Annex 2 & Co
GMP Compliance for Biopharmaceuticals
16/17 March 2021 | Munich, Germany

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

Speakers
- Dr Markus Fido
  MFI Bio-Consulting
- Dr Hiltrud Horn
  Horn Pharmaceutical Consulting
- Stephan Löw
  CSL
- Dr Daniel Müller
  GMP Inspector,
  German Local Government
- Axel Schroeder
  Concept Heidelberg
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.

Moderator
Axel. H. Schroeder, Concept Heidelberg

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

Case Study: 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

Workshop: Case Studies Hygienic GMP Deviations

- 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

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 Tenampus Group. In May 2020 he founded his new company MFI Bio Consulting GmbH.

Dr Hiltrud Horn, Horn Pharmaceutical Consulting, Germany

Dr Hiltrud Horn is managing director of Horn Pharmaceutical Consulting providing consulting services for the pharmaceutical and biotech industry in EU and US. From 1990 to 1999, she worked at Hoffmann-La Roche, Basel in QC/QA and in Regulatory Affairs. In 1999, she joined Knoll AG as Head of “Regulatory Compliance and CMC Documentation”. In 2002, she was working as consultant at Cap Gemini Ernst &Young (biotechnology and life sciences) prior to starting her own business.

Stefan Löw, CSL Behring, Marburg, 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

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)

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)

Date

Tuesday, 16 March 2021, 09.00 h – 17.30 h

Wednesday, 17 March 2021, 08.30 h – 16.30 h

Venue

HYPERION Hotel München
Truderinger Str. 13
81677 Munich, Germany
Phone +49 89 4110900
Email: Hyperion.Muenchen@h-hotels.com

Fees (per delegate, plus VAT)

- ECA Members € 1,590
- APIC Members € 1,690
- Non-ECA Members € 1,790
- EU GMP Inspectorates € 895

The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunches on both days, and all refreshments. VAT is reclaimable.

Accommodation

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

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.