



## 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

# 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

Regulatory Requirements and  
Practical Implementation

## 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 Tentamus 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.

## Reservation Form (Please complete in full)

### Annex 2 + Co - GMP Compliance for Biopharmaceuticals, 16/17 March 2021, Munich, Germany

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

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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)

CONCEPT HEIDELBERG

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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 %
    - Cancellation until 1 week prior to the conference 50 %
    - Cancellation within 1 week prior to the conference 100 %
- CONCEPT HEIDELBERG reserves the right to change the materials, instructors,

or speakers without notice or to cancel an event.

If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. CONCEPT HEIDELBERG will not be responsible for discount airfare penalties or other costs incurred due to a cancellation.

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

Important: This is a binding registration and above fees are due in case of cancellation.

cellation or non-appearance. If you cannot take part, you have to inform us in writing. The cancellation fee will then be calculated according to the point of time at which we receive your message.

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 2022).

German law shall apply. Court of jurisdiction is Heidelberg.

Privacy Policy: By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at [http://www.gmp-compliance.org/eca\\_privacy.html](http://www.gmp-compliance.org/eca_privacy.html)). I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.

## Date

Tuesday, 16 March 2021, 09.00 h – 17.30 h  
(Registration and coffee 08.30 h – 09.00 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](mailto: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, 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.

## 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.

## Registration

Via the attached reservation form, by e-mail or by fax message. Or you register online at [www.gmp-compliance.org](http://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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For questions regarding content please contact:

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For questions regarding reservation, hotel, organisation etc. please contact: Mr Niklaus Thiel (Organisation Manager) at +49(0)62 21/84 44 43, or at [thiel@concept-heidelberg.de](mailto:thiel@concept-heidelberg.de).