ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Biotech Manager

Speakers

Dr Markus Fido
MFI Bio-Consulting

Dr Matthias Leitritz
Rentschler Biopharma

Stephan Löw
CSL

Dr Daniel Müller
GMP Inspector,
German Local Government

Axel Schroeder
Concept Heidelberg

Annex 2 & Co GMP Compliance for Biopharmaceuticals

Live Online Training on 10/11 May 2022

Highlights

- Regulatory Requirements on Biopharmaceuticals
- Validation of Analytical Methods and Processes
- Process Transfer from Development to Commercial Production
- Quality Assurance for Biopharmaceuticals
- Case Studies: Hygienic Deviations
- Cleaning Validation in Biopharmaceutical Manufacturing

Regulatory Requirements and Practical Implementation

Programme

Objective

This Live Online Training 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 particular 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 Live Online Training 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 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

GMP Guidelines for Biopharmaceuticals – a Brief Summary

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

Development of Biopharmaceuticals - GMP and Regulatory Aspects

- GMP and regulatory documents
- Ways to Success
- Interaction with authorities (meetings/inspections)

Development, Qualification and Validation of Process Analytics for Biopharmaceuticals

- Relevant guidelines
- Phases of product development / testing requirements
- Method portfolio/method development / method qualification / method validation

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

- Key Aspects for EU and US
- Difference between development and commercial production

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

- Introduction
- Current initiatives in pharmaceutical development
- Biopharmaceuticals / Biosimilars / Biological
  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, Q's)
- Process development & quality by design
- Early clinical phase
- Late clinical phase
- Post approval

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

Interactive Case Studies – Deviations, Root Causes, CAPA

- Examples of pitfalls
- Chemical interactions
- Human errors
- Incorrect use

Prevention of Cross Contamination: Dedicated Manufacturing or Cleaning Validation?

- Requirements of Chapter 3 and 5 and Annex 2
- Decision with consequences: multipurpose equipment or disposables
- Dirt or product: The perspective defines contamination
- Ways to remove contaminants: cleaning procedures and their testing
- Risk-based approach: Crucial element of the validation programme

Moderator

Axel. H. Schroeder, Concept Heidelberg

Dr Markus Fido, MFI Bio-Consulting, Austria

Markus Fido holds a doctorate in biochemistry & cell biology. He has worked in quality and product development at Octapharma, Baxter and Igeneon. He then founded Vela Laboratories which he led as CEO for many years. In 2019/2020 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.

Dr Matthias Leitritz, Senior Director Project Quality, Rentschler Biopharma SE, Germany

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. 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.

Stefan Löw, CSL Behring, Germany

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

Dr Daniel Müller, GMP Inspector, Local Government Tübingen, Germany

Daniel Müller studied Pharmacy at the University of Wuerzburg, followed by doctorate. He started working in the pharmaceutical industry in 1998. Among other positions he served as a Qualified Person of large volume parenterals. In 2001 he joined a German inspectorate at Tübingen. Since that time he has been working as a GMP Inspector with focus on biotechnological active ingredients and sterile drug products.

Axel H. Schroeder, Concept Heidelberg, Germany

Axel Schroeder got his degree in Biology at Ruprecht-Karls University Heidelberg. From 1994 to 2005 he worked in the division for Industrial Hygiene and Contamination Control at Ecolab GmbH, Düsseldorf. Between 2005 and 2008 he was engaged at Basan GmbH. Since 2008 he is operation director for microbiology and biotechnology at Concept Heidelberg.

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Reservation Form (Please complete in full)

Annex 2 + Co - GMP Compliance for Biopharmaceuticals, Live Online Training on 10/11 May 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)

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Date of the Live Online Training

Tuesday, 10 May 2022, 09.00 h – 18.00 h CEST
Wednesday, 11 May 2022, 08.30 h – 17.00 h CEST

Technical Requirements

For our Live Online Training Courses and Webinars, we use Cisco WebEx, one of the leading suppliers of online meetings.
At http://www.webex.com/test-meeting.html you can check if your system meets the necessary requirements for the participation at a WebEx meeting and at the same time install the necessary plug-in. Please just enter your name and e-mail address for the test. If the installation is not possible because of your rights for the computer 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.

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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