

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



Protein Analytical Technologies

23 - 24 March 2011, Vienna, Austria

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.

Reservation Form: CONCEPT HEIDELBERG



e-mail: info@concept-heidelberg.de Internet: www.gmp-compliance.org

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appear at the event without having informed us, you will have to pay the even if you have not made the payment yet. Only after we have received are entitled to participate in the conference (receipt of payment will not

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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 +43 (1) 711 75 - 0 Phone +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

CONCEPT HEIDELBERG P.O. Box 10 17 64 D-69007 Heidelberg, Germany Phone +49 (0) 62 21/84 44-0 Fax +49 (0) 62 21/84 44 34 E-mail: info@concept-heidelberg.de www.concept-heidelberg.de

For questions regarding content:

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 Susanne Ludwig (Organisation Manager) at +49-62 21 / 84 44 44, or per e-mail at ludwig@concept-heidelberg.de.