ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Biotech Manager

Speakers

Dr Markus Fido
Mfi Bio-Consulting, Austria

Dr Sabine Hauck
Chair of ECA ATMP Interest Group, Germany

Dr Paul Stockbridge
Stockbridge Biopharm Consulting, UK

Pharmaceutical Biotechnology for Non-Biotechnologists

09/10 October 2024, Berlin, Germany

Highlights

- Basics & Regulatory Requirements
- Overview and Step in into the Field of Biotechnology
- Master & Working Cell Banks
- GMP Requirements on Rooms and Personnel
- Biotechnical Manufacturing of APIs – Focus on Bacteria & Yeast
- Biotechnical Manufacturing of APIs – Focus on Cell Culture Technologies & their Products
- Virus Reduction
- Fill & Finish
- Clinical Studies & Market Authorisation
- Regulations & Challenges for ATMPs

An Overview and Insight in Pharmaceutical Biotechnology

Programme

Objective

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 and quality control.
Common aspects of product analytics will be discussed just as well as regulatory aspects of Biopharmaceuticals (bacteria, yeast and cell culture) and specific requirements on clinical studies and marketing authorisation. It will furthermore focus on topics like virus clearance reduction, cell banking, media fills and on 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 & biosimilars are no new business. Antibiotics and vaccines have been well known for more than 60 years. But with the marketing authorisation of the first biopharmaceutical product, produced by gene technology in the 80s, a new era of biopharmaceutical and biotechnological development and manufacturing started.
Future pharmaceutical products based on biotechnology and Biosimilars as well as Biologics 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, analytics, product release and marketing authorisation.

Moderator

Clemens Mundo, Concept Heidelberg

Your Benefit: Internationally Acknowledged Certificate from ECA Academy


CERTIFICATE

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 manufacturing, production, & analytics
- View into different areas of business segments
- Market figures 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 Technologies and their Products

- Different cell lines as production platforms
- The manufacturing process in development (upstream, upscaling, harvest, downstream)
- Contamination risks during cell culture, manufacturing, harvesting & DSP
- Analytical methods for product characterisation
- Quality & regulatory aspects

Virus Reduction

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

Manufacturing of Biotechnological APIs – Focus on Bacteria & Yeast (E. coli / S. cerevisiae)

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

Programme Day 2

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

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

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

Fill & Finish of Biotechnological Products

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

ATMPs - Regulations & Challenges

- Classification of ATMPs
- Regulatory landscape
- GMPs for ATMPs

From (Pre)clinical Studies to Market Authorization

- Clinical studies and drug regulatory affairs for biotechnological products
- From preclinical to late clinical studies
- Bioanalytics applied for clinical trials
- Centralised procedure is a favourite scenario
- Changes and variations of biotechnological products

Social Event

In the evening of the first course day, you are cordially invited to a social event. This is an excellent opportunity to share your experiences with the trainers and colleagues from other companies in a relaxed atmosphere.

Speakers

Dr Markus Fido, Mfi Bio-Consulting, Austria

Markus Fido, former CEO & founder of VelaLabs, where he was responsible for 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 has founded his own company – Mfi Bio-Consulting with consulting activities in different areas for the Biotech industry worldwide.

Dr Sabine Hauck dequra pharma consult hauck

Sabine Hauck has 20+ years of experience in the biotech industry, in which she held various positions in pharmaceutical development, quality assurance, regulatory affairs and corporate development. Her product experience spans from small molecules to cell therapies and includes a variety of dosage forms. After gaining experience in several biotech companies she is now providing freelance consulting and trainings for biotech and biopharma companies in the field of pharmaceutical development, quality assurance, and regulatory affairs. Sabine is also active as the chair of the ECA ATMP interest group.

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 Biopharma, 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.

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

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GERMANY

Reservation Form (Please complete in full)

Pharmaceutical Biotechnology for Non-Biotechnologists
09/10 October 2024, Berlin, Germany

Title, first name, surname

Department | Company

Important: Please indicate your company's VAT ID Number | Purchase Order Number, if applicable

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 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 %.

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 HEIDELBERGwill 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)! (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
Wednesday, 09 October 2024, 09.00 h – 18.00 h
(Registration and coffee 08.30. h – 09.00 h)
Thursday, 10 October 2024, 08.30 h – 16.00 h

Venue
HYPERION Hotel Berlin
Prager Straße 12
10779 Berlin, Germany
Phone +49(0)30 236250 0
Email hyperion.berlin@h-hotels.com

Fees (per delegate, plus VAT)
ECA Members € 1,690
APIC Members € 1,790
Non-ECA Members € 1,890
EU GMP Inspectorates € 945
The conference fee is payable in advance after receipt of invoice and includes 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/POG when you have registered for the course. 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.

Presentations/Certificate
The presentations for this event will be available for you to download and print before and after the event. Please note that no printed materials will be handed out on site and that there will not be any opportunity to print the presentations on site. After the event, you will automatically receive your certificate of participation.

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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