Photo: Courtesy Rentschler Biotechnologie, Laupheim, Germany

Workshop on 12 October 2012
"GMP for Advanced Therapy Medicinal Products (ATMP)"

GMP Compliance for Biopharmaceuticals and ATMP

Regulatory Requirements and Practical Implementation

10 – 11 October 2012, Heidelberg, Germany

SPEAKERS:

GMP Compliance for Biopharmaceuticals
Dr Markus Fido
Vela Laboratories
Dr Hiltrud Horn
Horn Pharmaceutical Consulting
Dr Falk Klar
IDT Biologika
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 Hiltrud Horn
Horn Pharmaceutical Consulting
Dr Ralf Sanzenbacher
Paul-Ehrlich-Institut

HIGHLIGHTS:

GMP Compliance for Biopharmaceuticals
- Incl. New Annex 2 Regulatory Requirements on Biopharmaceuticals
- Qualification or Validation of Analytical Methods
- Process Validation in Clinical Phases I-III
- Case Study: Process Transfer from Development to Commercial Production
- Quality Assurance for Biopharmaceuticals
- Requirements to Rooms, Equipment and Staff
- Case Studies: Hygienic Deviations
- Cleaning Validation in a Prokaryotic Multipurpose Facility

Workshop GMP for ATMP
- Regulatory Background – Authority's and Users View
- Inspection Findings
- Common Deficiencies in Clinical Trial Applications
- Practical Approaches

ECA
EUROPEAN COMPLIANCE ACADEMY

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

Organisation and Contact

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For questions regarding content:
Axel H Schroeder (Operations Manager) at +49-62 21 / 84 44 10, or per e-mail at schroeder@concept-heidelberg.de.
For questions regarding reservation, hotel, organisation etc.:
Jessica Stürmer (Organisation Manager) at +49-62 21/84 44 43 or per e-mail at stuermer@concept-heidelberg.de.

Conference Language

The official conference language will be English.

About CONCEPT HEIDELBERG

Founded in 1978, CONCEPT HEIDELBERG is the leading organiser of seminars on pharmaceutical production, quality control, quality assurance and GMP in Europe. This year more than 240 events will be organised by CONCEPT HEIDELBERG.

ECA has entrusted CONCEPT HEIDELBERG with the organisation of its events.

What Is ECA?

The European Compliance Academy (ECA) is an independent educational organisation chaired by a Scientific Advisory Board with members of the pharmaceutical industry and regulatory authorities.
The ECA will provide support to the Pharmaceutical Industry and Regulators to promote the move towards a harmonised set of GMP and regulatory guidelines by providing information and interpretation of new or updated guidances.

What Are the Benefits of ECA?
First benefit:
During the membership, you enjoy a € 200,- discount on the regular participation fee of any European Conference organised by ECA in co-operation with CONCEPT HEIDELBERG.

Second benefit:
The GMP Guideline Manager software with a large number of guidelines, e.g. EC Directives, FDA Guidelines, ICH Guidelines, will be forwarded to you when you are using your membership for a conference registration.

How Do You Become a Member of ECA?
By participating in one of the European Compliance Conferences or Courses marked with ECA, you will automatically become a member of ECA for two years – free of charge. Conferences and Education Courses organised by ECA will be realised in co-operation with CONCEPT HEIDELBERG. More information about ECA can be obtained on the Website **www.gmp-compliance.org.**

GMP Certification Programme

This seminar is recognised within the GMP Certification Programme Module "Biotech Manager". By attending selected seminars, the participant can acquire an additional certificate. We offer the following modules:

- ECA Validation Manager
- ECA QA Manager
- ECA API Production Manager
- ECA Quality Control Manager
- ECA Technical Operations Manager
- ECA Computer Validation Manager
- ECA Regulatory Affairs Manager
- ECA Microbiological Laboratory Manager
- ECA Sterile Production Manager
- ECA Biotech Manager
- ECA Pharmaceutical Development Manager

On the internet at www.gmp-compliance.org you will find a text explaining which seminars are recognised for which certificates. Or you send an e-mail to info@gmp-compliance.org or a fax to +49-6221- 84 44 64 with the request for information about the GMP Certification Programme. We will then send you our brochure on the topic.

