**GMP Compliance for Biopharmaceuticals and ATMP**

Regulatory Requirements and Practical Implementation

13 - 14 & 15 April 2016, Heidelberg, Germany

**SPEAKERS:**

**GMP Compliance for Biopharmaceuticals**
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

**Workshop GMP for ATMP**
Dr Andrea Hauser, Jose-Carreras Center, University Hospital Regensburg
Dr Ralf Sanzenbacher, Paul-Ehrlich-Institut; German Federal Agency for Vaccines and Biomedicines
Dr Ohad Karniel, Karniel Ltd
Jan-Oliver Karo, PEI, German Federal Agency for Vaccines and Biomedicines

**HIGHLIGHTS:**

**GMP Compliance for Biopharmaceuticals**
- 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

**Workshop GMP for ATMP**
- Regulatory Background – an update of recent developments – Authority’s and Stakeholders View
- Inspection Experiences
- GMP Implementation in Clinical Trial Applications and Manufacturing
- Microbiological Safety
**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 found particular challenges to fulfil the regulatory requirements on production and quality assurance. Industry and authorities are treated with 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

**Social Event**

On 13 April you are cordially invited to a conference dinner. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

**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
  Dr Daniel Müller

**GMP Guidelines for Biopharmaceuticals – a brief summary**
- Relevant international regulations
- European biotech guidances
- Recent developments & possible impacts
  Dr Daniel Müller

**Development of Biopharmaceuticals - GMP and Regulatory Aspects**
- GMP and Regulatory Documents
- Ways to Success
- Interaction with Authorities (Meetings/Inspections)
  Dr Hiltrud Horn

**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
  Markus Fido

**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
  Dr Daniel Müller

**GMP-conform process development and qualification (including equipment qualification)**
- Current Regulatory Initiatives
  - ICH Q8 / ICH Q9
- Process Development Approaches
  - Design Space / Analytical Methods
- Equipment Qualification for Development Studies
  Markus Fido

**Case Study: Process Transfer from Development to commercial Production**
- Key Aspects for EU and US
- Difference between Development and Commercial Production
- Case Study
  Dr Hiltrud Horn
Quality Assurance for Biopharmaceuticals

- Classical responsibilities of QA dept.
- 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

Dr Daniel Müller

Process Validation in Clinical Phases I-III

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

Markus Fido

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

Stephan Löw

Part 2

- Overview of a typical biotech process
- Requirements on production areas, raw materials and equipment
- Specialities on biotech products
- Fill and finish

Stephan Löw

Workshop: Case Studies Hygienic GMP Deviations

- Examples of Pitfalls
- Chemical Interactions
- Human Errors
- Incorrect use

Axel Schroeder

Prevention of cross contamination: dedicated manufacturing or cleaning validation?

- Requirements of Chapter 3 and 5 and Annex 2
- Decision with Consequences: Multipurpose Equipment or Disposable
- 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

Dr Daniel Müller and Stephan Löw

Objectives

This Workshop aims to provide an insight view in the regulatory requirements on ATMP with a focus on GMP aspects during development and manufacturing of Advanced Therapy Medicinal Products. 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 implicates special challenges for compliance these SME with regulatory requirements on marketing authorization and GMP.

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

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

Dr Ralf Sanzenbacher

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

Dr Andrea Hauser
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

Dr Ralf Sanzenbacher

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

Dr Andrea Hauser

GMP Implementation - Practical Industrial Experiences/ Common pitfalls and issues

- Aseptic challenges in cell therapy from media preparation to final product.
- Dealing with research grade raw materials in a cGMP environment.
- Closing the critical gaps in open manipulations of cell therapy.
- Autologous verses Allogeneic cGMP cell therapy challenges
- Cell Therapy specific cGMP challenges and possible solutions.

Ohad Karnieli

Microbiological Safety of ATMPs

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

Jan Oliver Karo

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/Apton 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 Andrea Hauser,
Jose-Carreras-Centrum, University Hospital Regensburg, Germany
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.

Dr Ohad Karnieli,
Karnieli Ltd, prior to that at Pluristem, Israel
Dr Karnieli is the founder and CTO of Karnieli Ltd, a company that focuses on process development, cell therapy cGMP consulting & Innovative solutions for cell therapy. He earned his PhD in Biotechnology from the Tel Aviv University and MBA from the Haifa University. Dr Karnieli served as the Vice President for Technology and Manufacturing at Pluristem Therapeutic where he managed a group of 70 biotech engineers in both process & product development and cGMP clinical manufacturing. As part of his responsibility he designed, qualified and ran the new state of the art cGMP manufacturing site which was approved for clinical manufacturing in the EU, USA, South Korea, Japan and Israel.

