

GMP Compliance for Biopharmaceuticals

Regulatory Requirements and Practical Implementation

SPEAKERS:



Dr Markus Fido
Vela Laboratories



Dr Hiltrud Horn
Horn Pharmaceutical Consulting,



Stephan Löw
GSK



Dr Daniel Müller
GMP Inspector, German Local Government



Axel Schroeder
Concept Heidelberg



Photo: Courtesy Rentschler Biotechnologie, Laupheim, Germany

19-20 June 2018, Berlin, 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



GMP Compliance for Biopharmaceuticals

19-20 June 2018, Berlin, Germany

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 and as 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 Würzburg, 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)

- GMP Compliance for Biopharmaceuticals, 19-20 June 2018, Berlin, Germany**
- GMP for Advanced Therapy Medicinal Products (ATMP), 21-22 June, Berlin, Germany**

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Title, first name, surname

Company

Department

Important: Please indicate your company's VAT ID Number

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Street/P.O. Box

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GERMANY

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General terms and conditions

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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
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 - until 1 weeks prior to the conference 50 %
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Terms of payment: Payable without deductions within 10 days after receipt of invoice.

German law shall apply. Court of jurisdiction is Heidelberg.

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Date

Tuesday, 19 June 2018 , 09.00 h - 17.30 h
(Registration and coffee 08.30 h - 09.00 h)
Wednesday, 20 June 2018, 08.30 h - 16.30 h

Venue

Steigenberger Hotel Berlin
Los-Angeles-Platz 1
10789 Berlin, Germany
Phone +49 (0)30 212 7 - 0
berlin@steigenberger.de

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.

Would you like to save money?
 You can save up to € 500 if you book "GMP Compliance for Biopharmaceuticals" AND "GMP for ATMP" simultaneously:
 Fees (per delegate plus VAT):
 ECA Members € 2,780
 APIC Members € 2,880
 Non-ECA Members € 2,980
 EU GMP Inspectorates € 1,680
 Academic Scientists/ Students € 1,680

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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 P.O. Box 10 17 64, 69007 Heidelberg, Germany
 Phone +49 (0) 62 21/84 44-0, Fax +49 (0) 62 21/84 44 34
info@concept-heidelberg.de, www.concept-heidelberg.de

For questions regarding content please contact:
 Mr Axel H Schroeder (Operations Manager) at
 +49-62 21 / 84 44 10, schroeder@concept-heidelberg.de

For questions regarding reservation, hotel, organisation, etc. please contact:
 Ms Katja Kramer (Organisation Manager) at
 +49-62 21/84 44 16 or per e-mail at
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GMP for Advanced Therapy Medicinal Products (ATMP)

Regulatory Requirements and Practical Implementation

SPEAKERS:



Dr Rainer Gnibl
Government of Upper Bavaria



Dr Andrea Hauser
*Jose-Carreras Center, Univer-
sity Hospital Regensburg*



Dr Hiltrud Horn
*Horn Pharmaceutical Consult-
ing*



Jan-Oliver Karo
*PEI, German Federal Agency
for Vaccines and Biomedicines*



Dr Ralf Sanzenbacher
*Paul-Ehrlich-Institut; German
Federal Agency for Vaccines
and Biomedicines*



Niina Taylor
Pfizer



Discussing the new
GMP Guide

21-22 June 2018, Berlin, Germany

HIGHLIGHTS:

- New European Guideline – Development, Background and Impact
- US Regulation
- Inspection Experiences
- GMP Implementation in Clinical Trial Applications and Manufacturing
- GMP Implementation in Industry
- Microbiological Safety



GMP for Advanced Therapy Medicinal Products (ATMP)

21-22 June 2018, Berlin, Germany

Objectives

Relating to the fact of the new GMP Guidelines on GMP requirements for ATMP and the ongoing scientific developments, this Workshop aims to provide an insight view in the regulatory requirements on ATMP with a focus on GMP aspects. During development as well as during manufacturing of Advanced Therapy Medicinal Products for clinical trials and on industrial level. Representatives from authority, consulting as well as from science and manufacturers will share their experiences with you and give you the possibility to discuss intensively the special challenges for ATMPs.

Background

Advanced therapy medicinal products (ATMP) are a emerging class of innovative biopharmaceutical medicines, summarizing gene therapy, somatic cell therapy and tissue-engineered products. With the adoption of the ATMP regulation EC 1394/2007, ATMPs are regarded as medicinal products and must consequently comply with current EU drug legislation including GMP. Although pharma industry recently increased their activities to this new area, but the development of these complex products is still focused at universities, hospitals and spin off companies derived thereof (small medium enterprises, SME). This academic/medical roots of these SME implicates generally special challenges to stay in compliance with regulatory requirements on marketing authorization and GMP. Especially open manipulations of cells and tissues on medical level necessitate adapted procedures. With the publishing of the new stand-alone guidance document on the GMP requirements in November 2017, EMA tried to define the expected standards for this special kind of medicinal products.

