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

Annex 2 & Co - GMP Compliance for Biopharmaceuticals

27/28 May 2025 | Vienna, Austria

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

Programme

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

In defiance of all throwbacks in the last years, a progression of new approvals of biopharmaceuticals is expected. Furthermore after the end of the protection of patents, biotechnical generics will be added.

Especially in the field of biotechnology you find often challenges to fulfil the regulatory requirements on production and quality assurance.

Industry and authorities have to face the new and expected changes in the regulatory guidelines.

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

Moderator

Clemens Mundo, Concept Heidelberg

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 Senior Director Project Quality (product related Quality Assurance) and 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.

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Reservation Form (Please complete in full)

Annex 2 & Co - GMP Compliance for Biopharmaceuticals, 27/28 May 2025, Vienna, Austria

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

Tuesday, 27 May 2025, 09.00 h – 17.30 h
(Registration and coffee 08.30 h – 09.00 h)
Wednesday, 28 May 2025, 08.30 h – 17.30 h

Venue

Doubletree by Hilton Vienna Schönbrunn
Schlossallee 8
1140 Vienna, Austria
Phone +43/1/89110
Email info@doubletree-schonbrunn.at

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..

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 21817.

Conference language

The official conference language will be English.

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.

Organisation and Contact

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