20 YEARS ECA Academy Your GMP/GDP Information Source

Annex 2 & Co GMP Compliance for Biopharmaceuticals

Regulatory Requirements and Practical Implementation

Photo: Courtesy Rentschler Biotechnologie, Laupheim, Germany

SPEAKERS:

Dr Markus Fido
Vela Laboratories

Dr Hiltrud Horn
Horn Pharmaceutical Consulting

Stephan Löw
CSL Behring

Dr Daniel Müller
GMP Inspector, German Local Government

Axel Schroeder
Concept Heidelberg

16-17 May 2019, Vienna, Austria

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

This education course is recognised for the ECA GMP Certification Programme „Certified Biotech Manager".
Please find details at www.gmp-certification.eu

Annex 2 & Co - GMP Compliance for Biopharmaceuticals

16-17 May 2019, Vienna, Austria

Objectives

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 are 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
- Case Study

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

Process Validation in Clinical Phases I-III

- Definition of Validation
- Validation in early Clinical Phase
- Validation in late Clinical Phase
- Validation Documentation
- Guidelines

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

Social Event

On 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

Speakers

Dr Markus Fido,
CEO, Vela Laboratories, Austria
Markus Fido is CEO and Founder of Vela Laboratories. Before that he was Head Quality Control at Igeneon / Aphton Biopharma AG andas a Group Leader of Immunology and Product Development at Biomin GmbH, Head Biochemical Control at Baxter AG and Head Quality Operations at Octapharma GmbH. His focus is GMP/GCP concerns during the development of Biopharmaceuticals, Biosimilars and Biologics. He holds a Ph.D. in biochemistry and molecular microbiology from the Technical University in Graz (Austria).

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.

Easy Registration

Reservation Form:
CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg, Germany

Reservation Form:
+ 49 6221 84 44 34

e-mail:
info@concept-heidelberg.de

Internet:
www.gmp-compliance.org

If the bill-to-address deviates from the specifications on the right, please fill out here:

Reservation Form (Please complete in full)

+ 49 6221 84 44 34

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☐ Mr ☐ Ms

Title, first name, surname

Company Department

Important: Please indicate your company's VAT ID Number **P.O. No if applicable**

Street/P.O. Box

City Zip Code Country

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E-Mail (please fill in)

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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 2 weeks prior to the conference 10 %,
- until 1 weeks prior to the conference 50 %
- within 1 week prior to the conference 100 %.

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Terms of payment: Payable without deductions within 10 days after receipt of invoice.
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Date

Thursday, 16 May 2019 , 09.00 h – 17.30 h
(Registration and coffee 08.30 h – 09.00 h)
Friday, 17 May 2019, 08.30 h – 16.30 h

Venue

Radisson Blu Park Royal Palace Hotel Vienna
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Fax: +43 (1) 891 10-9090
Email: info.parkroyalpalace.vienna@radissonblu.com

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 event. Reservation should be made directly with the hotel. Early reservation is recommended.

Fees (per delegate plus VAT)

ECA Members € 1,590
APIC Members € 1,690
Non-ECA Members € 1,790
EU GMP Inspectorates € 895
Academic Scientists/ Students € 895
The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on both days and all refreshments. VAT is reclaimable.

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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