromatography
- Methods for antibody characterization
- Mass Spectrometry
- Validation of Protein Analytical Technologies
- FACS and Biacore Methods
- Method Development and Validation during Preclinical and Clinical Phases
- Case Study: Analytical tools in the analysis of biopharmaceuticals at MSD

ECA
EUROPEAN COMPLIANCE ACADEMY

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

Protein Analytical Technologies

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Objectives

Biopharmaceutical processes and the specifics in the control of these processes are highly complex. A profound analysis of the quality of the drug substance, e.g. in the production of recombinant proteins, is of utmost importance – in many cases on a much higher level compared to the „classical" pharmaceutical industry. In addition, the drug product alone may cause 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, at the same time new tests have to be developed, validated, transferred, applied – and last but not least have to be accepted by regulatory authorities.

During 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 a focus will be set on validation issues.

This course will bring together representatives of the biopharmaceutical industry and regulatory authorities. It has been designed to answer your individual questions concerning assays for the quality control of proteins.

Therefore, the number of participants is strictly limited. We recommend early registration.

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.

Moderator

Axel H. Schroeder, Concept Heidelberg

Social Event

On 23 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.

Programme

Why do we test? What must be analyzed?
- ICH guideline Q6B
- Composition of product (desired product, excipients, impurities, contaminants)
- Application of tests

Markus Fido, *Vela Laboratories*

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

Ron Hamelinck, *MSD*

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

Harald Wegele, *Roche Diagnostics*

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

Markus Fido, *Vela Laboratories*

Non-cellular assays (ELISA and Biacore)
- ELISA using NiNTA technology
- SPR based immunogenicity assay

Andreas Nechansky, *Vela Laboratories*

Electrophoresis / Capillary Electrophoresis
- CE, CZE
- SDS-PAGE (reduced, non reduced) - visualisation of proteins
- IEF - identification and impurity profile
- QC/validation aspects
- Gel characteristics of antibodies

Markus Roucka, *Vela Laboratories*

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

Dietmar Reusch, *Roche Diagnostics*

Cellular assays (Bioassays)

- Introduction into biological assays
- Assay Qualification – Risk Analysis
- Compliance criteria
- FACS based potency assay
- Proliferation assays
- Applications / Benefits

Andreas Nechansky, *Vela Laboratories*

Workshops

During the workshop you will work on industry case studies. You will have to define how you want to perform a validation under certain given conditions. The workshop leaders will support you in finding an efficient solution to the pre-defined challenge.

Immunochemical Methods
Markus Fido, Andreas Nechansky, Vela Laboratories

Electrophoresis
Andreas Nechansky, Vela Laboratories

Spectroscopic Analysis
Harald Wegele/Dietmar Reusch,
Roche Diagnostics

Chromatography
Ron Hamelinck, MSD

Each participant will have the opportunity to take part in two workshops. Please mark your choice on the registration form.

Method Development and Validation during Preclinical and Clinical Phases

- Method development and time frames
- Requirements for preclinical projects
- Method changes during the clinical program
- Product release and validation aspects

Markus Fido, *Vela Laboratories*

Case Study: Analytical tools in the analysis of biopharmaceuticals at MSD

- Chemicals vs (glyco)proteins
- Overview of tests for a recombinant glycoprotein
- Practical examples and explanation
- Additional investigations in QC

Ron Hamelinck, *MSD*

Speakers

DR MARKUS FIDO, Vela Laboratories, 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 are GMP/GCP 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).

RON HAMELINCK (BSc), MSD, The Netherlands

Ron is Departmental Head of the QC labs for Biologics at MSD in Oss, the Netherlands. Since joining the company in 1977 he worked as a scientist in various R&D departments on bioanalytical methods. Since 1993 he continued at the QC labs to support release and compliance activities of recombinant (glyco) proteins. Now he is responsible for all release, stability and in process analyses of biotech and biochemical processes.

DR ANDREAS NECHANSKY, Vela Laboratories, Austria

Andreas graduated in 1997 ('Molecular Genetics') from the University of Vienna and did his postdoctorial work at the Novartis Research Institute in Vienna and The Scripps Research Institute in La Jolla, USA. He held the position of Head of Analytical Development at Igeneon/Aphton Biopharma where he was responsible for the method establishment and qualification. He is Founder/COO of Vela Laboratories and responsible for analytical operations. His extensive experience covers the field of antibody/protein characterization, the underlying immunology and the regulatory requirements.

DIETMAR REUSCH, Roche Diagnostics, Germany

After his study of chemistry, he was engaged at TÜV Stuttgart as specialist of environmental safety. Since 1988 he is working at Roche Diagnostics as teamleader development analytics and pharma production development. Currently he is the operation director of a international biologic project.

MARKUS ROUCKA, Vela Laboratories, Austria

DR HARALD WEGELE, Roche Diagnostics, Germany

Harald studied biochemistry at the University of Regensburg and the University of Colorado at Boulder (USA). He was awarded a doctorate from the Technical University of Munich in the field of physical biochemistry in 2004. At present, Harald is heading the Biochemical Development Analytics department at Roche Diagnostics (Penzberg, Germany). His responsibilities are the biochemical characterization and release of new drug substances as well as the evaluation and establishment of new analytical methods in a GMP environment.

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

Reservation Form (Please complete in full)

+ 49 6221 84 44 34

Protein Analytical Technologies, 23 – 24 March 2011, Vienna, Austria
Each participant will have the opportunity to take part in **TWO** workshops. Please mark your choice:

☐ Immunochemical Methods
☐ Electrophoresis
☐ Spectroscopic Analysis
☐ Chromatography

☐ 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)

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

CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49 (0) 62 21/84 44 34

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)!

Date

Wednesday, 23 March 2011, 09.00 – 18.15 h
(Registration and coffee 08.30 – 09.00 h)
Thursday, 24 March 2011, 08.30 – 16.30 h

Venue

THE IMPERIAL RIDING SCHOOL VIENNA,
A RENAISSANCE HOTEL
Ungargasse 60
1030 Vienna, Austria
Phone +43 (1) 711 75 – 0
Fax +43 (1) 711 75 – 8143

Fees

ECA Members: € 1,490.– per delegate + VAT
APIC Members; € 1,590,- per delegate + VAT (does not include ECA Membership)
Non-ECA Members: € 1,690.– per delegate + VAT
EU GMP Inspectorates: € 845.– per delegate + VAT
The 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 has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form when you have registered for the course. Please use this form for your room reservation or be sure to mention "VA 6817 ECA Course" to receive the specially negotiated rate for the duration of your stay. Reservation should be made directly with the hotel not later than 22 February 2011. 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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