ECA Certified Biotech Manager Course*

- Visit of Roche Diagnostics GmbH Penzberg Analytical Laboratory
- Two Workshops available

Protein Analysis Technologies

Method Development, Optimization and Validation

18 – 20 September 2012, Bad Tölz (near Munich), Germany

SPEAKERS:

Dr Markus Fido
Vela Laboratories, Austria

Ron Hamelinck (BSc)
MSD, The Netherlands

Dr Henno van den Hooven
MSD, The Netherlands

Sidonie Karlsson
Bioinvent International, Sweden

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 Analysis Technologies
- FACS and Biacore Methods
- Method Development, Optimization and Validation
- 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 Analysis Technologies

18 – 20 September 2012, Bad Tölz, Germany

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.

At 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 18 September, 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 Day 1

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

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

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
- Electrophoresis
- Spectroscopic Analysis
- Chromatography

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

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

Programme Day 2

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

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

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

Glycoanalytics – state-of-the-art techniques and case studies

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

Visit of Roche Diagnostics GmbH Penzberg Analytical Laboratory - Focus on optimizing and accelerating Protein Analytics

Penzberg, Bavaria, is Roche Diagnostics GmbH's location near Munich. It is one of the largest biotech centers in Europe and the only Roche location performing research, development and production for both divisions: Diagnostics and Pharmaceuticals.
Diagnostics' strengths include system platforms for immunology, clinical chemistry, genetic and cellular analysis, as well as reagents and systems for the life sciences market. Over 40 years of experience in biotechnological production of reagents for medical and research applications make this site a pioneer of industrial biotechnology. Roche at Penzberg, employing about 4,800 people, is an important economic factor in the region.
Intensive cross-networking between the two divisions creates synergies. These are proving particularly useful for driving forward initiatives such as stem cell research or the Roche "Personalised Healthcare" program. The goal is to offer custom-tailored patient therapy with greater safety, efficacy and yet good tolerability. Personalised Healthcare is a key element of Roche's corporate strategy.
As a pharmaceutical production location, Penzberg makes great contributions to the therapy of severe diseases like cancer and anemia. Four biotechnologically manufactured active pharmaceutical ingredients (API) are produced at the Pharma Biotech production. Recently, the capacity of research and technical development of therapeutic proteins was significantly enlarged which in turn will further enhance the value chain, from early research on active substance candidates to the production of protein drugs for the market.

Programme Day 3

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
- Electrophoresis
- Spectroscopic Analysis
- Chromatography

Each participant will have the opportunity to take part in two workshops. Please mark your first and second choice at your confirmation sheet.

New Case Study: Early development and optimization of methods for purification and analysis, including set up for HTP production
- HTP production for IgG (and other proteins) for screening purpose
- Analysis of the above, choice of "fit for purpose" methods and method development
- Optimization and tech transfer to GMP analysis
- Case study: example in our laboratory

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

Speakers

Dr Markus Fido, *Vela, 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 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, The Netherlands. He did postdoctoral work in the field of biochemistry at the Dutch Institute for Dairy Research (NIZO), and at the Wageningen University, The Netherlands. At present, he 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.

Sidonie Karlsson, *Bioinvent International, Lund, Sweden*

Sidonie is a Diplomed'ingénieur in Chemistry. She worked in different positions in the analytical laboratories of Astra Zeneca in United Kingdom, Novo Nordisk in Denmark. 2008 she joined as Bioinvent International AB, Lund, Sweden as analytical engineer with responsibilities in Small scale purification and analysis (HPLC, electrophoresis, MALDI-TOF) of antibodies and antigen proteins for Research Dept.

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, Dietmar was engaged at TÜV Stuttgart as specialist of environmental safety. 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 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 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

Date

Tuesday 18 September 2012, from 09.00 - 18.00 h
(Registration and coffee 08.30 – 09:00 h)
Wednesday 19 September 2012 08.30 – 17:00 h
Thursday 20 September 2012, 08.30 – 13.30 h

Venue

Resort Hotel Jodquellenhof Alpamare
Ludwigstraße 13-15
83646 Bad Tölz (near Munich), Germany
Phone +49 (0)8041 509 581
Fax +49 (0)8041 509585

Fees

ECA Members: € 1,890.– per delegate + VAT
APIC Members; € 1,990,- per delegate + VAT (does not include ECA Membership)
Non-ECA Members: € 2,090.– per delegate + VAT
EU GMP Inspectorates: € 1,045.– 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 "ECA" to receive the specially negotiated rate (single room 109,- per night, incl. breakfast) for the duration of your stay. Reservation should be made directly with the hotel not later than 20 August 2012. 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
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.:
Mr Ronny Strohwald (Organisation Manager) at
+49-62 21 / 84 44 51, or per e-mail at
strohwald@concept-heidelberg.de.

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

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.

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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.

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

Conference Folder

You cannot take part in this event? Just order the documentation at the price of € 180.- + VAT+ postage and packing. You can use the registration form for this purpose. Please note: In order to ensure that the documentation is complete, the conference folder will not be available until two weeks after the event.

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

Reservation Form (Please complete in full)

+ 49 6221 84 44 34

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Each participant will have the opportunity to take part in **TWO** workshops.
Please mark your first and second choice:

1st choice	2nd 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)

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)!