Lufthansa is Mobility Partner for all ECA Events

As an ECA course or conference attendee, you will receive **up to 20% discounted travel fares** (according to availability). And as Lufthansa German Airlines offers a comprehensive global route network linking major cities around the world you will most likely be able to benefit from these special prices and conditions.

Lufthansa Mobility Partner

And this is how it works: Once you registered for a course or conference you will receive a link together with your registration confirmation. Opening that link will take you to the Mobility Partner Program website where you can enter a code in the "Access to Event Booking" area you will also receive. This will take you into an online booking platform* that will automatically calculate the discount offered or provide you with an even better offer if another promotional fare is available.

We look forward to welcoming at one of our next events – and we already wish you a pleasant flight!

*Please note: You may have to enable pop-ups on the Mobility Partner Program website – other-wise the booking platform window will not open.

GMP Compliance for Biopharmaceuticals

10-11 October 2012, Heidelberg, Germanyy

Objectives

This Education Course concentrates on regulatory requirements regarding biopharmaceutical production. Further, 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.
Furthermore, the experience of biotech manufacturers as well as contract manufacturers will be emphasised through samples of clinical trial biologicals and fill and finish production.

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

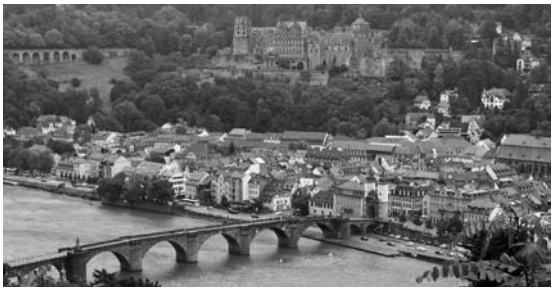
- Are involved in regulatory inspections
- Work in quality units at biotech companies
- Implement GMP in biotech production
- Are responsible for GMP requirements pre-approval phases

Moderator

Axel H Schroeder, Concept Heidelberg

Social Event

On 10 October 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)

- International Guidance Documents & EU-Regulations
- Examples National Regulations
- State–of-the-art Manufacturing
- Recent Developments

Dr Daniel Müller

The New Annex 2 of the European GMP Guideline – A brief summary

- Important changes
- Possible impacts

Dr Daniel Mülle

Development of Biopharmaceuticals - GMP and Regulatory Aspects

- GMP and Regulatory Documents
- Ways to Success
- Interaction with Authorities (Meetings/Inspections)

Dr Hiltrud Horn

Qualification or Validation of Analytical Methods for Biopharmaceuticals

- Relevant Guidelines
- Phases of Product Development / Testing Requirements
- Method Portfolio/Method Development / Method Qualification / Method Validation

Dr Markus Fido

Process Validation in Clinical Phases I-III

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

Dr Markus Fido

GMP Inspections in Biopharmaceutical Production

- Clean Room Classes for Biotech Facilities
- Open vs. Closed Processing
- Single - vs. Multi Purpose Equipment
- Cell Banking Activities
- Inspector's Experience, Examples of Observations & Discussion Points

Dr Daniel Müller

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

- Interaction with others: Allocation of Responsibilities and Training of Staff
- Areas of Interference: From Development to Authorisation, from Raw Material to finished Product
- Struggling with Paper: Document Control, Batch Record and Product Quality Review
- Dealing with Vendors: Cooperation with Contract Laboratories and CMOs
- The Police is coming: Self Inspections and Audits
- Daily Routine and Highlights: Equipment Qualification and Process Validation
- Managing Key Processes: Deviations, Changes and Complaints

Dr Falk Klar

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

Dr Markus Fido

GMP requirements for buildings and rooms

- Positive or Negative Pressure: Balancing GMP Guidelines and Requirements from Gene Technology
- Different Environments for different Processes: Zone Concept and Locks
- Ways to achieve Clean Air: HVAC System and Filters
- Plastic, Wood or Metal: Materials to be Used for Clean Rooms
- Maintaining the Rooms Clean: Cleaning Procedures and Pest Control
- Handling Plenty of Data: Room Validation and Environmental Monitoring

