ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Biotech Manager

Speakers

Dr Markus Fido
Mfi Bio-Consulting

Dr Marcel Günther
GMP Inspector, Local Government Tübingen

Dr Matthias Leitritz
Rentschler Biopharma

Stephan Löw
CSL

Friederike Wedelich
GMP Inspector, Local Government of Tübingen

GMP for Biopharmaceuticals

Live Online Training on 12/13 May 2026

Highlights

- Regulatory Requirements on Biopharmaceuticals
- Validation of Analytical Methods and Biotech Processes
- Process Transfer from Development to Commercial Production
- Quality Assurance for Biopharmaceuticals
- Impact of Annex 1 in Biopharmaceutical Manufacturing with Case Study

Regulatory Requirements and Practical Implementation

Objective

This Education Course concentrates on regulatory and practical requirements regarding biopharmaceutical production. From clinical phases to routine manufacturing practical examples and case studies will facilitate the implementation of GMP in your daily business.
The course will treat the topics of routine inspection from regulatory bodies and customers, quality assurance and quality control as well as in laboratory and production.
Speakers from manufacturing, laboratory, consultancy, and authority will show their expectations as well as their experiences in GMP implementation.

Background

Good Manufacturing Practice (GMP) is a fundamental regulatory framework designed to ensure that medicinal products are consistently produced and controlled according to quality standards. GMP plays a particularly critical role for biopharmaceuticals - therapeutics derived from living cells or biological processes - given their inherent complexity, variability and sensitivity compared to traditional small-molecule drugs.

Unlike chemically synthesised medicines, biopharmaceuticals such as monoclonal antibodies, recombinant proteins, vaccines and nucleic acid-based therapies are produced using living systems. This introduces unique challenges, including biological variability in raw materials, the susceptibility of production processes to subtle changes, and the risk of contamination by adventitious agents. GMP regulations mitigate these risks by requiring robust systems that safeguard product quality, safety, and efficacy throughout the manufacturing life cycle.

Regulatory authorities such as the U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMA) and the International Council for Harmonisation (ICH) have established guidelines that set global expectations. For example, EMA Annex 2 addresses GMP specifically for biologics. Both industry and the authorities must prepare for new and anticipated changes in regulatory guidelines. Compliance with these guidelines is a legal requirement and a means of ensuring patient safety.

Ultimately, GMP in biopharmaceutical manufacturing ensures that complex biological products reach patients with the highest level of assurance regarding their safety, purity, and therapeutic effectiveness. GMP is the backbone of quality systems in the biopharmaceutical industry, balancing regulatory compliance with innovation to support the delivery of life-saving medicines worldwide.

Target Audience

This course is advisable to people who,

- are involved in regulatory inspections
- work in quality units at biotech companies
- implement GMP in biotech production
- are responsible for GMP requirements pre-approval phases

Programme

GMP Guidelines for Biopharmaceuticals – a Brief Summary

- Relevant international regulations
- European biotech guidance
- Recent developments & possible impacts

GMP Requirements Applying to Biotechnological Investigational Medicinal Products (IMPs of Clinical Phases I-III & APIs for use in IMPs)

- EU regulations & guidances
- Examples of national regulations
- State-of-the-art manufacturing for clinical phases

Development of Biopharmaceuticals – GMP, Regulatory Aspects and Inspection & Audit Experiences

- EU and US guidances related to clinical trials GMP/CMC incl. Annex 13 update
- CDMO considerations on specifications
- Inspection and audit experiences “pre-approval”

Development, Qualification and Validation of Process Analytics for Biopharmaceuticals

- Phases of product development / testing requirements
- Method portfolio / method development / method qualification / method validation
- Product analytics & QC methods for product characterisation
- Relevant guidelines & publications

GMP Inspections in Biopharmaceutical Production

- Inspections of biopharmaceutical companies
- Focus & discussion points during inspections
  - Clean room classes for biotech facilities
  - Open vs. closed processing
  - Single- vs. multi-purpose equipment
  - Cell banking activities
- Inspector’s experience, examples of observations

Process Transfer from Development to Commercial Production from a Quality Perspective

- Definition and types of transfers
- Specific quality considerations for transfers
- Transition from “development” to “commercial”

GMP-conform Process Development and Validation (incl. Equipment Qualification)

- Process development, manufacturing & dedicated instruments
- Current initiatives in pharmaceutical development
- Biopharmaceuticals / Biosimilars / Biologicals
  1. Process
  2. Analytical methods
  3. Equipment / instruments and facility

