Pharmaceutical Biotechnology for Non-Biotechnologists

An Overview and Insight in pharmaceutical Biotechnology

24 – 25 June 2015, Berlin, Germany

SPEAKERS:

Dr Markus Fido
VelaLabs, Austria

Arjan Langen
MSD, The Netherlands

Dr Paul Stockbridge
Stockbridge Biopharm Consulting

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 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

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.

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 those 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

Paul Stockbridge

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

Paul Stockbridge

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

- Clinical 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

Paul Stockbridge

GMP Requirements for Master and Working Cell Banks

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

Paul Stockbridge

Virus Reduction

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

Arjan Langen

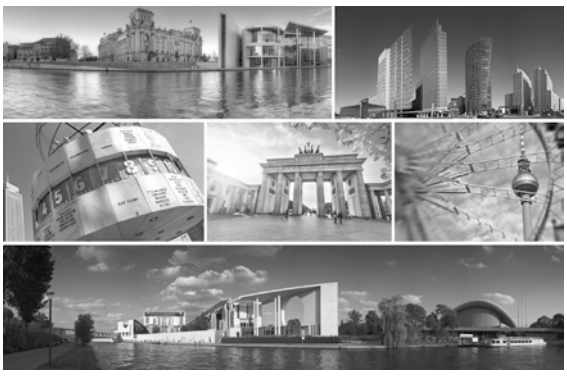
Fill and Finishing

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

Arjan Langen

Social Event

On 24 June 2015, 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 Markus Fido, *VelaLabs, 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. He holds a Ph.D. in Biochemistry and Molecular Microbiology from the Technical University in Graz (Austria).

Arjan Langen, *MSD, The Netherlands*
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. In 2008 Arjan became Director Compliance at DSM Pharmaceutical products and in 2009 he founded his own company for training and consulting in the field of pharmaceutical microbiology. In 2011 he became Pharmaceutical Specialist at MSD in The Netherlands, being responsible for sterile manufacturing of new products in Oss. He is a member of the PDA and a member of the Dutch Society of Pharmaceutical Microbiology.

Dr Paul Stockbridge, *Stockbridge Biopharm Consulting, United Kingdom*
Dr Stockbridge spent 23 years with Eli Lilly, initially in fermentation development and then in quality assurance where he became a Q.P. and Q.A. Advisor for biotechnology projects for which he travelled globally. He then moved to a Head of Quality Operations role with Aventis Pharma before being appointed to the role of Corporate Quality Director for Cobra Biomanufacturing Plc. After over 7 years with Cobra he is now providing independent consulting and training services for the steriles, aseptic and biotechnology industries. Paul has a degree in biology, a PhD in fermentation, is an EU Qualified Person and is a Fellow of the U.K. Society of Biology.

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:

Reservation Form (Please complete in full)

+ 49 6221 84 44 34

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☐ 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

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D-69007 Heidelberg
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Date

Wednesday, 24 June 2015, 09.30 h – 18.00 h
(Registration and coffee 09.00 -09.30 h)
Thursday, 25 June 2015, 08.30 h – 17.00 h

Venue

Steigenberger Hotel Berlin
Los-Angeles-Platz 1
10789 Berlin, Germany
Phone +49 (0)30 212 7 - 0
Fax +49 (0)30 212 7- 117

Fees (per delegate plus VAT)

ECA Members € 1,590
APIC Members € 1,690
Non-ECA Members € 1,790
EU GMP Inspectorates € 895

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 with all further information when you have registered for the event. 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

ECA has entrusted Concept Heidelberg with the organisation of this event.

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