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.
Speakers

Dr Daniel Müller, GMP Inspector, Local Government Tübingen, Germany
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.

Dr Ralf Sanzenbacher, Paul-Ehrlich-Institut, German Federal Institute for Vaccines and Biomedicines, Germany
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.

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 operations director at Concept Heidelberg for microbiology and biotechnology.

Use the GMP App at no costs!

The ECA Foundation has developed a GMP App which offers a comprehensive GMP Guideline database with more than 1,400 GMP Guidelines and ten thousands of pages. Check relevant Guidelines (full text versions) during internal audits, regulatory inspections or GMP compliance meetings – simply on your smartphone or tablet PC. In addition to this wealth of guideline information the GMP App also comprises features like GMP News, a comprehensive GMP Search Engine. To open the app just enter app.gmp-compliance.org in your browser and the WebApp opens immediately.

Organisation and Contact

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

For questions regarding reservation, hotel, organisation etc.:
Ms Katja Kramer (Organisation Manager) at phone +49-62 21/84 44 16 or per e-mail at kramer@concept-heidelberg.de.

Heidelberg – Optimal Accessibility via Frankfurt

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Lufthansa Bus Airport Shuttle
Tel. +49 (0)6152 – 97 69 099, info@frankfurt-airport-shuttles.de

Train
You can get on the train directly at the airport. Trains leave up to two times per hour and it takes less than one hour to get to Heidelberg. www.bahn.de
Reservation Form (Please complete in full)

GMP Compliance for Biopharmaceuticals, 13-14 April 2016, Heidelberg, Germany

Workshop: GMP for Advanced Therapy Medicinal Products (ATMP), 15 April 2016, Heidelberg, Germany

**Important:** Please indicate your company’s VAT ID Number

**P.O. No.** if applicable

Street/P.O. Box

City  Zip Code  Country

Phone/Fax

E-Mail (please fill in)

Date

GMP Compliance for Biopharmaceuticals
Wednesday, 13 April 2016, 09.00 h – 17.30 h
(Registration and coffee 08.30 h – 09.00 h)

Thursday, 14 April 2016, 08.30 h – 16.30 h

Workshop GMP for ATMP
Friday 15 April 2016, 09.00 – 16.30 h
(Registration and coffee 08.30 h – 09.00 h)

Venue

NH Heidelberg
Bergheimer Strasse 91
69115 Heidelberg
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Fees (per delegate plus VAT)

GMP Compliance for Biopharmaceuticals

ECA Members € 1,590
APIC Members € 1,690
Non-ECA Members € 1,790
EU GMP Inspectorates € 895
Academic Scientists/ Students € 895

Workshop: GMP for Advanced Therapy Medicinal Products (ATMP)

ECA Members € 790
APIC Members € 840
Non-ECA Members € 890
EU GMP Inspectorates € 445
Academic Scientists/ Students € 445

GMP Compliance for Biopharmaceuticals AND Workshop GMP for ATMP

ECA Members € 2,080
APIC Members € 2,180
Non-ECA Members € 2,280
EU GMP Inspectorates € 1,140
Academic Scientists/ Students € 1,140.

Accommodation

Concept Heidelberg has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form with all further information when you have registered for the event. Reservation should be made directly with the hotel. Early reservation is recommended.

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.

General terms and conditions

1. Changes to the program or the meeting location are possible under special circumstances.
2. Cancellations. In case of cancellation of your attendance, the following cancellation fees will be levied:
   - up to 3 weeks prior to the event: 10% of the fees
   - up to 1 week prior to the event: 50% of the fees
   - within 1 week prior to the event: 100% of the fees
3. 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.
4. **Important:** This is a binding registration and above fees are due in case of cancellation 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, you are entitled to participate in the conference (receipt of payment will not be confirmed)!

Privacy Policy:

By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the conference purposes. My data will be processed using an automated data processing system for the purpose of providing the services and will be used for the presentation of offers. All personal data will be deleted after the conference. The data is stored on servers located within the EU and are not transferred. I agree to the Privacy Policy at 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.