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

Annex 2 & Co GMP Compliance for Biopharmaceuticals

09/10 May 2023 | Heidelberg, Germany

Highlights

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

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 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 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 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, 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

- 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 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)

- 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, Qs)
- 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

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

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

Speakers

Dr Markus Fido, MFi Bio-Consulting

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, Rentschler Biopharma SE

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.

Stefan Löw, Senior Manager Technical Support Laboratories, 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, Head GMP Inspectorate, Local Government Tübingen

Currently, Daniel Mueller is head of GMP inspectorate (local competent authority) at Tuebingen, Germany. Since 2001 he has been working as GMDP inspector with focus on biotechnology and sterile manufacture, conducting national inspections as well as EMA- and overseas inspections. Before joining the authority Dr Mueller was working in pharmaceutical industry, last serving as qualified person for sterile drug products. He is member of german expert groups 'biotechnology & tissue' and 'quality assurance'.

Social Event

In the evening of the first course day, you are cordially invited to a social event. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere

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GERMANY

Reservation Form (Please complete in full)

Annex 2 + Co - GMP Compliance for Biopharmaceuticals
09/10 May 2023, Heidelberg, Germany

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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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
Tuesday, 09 May 2023, 09.00 h – 18.00 h
(Registration and Coffee 08.30 h – 09.00 h)
Wednesday, 10 May 2023, 08.30 h – 17.00 h

Venue
NH Hotel Heidelberg
Bergheimer Strasse 91
69115 Heidelberg, Germany
Phone +49(0)6221 / 1327 0
Email nhheidelberg@nh-hotels.com

Fees (per delegate, plus VAT)
ECA Members € 1,690
APIC Members € 1,790
Non-ECA Members € 1,890
EU GMP Inspectorates € 945
Academic Scientists/ Students € 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.

Accommodation
CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form/POG when you have registered for the conference. Reservation should be made directly with the hotel. Early reservation is recommended.

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 you register online at www.gmp-compliance.org.

Conference language
The official conference language will be English.

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