ECA Certified Biotech Manager Course*

Biotechnology for Non-Biotechnologists

An Overview and Insight in pharmaceutical Biotechnology

24-25 May 2011, Berlin, Germany

SPEAKERS:

Dr Falk Klar
IDT Biologika, Germany

Dr Markus Fido
Vela Laboratories, Austria

Arjan Langen
Langen Pharmatraining, The Netherlands

LEARNING GOALS:

- Introduction into Biotechnology
- GMP Guidelines in Biotechnology
- Master and Working Cell Banks
- GMP Requirements on Rooms and Personnel
- Biotechnical Manufacturing of API – Focus on E.coli
- Biotechnical Manufacturing of API - Cell Cultures
- Virus Reduction
- Fill and Finish
- Clinical Studies and Authorisation

ECA
EUROPEAN COMPLIANCE ACADEMY

* This education course is recognised for the ECA GMP Certification Programme „Certified Biotech Manager“

Biotechnology for Non-Biotechnologists

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Objectives

This course will provide Non-Biotechnologists with an overview and insight in pharmaceutical biotechnology. It will also present the opportunities of biotechnology in GMP manufacturing.

Common aspects of production analytics will be discussed just as well as regulatory aspects of Biopharmaceuticals (bacteria and cell culture) and specific requirements on clinical studies and marketing authorisation. It will furthermore concentrate on topics like virus reduction, cell banking, media fills and dedicated rooms and personnel. The course will be completed by a presentation of the current comprehensive bodies of legislation.

Background

From a historical view, Biopharmaceuticals are no new business. Antibiotics and vaccines have been well known for more than 60 years. But with the marketing authorisation of the first pharmaceutical product, produced by gene technology in the 80s, a new era of biopharmaceutical and biotechnological development and manufacturing started.

In 2007, 20% of all new released pharmaceuticals were Biopharmaceuticals. Future pharmaceutical products based on Biotechnology and the Biosimilars (Biogenerics) will become more and more important and present a higher share of pharmaceutical products

Target Audience

This Course is addressed to all people interested in pharmaceutical biotechnology related to GMP manufacturing and marketing authorisation.

Moderator

Axel H. Schroeder, Concept Heidelberg

Programme

What is Biotechnology/Introducing in Biotechnology

- Definition of Biotechnology/Biopharmaceuticals
- Small Chemical Entities versus Biopharmaceuticals
- History of production and analytics
- View into different areas of the business
- Market and future investigations

Markus Fido

GMP Guidelines in Biotechnology

- European guidelines
- FDA guidelines
- ICH
- ISPE
- PIC/S
- PDA
- WHO
- APIC
- ISO

Falk Klar

Manufacturing of biotechnological API – Focus on E. coli

- Suitability of raw material
- TSE safety of raw materials
- Water as raw material
- Fermentation
- Cell harvesting
- Purification
- Filling of bulk API
- From drug substance to drug product

Falk Klar

Manufacturing of Biotechnological API – Focus on Cell Culture

- Different cell lines as production platforms
- The manufacturing process (up/downstream)
- Contamination risks during cell culture and production
- Analytical methods for product characterisation
- Quality & Regulatory aspects

Markus Fido

Clinical Studies/ Authorisation

- Clinicals studies and drug regulatory affairs for biotechnological products
- From preclinical to clinical studies
- Bioanalytics during clinical trials
- Centralised procedure is favourite
- Changes and variations of biotechnological products

Markus Fido

GMP Requirements for Rooms and Personnel

- Regulatory requirements
- Balancing GMP and laws of gene technology
- Zone concept
- Flow of material and personnel
- Clean rooms
- Cleaning and hygiene procedures
- Monitoring and validation

Falk Klar

GMP Requirements for Master- and Working Cell Banks

- From initial cell to product
- Manufacturing
- Storage
- Quality Control
- Release Documentation

Falk Klar

Virus Reduction

- Regulatory background
- Relevant and model viruses
- Common and new methods of virus reduction
- TSE Safety

Arjan Langen

Fill and Finishing

- Aseptic processing and media fill
- Liquid formulation or lyophilisation?
- Stability tests of Biopharmaceuticals

Arjan Langen

Social Event

On 24 May, 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.

Speakers

Dr Falk Klar

IDT Biologika, Germany

After completing his studies in physics and obtaining the PhD, Mr Falk Klar started his industrial career in a medical device company. Between 1995 and 1999 he was responsible for organisation, conducting and data evaluation of preclinical and clinical studies. During that time he attended a qualification programme to become a Quality Manager. In 1999 he joined an international Contract Research Organisation as Project Manager responsible for conducting clinical trials in phases I to IV. Between 2002 and 2009 Dr Klar was employed as Head of Quality Assurance of Biomeva GmbH, a biotech Contract Manufacturing Organisation producing APIs. He gained comprehensive experience in the wide spectra of GMP quality management including validation of manufacturing processes and computerised systems. Since 2010 Dr Klar has been working as Head Quality Systems at IDT Biologika GmbH, a global supplier to the pharmaceutical and biotechnology industry. In this position he is responsible for establishing and maintaining quality strategies in the branches human vaccines, contract manufacturing of biopharmaceuticals and animal health.

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 is 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).

Arjan Langen

Langen Pharmatraining and Consulting

Arjan Langen was manager of Microbiological Quality Control and Quality Assurance officer at Intervet International in The Netherlands before he joined Nobilon International. At Nobilon he was appointed Quality Assurance Manager, responsible for the cGMP-approval of the new multi-purpose vaccine production facility in Boxmeer , The Netherlands. 2008 Arjan takes over the position of Director Compliance at DSM. In 2009 he founded his own company for training and consulting. He is a member of the PDA and a member of the Dutch Society of Pharmaceutical Microbiology.

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:

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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24-25 May 2011, Berlin, Germany

☐ 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 %.

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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

Tuesday, 24 May 2011, 10.00 h – 18.15 h
(Registration and coffee 09.30 -10.00 h)
Wednesday, 25 May 2011, 08.30 h – 17.00 h

Venue

Steigenberger Hotel Berlin
Los-Angeles-Platz 1
10789 Berlin, Germany
Phone +49(0)30 2127 0
Fax +49(0)30 2127 117

Fees

ECA Members € 1.490,- per delegate plus VAT
APIC Members € 1,590- per delegate plus VAT (does not include ECA Membership)
Non-ECA Members € 1.690,- per delegate plus VAT
EU GMP Inspectorates € 845,- per delegate plus VAT
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 when you have registered for the event. Please use this form for your room reservation or be sure to mention "VA 6755 ECA Event" to receive the specially negotiated rate for the duration of your stay. Reservation should be made directly with the hotel not later than 13 April 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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