ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Biotech Manager

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

Ms Clarissa Häger, 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 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, were 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 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.

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CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49 (0) 62 21/84 44 34

D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

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

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:
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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.

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
info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content please contact:
Ms Clarissa Häger (Operations Director) at
+49(0)62 21/84 44 42, or at
haeger@concept-heidelberg.de.

For questions regarding organisation please contact:
Mr Rouwen Schopka (Organisation Manager) at
+49(0)62 21/84 44 13, or at
schopka@concept-heidelberg.de.