ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Biotech Manager

Speakers

Dr Markus Fido
Mfi Bio-Consulting, Austria

Dr Rainer Gallitzendörfer
Local Government of Upper Bavaria, GMP Inspector

Dr Sabine Hauck
Chair of ECA ATMP Interest Group, Germany

Stephan Löw
CSL Behring

Pharmaceutical Biotechnology for Non-Biotechnologists

Live Online Training on 17/18 September 2025

Highlights

- Basics & Regulatory Requirements
- Overview and Step in into the Field of Biotechnology
- Process Overview: From Manufacturing of API to Fill & Finish
- Regulations & Challenges for ATMPs

An Overview and Insight in Pharmaceutical Biotechnology

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.

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.

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

Regulatory Requirements and Guidelines for Manufacturing Biopharmaceuticals

- Overview of the legal framework on biopharmaceuticals in the EU
- Guidelines (EU / US FDA / WHO / supporting documents)
- Expectations and findings

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 materials and consumables
- Media and buffers
- Water as raw material
- Fermentation
- Cell harvesting
- Purification

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 production cell
- Establishing cell banks
- Where does GMP start during cell banking
- Storage of cell banks
- Maintenance of cell banks

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

Speakers

Dr Markus Fido, Mfi Bio-Consulting, Founder & CEO

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 Rainer Gallitzendörfer Local Government of Upper Bavaria, GMP Inspector

Dr Rainer Gallitzendörfer is a specialist pharmacist for pharmaceutical analytics and a food chemist with broad experience in the assessment of medicinal products, medical devices and foodstuffs. He has been working since 2016 for authorities for medicinal product and food surveillance in Bavaria. Today, he is GMP/GDP-Inspector for the District Government of Upper Bavaria and performs GMP inspections world-wide.

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.

Stephan Löw, CSL Behring Senior Manager Technical Support Laboratories

Stefan studied bioprocess engineering and is employed at CSL Behring in Marburg. Before this he worked for GSK Vaccine in different positions like Aseptic Expert, Formulation and Filling of Vaccines and Project Management. He started his career at the former Hoechst AG – later Sandoz Frankfurt, with responsibilities in QA Microbiology and aseptic processing of sterile penicillins.

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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 17/18 September 2025

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 %.

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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)! (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

Wednesday, 17 September 2025, 09.00 h – 17.30 h
Thursday, 18 September 2025, 08.30 h – 16.00 h
All times mentioned are CEST

Technical Requirements

We use Webex 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 € 1,890
APIC Members € 1,990
Non-ECA Members € 2,090
EU GMP Inspectorates € 1,045
The conference fee is payable in advance after receipt of invoice.

Registration

Via the attached reservation form, by e-mail or by fax – or search and register directly at www.gmp-compliance.org under the number 22066.

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.

You cannot attend the Live Online Event?

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:
Mr Clemens Mundo (Operations Director) at
+49(0)62 21/84 44 42, or at
mundo@concept-heidelberg.de.

For questions regarding organisation please contact:
Ms Julia Grimmer (Organisation Manager) at
+49(0)62 21/84 44 44, or at
julia.grimmer@concept-heidelberg.de.