Target Audience

This course is advisable to people who

- Are involved in basic or translational research on cell-based therapy concepts with the perspective of clinical application
- Are responsible on quality aspects on ATMP
- Implement GMP in ATMP manufacturing
- Are involved in regulatory inspections of ATMP
- Are responsible for GMP requirements during pre-approval phases

Moderator

Axel. H. Schroeder, Concept Heidelberg

Programme

Tissues, Tissue Preparations and ATMPs: Introduction

- Overview on Products and Therapies: Reality and Future
- Legal Framework in EU and Germany
- CTA, Hospital Exemption and Marketing Authorisation: Steps to Consider in the Development of ATMPs

The New EU-GMP Guideline for ATMP (Part I)

- Guideline Overview
- ATMPs & Quality Risk Management
- Zone-Concept for ATMP Facility
- Focus: Qualification & Monitoring

The New EU-GMP Guideline for ATMP (Part II)

- Focus: Process-Validation & Media Fill
- Focus: Documentation
- How to certify/release an ATMP Batch
- Specific Products/Processes

GMP for ATMP – Considerations to European and US Requirements from industrial point of view

- Essential Effects of the New Guideline
- Challenges in Practice
- US Requirements

Regulatory and Practical Aspects for ATMPs - requirements for QPs

- Starting materials for ATMPs
- Raw/ancillary materials for production
- Specifics for process validation and quality control of ATMPs
- Responsibilities of the QP - what is different for ATMPs

Requirements on Manufacturing of Cell-based products under GMP

- Important Aspects for Characterisation and Control
- Quality of Reagents and Materials
- Relevant guidance documents
- Inspection Experiences and Findings
- Common Deficiencies in Clinical Trial Applications

Case Study – Manufacture of an ATMP for a phase I/II clinical trial in an academic setting

- Installation of a clean room facility for manufacture of ATMPs in an academic setting
- Establishment and validation of the manufacturing process with special focus on GMP-compliant FACS sorting
- Application for a phase I/II investigator initiated clinical trial

GMP Implementation - Practical Industrial Experiences

- Challenges in aseptic manufacturing
- Dealing with research grade raw materials in a cGMP environment
- Dealing with Contract Manufacturing organisations
- Specific cGMP challenges and possible solutions

Microbiological Safety of ATMPs

- Challenges and Critical Aspects
- Relevant Guidance Documents
- Modern Microbiological Safety Concepts
- Case Studies from Microbiological Assessment

Speakers



Dr Rainer Gnibl

Government of Upper Franconia, Germany

Dr Rainer Gnibl is EU-GMP inspector in Germany and performs GMP inspections worldwide also on behalf of the European Medicines Agency (EMA).



Dr Andrea Hauser

Jose-Carreras-Centrum, University Hospital Regensburg

Andrea Hauser is Head of Operations, Head of Production and Head of Quality Assurance at the José-Carreras-Centre for Somatic Cell Therapy, a department of the University Hospital Regensburg. She studied Pharmacy at the University of Regensburg. After that she was working as a GMP inspector at the Government of Upper Bavaria in Munich, where she conducted numerous GMP and GCP inspections mainly in the field of blood, tissue and (stem) cell therapy. Dr Hauser holds the qualification to act as Qualified Person.



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.



Jan-Oliver Karo

Paul-Ehrlich-Institut, German Federal Institute for Vaccines and Biomedicines

Oliver studied biology at the Technical University in Darmstadt with focus on microbiology. Since 2009 he is at the Paul-Ehrlich-Institut, in the Division Microbial Safety. He is quality assessor and national expert advisor for the microbial safety of advanced therapy medicinal products (ATMPs) and member of the "Cell Therapy Products" Working Party of the German Pharmacopoeia Commission.



Dr Ralf Sanzenbacher

Paul-Ehrlich-Institut, German Federal Institute for Vaccines and Biomedicines

Dr Ralf Sanzenbacher works at the Section of Somatic Cell Therapy and Tissue Engineering at the Paul-Ehrlich-Institut. He is an expert for regulatory aspects, as well as quality and preclinical issues aspects within the scope of manufacturing license, clinical trials and marketing authorisation. He is also member of several expert panels on cell therapies.



Niina Taylor

Qualified Person, Pfizer, UK

In 1992, Niina entered commercial APS/Berk Pharmaceuticals progressing from the role of a microbiologist to Qualified Person. In 1999, Niina joined Pharmaceutical Sciences, Pfizer Global Research and Development, Quality Assurance in the UK. She has since held various positions within Pfizer QA; supporting sterile, biologics, solid dose and pharmacy operations. She is currently working in the QA group in Sandwich, UK acting as a Qualified Person for Investigational Medicinal Products (IMPs) for use in Pfizer-sponsored and Investigator initiated clinical trials. She provides QP support for Gene and Cell therapy portfolio.

Social Event

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- GMP Compliance for Biopharmaceuticals**, 19-20 June 2018, Berlin, Germany

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Title, first name, surname

Company

Department

Important: Please indicate your company's VAT ID Number

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Date

Thursday 21 June 2018, 09.00 – 17.30 h
(Registration and coffee 08.30 h – 09.00 h)
Friday, 22 June 2018, 09.00 – 13.00 h

Venue

Steigenberger Hotel Berlin
Los-Angeles-Platz 1
10789 Berlin, Germany
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berlin@steigenberger.de

Accommodation

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For questions regarding content:

Mr Axel H Schroeder (Operations Manager) at +49-62 21 / 84 44 10, schroeder@concept-heidelberg.de

For questions regarding reservation, hotel, organisation etc.:

Ms Katja Kramer (Organisation Manager) at +49-62 21/84 44 16 or per e-mail at kramer@concept-heidelberg.de.