Quality Assurance for Biopharmaceuticals

- Classical responsibilities of QA department
- Allocation of responsibilities, training of staff
- Dealing with suppliers & contractors
- The world changes: Change management
- Shit happens: Deviation management & CAPA
- Handling complaints & product recalls
- Paper, paper, paper - documentation works: SOPs, MBR, PQR & management report
- Surveillance of qualification & validation, calibration and maintenance
- Self inspections & auditing

Bioanalytics for Clinical Trials – Method/Process Development and Validation for Phase I – III Studies

- Definitions of terms (ICH guidelines, GCLP, GCP, GLP)
- Process development & Quality by Design
- Early clinical phases
- Late clinical phases
- Post-approval items & activities

State-of-the-art Biotechnological Manufacture (Bacteria, Yeast, Mammalian Cells) and Cell Banking Activities - Part 1

- Reasons for cell banking
- Where does GMP start?
- Characterisation of cell banks
- Storage of cell banks

State-of-the-art Biotechnological Manufacture (Bacteria, Yeast, Mammalian Cells) and Cell Banking Activities - Part 2

- Overview of a typical biotech process
- Requirements on production areas, raw materials and equipment
- Specialities on biotech products
- Fill and finish

mRNA Technology – Principles, Manufacturing and Regulatory Perspective

- COVID vaccines: Viral and mRNA vaccines
- Modular principle of mRNA-based vaccines and mRNA vaccine manufacturing
- Regulatory perspective on mRNA products
- Application process for updating the MIA
- GMP challenges for new biological products

Annex 1 – Impact on the Manufacturing of Biopharmaceuticals

- Annex 1: What is the Annex 1 and why has it been revised?
- Key principles of the revised Annex 1
- Impact on facility, equipment, personal, raw materials, QRM, CCS, ...
- Case Study: Implementation in the daily business

Speakers

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

Markus Fido holds a PhD in biochemistry & cell biology from the Technical University Graz. He has worked in quality and product development departments at Octapharma, Baxter and Novartis. He then founded VelaLabs, an analytical service provider, which he led as a CEO for more than 15 years. In 2018/2019 he was responsible for the international Pharma Business Development of the Tentamus Group. In May 2020 he founded his new company, Mfi Bio-Consulting GmbH, a consultancy company, with focus on Biopharmaceuticals, Biologics, Biosimilars and ATMPs – especially for development products, clinical phases and (bio)analytics and regulatory requirements.

Dr Marcel Günther, GMP Inspector, Local Government Tübingen

Dr Marcel Günther is a pharmacist and has been a consultant at the Baden-Württemberg drug monitoring control centre at the Tübingen regional council. As a GMP inspector for the control centre and the EMA, he is responsible for the inspection of manufacturers of medicinal products and active pharmaceutical ingredients in Baden-Württemberg and worldwide.

Dr Matthias Leitritz, Rentschler Biopharma

Matthias Leitritz studied pharmacy at the University Tübingen, including Ph.D. in Pharmaceutical Technology. From 1996-2003 he worked at Pfizer as Head of QC (interim), Head of Production Planning and Head of Packaging Department. In 2003 he joined Boehringer Ingelheim as QP and later as Head of Quality Unit for non-steriles. Switching to Biotech in 2011, he took over responsibilities as Lean Six Sigma Manager, and later on as a QP for Biotech products at Boehringer Ingelheim. Since 2018 he is with Rentschler and his current position is Qualified Person.

Stephan Löw, Senior Manager Technical Support Laboratories, CSL Behring, Germany

Stephan 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 - with responsibilities in QA Microbiology and aseptic processing of sterile penicillin.

Friederike Wedelich, GMP Inspector, Local Government Tübingen

Friederike Wedelich studied Pharmacy at the University Tübingen. After that, she worked at Omega Pharma until 2019. Then she joined the Local Government of Baden-Württemberg at Tübingen. Currently, she is GMP Inspector with an increasing focus on biopharmaceutical manufacturing.

Moderator

Clemens Mundo, Concept Heidelberg

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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)

GMP for Biopharmaceuticals
Live Online Training on 12/13 May 2026

Title, first name, surname

Department | Company

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

City | ZIP Code | Country

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If you cannot attend the conference you have two options:
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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 %,
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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.

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Date of the Live Online Training

Tuesday, 12 May 2026, 09.00 h – 17.30 h
Wednesday, 13 May 2026, 08.30 h – 17.30 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.

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.

Registration

Via the attached reservation form, by e-mail or by fax message – or search and register directly at www.gmp-compliance.org under the number 22521. To avoid incorrect information, please give us the exact address and full name of the participant.

Conference language

The official conference language will be English.

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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 per email at mundo@concept-heidelberg.de

For questions regarding organisation etc.:
Mr Maximillian Bauer (Organisation Manager)
at +49(0)62 21/84 44 25
or per email at bauer@concept-heidelberg.de