



Speakers



Dr Markus Fido
MFi Bio-Consulting, Austria



Dr Sabine Hauck
Leukocare, Germany



Dr Paul Stockbridge
Stockbridge Biopharm Consulting,
UK

Pharmaceutical Biotechnology for Non-Biotechnologists



Live Online Training on 13/14 December 2022



Highlights

- Basics and Regulatory Requirements
- Master and Working Cell Banks
- GMP Requirements on Rooms and Personnel
- Biotechnical Manufacturing of API – Focus on *E.coli*
- Biotechnical Manufacturing of API – Focus on Cell Culture Products
- Virus Reduction
- Fill and Finish
- Clinical Studies and Market Authorization
- ATMP Regulations & Challenges

An Overview and Insight in
Pharmaceutical Biotechnology

Objective

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

Moderator

Axel H. Schroeder, Concept Heidelberg

Your Benefit:
Internationally Acknowledged Certificate from ECA Academy



The EU GMP Guide requires: „... All personnel should be aware of the principles of Good Manufacturing Practice that affect them and receive initial and continuing training,...“. This is why you receive an acknowledged participant certificate, which lists the contents of the seminar in detail and with which you document your training.

Programme Day 1

What is Biotechnology/ Introduction to the World of 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

GMP and Regulatory Guidelines in Biotechnology

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



Manufacturing of Biotechnological APIs – Focus on Cell Culture Products

- 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

Manufacturing of Biotechnological APIs – 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

Programme Day 2

GMP Requirements of Master and Working Cell Banks (MCB/WCB)

- From initial cell to product
- Manufacturing
- Storage
- Quality control
- Release documentation

Virus Reduction

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

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

ATMP Regulations & Challenges

- Classification of ATMPs
- Regulatory landscape
- GMPs for ATMPs

Clinical Studies - Market Authorization

- 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

Fill & Finish of Biotechnological Products

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

Speakers



Dr Markus Fido,
MFi Bio-Consulting, Austria

Markus Fido, former CEO and founder of Vela Laboratories, where he was responsible for Finance & Controlling, Regulatory Affairs & Quality Operations. Before that he was Head Quality Control at Igeneon GmbH (Novartis Oncology Division) where he was in charge for all QC aspects of pre-clinical and clinical projects such as stability studies, specifications, method development & validation, as well as product release. Prior he was working as a Group Leader of Immunology and Product Development at Biomin GmbH, Head Biochemical Control at Baxter Bioscience AG and Head Quality Operations at Octapharma AG. Until 2020 he was responsible for the international Pharma Business Development of the Tentamus Group with locations in India, Israel, USA and several countries in Europe. In 2020 he founded a new company – MFi Bio-Consulting.



Dr Sabine Hauck,
Vice President Research & Development,
Leukocare, Germany

Sabine Hauck has nearly 20 years of experience in drug product development and held various positions in the field of development, quality assurance and regulatory affairs in small to mid-size biotech and pharma companies, respectively. Prior to her industry career in drug product development, she was a scientist in biosensor development at Fraunhofer. Within Leukocare she is responsible for the research & development activities of the company.



Dr Paul Stockbridge,
Stockbridge Biopharm Consulting, UK

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 sterile, 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.

Reservation Form (Please complete in full)



Pharmaceutical Biotechnology for Non-Biotechnologists Live Online Training on 13/14 December 2022

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

Title, first name, surname

Department

Company

Important: Please indicate your company's VAT ID Number

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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 4 weeks prior to the conference 10 %,

- Cancellation until 3 weeks prior to the conference 25 %,

- Cancellation until 2 weeks prior to the conference 50 %,

- Cancellation within 2 weeks prior to the conference 100 %.

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cellation 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!) (As of January 2012).

German law shall apply. Court of jurisdiction is Heidelberg.

Privacy Policy: By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at http://www.gmp-compliance.org/eca_privacy.html). I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.



Date of the Live Online Training

Tuesday, 13 December 2022, 09.00 h – 17.30 h CET

Wednesday, 14 December 2022, 08.30 h – 17.00 h CET

Technical Requirements

We use WebEx Events for our live online training courses and webinars. At <https://www.gmp-compliance.org/training/online-training-technical-information> you will find all the information you need to participate in our trainings and you can check if your system meets the necessary requirements to participate. If the installation of browser extensions is not possible due to your rights in the IT system, please contact your IT department. WebEx is a standard nowadays and the necessary installation is fast and easy.

Fees (per delegate, plus VAT)

ECA Members € 1,590

APIC Members € 1,690

Non-ECA Members € 1,790

EU GMP Inspectorates € 895

The fee is payable in advance after receipt of invoice.

Registration

Via the attached reservation form, by e-mail or by fax message.

Or you register online at www.gmp-compliance.org.

Presentations/Certificate

The presentations will be made available to you prior to the Live Online Training as PDF files. After the event, you will automatically receive your certificate of participation

Conference language

The official conference language will be English.

Ordering Recordings

We also offer many of the training courses and conferences as recordings. This means that you can watch the videos of the event „on demand“ – whenever it suits you – on our web server. It is quite uncomplicated and doesn't require any software – you simply watch the video on your browser. You can find all recorded events at www.gmp-compliance.org/recordings.

Organisation and Contact

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

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