Dr Falk Klar

Workshop: Case Studies Hygienic GMP Deviations

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

Axel Schroeder

Cleaning Validation in a Prokaryotic Multipurpose Facility

- Decision with Consequences: Multipurpose Equipment or Disposables
- Dirt or Product: The Perspective Defines Contamination
- Ways to Remove Contaminants: Cleaning Procedures
- Dirty or clean: Sampling and Testing is Key
- Risk Based Approach: Crucial Element of the Validation Programme
- The Sequence of the Paperwork: Protocol, Record and Report

Dr Falk Klar

Workshop: GMP for Advanced Therapy Medicinal Products (ATMP)

12 October 2012, Heidelberg, Germany

Objectives

This Workshop provides you 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 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 new emerging class of innovative biopharmaceutical medicines , summarising 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. However, development of these complex products is currently focused at universities, hospitals and spin off companies derived there off (small medium enterprises, SME), implicating special challenges for compliance 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 Aspects for ATMPs – Industrial View

- Regulatory Background
- Procedures
- Information in the Dossier
- Practical Examples

Dr Hiltrud Horn

Requirements on Manufacturing of Cell-based products under GMP

- Important Aspects for Characterisation and Control of Cells
- Quality of Reagents and Materials
- Relevant guidance documents

Dr Ralf Sanzenbacher

GMP-Aspects for ATMPs

- GMP-Background
- Impact of Revised GMP Annex 2
- Inspections
- Case Studies

Dr Hiltrud Horn

Practicle Experiences with ATMP

- Installation of a clean room facility for manufacture of ATMP
- Application for a phase I/II clinical trial

Dr Andrea Hauser

Experiences during Inspections

- Inspection Findings
- Common Deficiencies in Clinical Trial Applications

Dr Ralf Sanzenbacher

Speakers

Dr Markus Fido, *CEO, Vela Laboratories, Austria*
Markus Fido is CEO and Founder of Vela Laboratories, were he is responsible for Finance & Controlling Regulatory Affairs & Quality Operations. Before that he was Head Quality Control at Igeneon / Aphton Biopharma AG where he was in charge for all QC aspects of pre-clinical and clinical projects such as stability studies, specifications, method validation, and product release. Prior he was working 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, *Operational Head, Jose-Carreras-Centrum, University Hospital Regensburg*
Andrea Hauser studied Pharmacy at the University of Regensburg. She received her PhD in Immunology at the University Hospital Regensburg. After her scientific work she joined the Government of Upper Bavaria in Munich working as a GMP inspector for the Central Authority for Supervision of Medicinal Products in Bavaria (ZAB), where she conducted numerous GMP and GCP inspections mainly in the field of blood, tissue and (stem) cell therapy. Since 2009 she is Operational Head of the José Carreras Center for Somatic Cell Therapy (JCC) at the University Hospital Regensburg and designated head of production.

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 1997, she worked at Hoffmann-La Roche, Basel in QC/QA. From 1997 to 1999, she was responsible for medical writing and project management in the "International Regulatory Affairs" department of the same company. In 1999, she joined Knoll AG as Head of "Regulatory Compliance and CMC Documentation" and later "Dossier Production and Compliance" for International Regulatory Affairs. In 2002, she was working as consultant at Cap Gemini Ernst & Young (biotechnology and life sciences) prior to starting her own business.

Dr Falk Klar, *IDT Biologika GmbH, Germany*
After completing his studies in physics and obtaining the PhD, Mr. Falk Klar started his industrial career in a medical device company. Between 1995 and 1999 he was responsible for organisation, conducting and data evaluation of preclinical and clinical studies. During that time he attended a qualification programme to become a Quality Manager. In 1999 he joined an international Contract Research Organisation as Project Manager responsible for conducting clinical trials in phases I to IV. Between 2002 and 2009 Dr. Klar was employed as Head of Quality Assurance of Biomeva GmbH, a biotech Contract Manufacturing Organisation producing APIs. He gained comprehensive experience in the wide spectra of GMP quality management including validation of manufacturing processes and computerised systems. In 2010 Dr. Klar joined IDT Biologika GmbH, a global supplier to the pharmaceutical and biotechnology industry. In his recent position of Chief Compliance Officer he is responsible for all quality assurance and compliance aspects in the branches human vaccines, contract manufacturing of biopharmaceuticals and animal health.

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.

Dr Ralf Sanzenbacher, *Paul-Ehrlich-Institut, German Federal Institute for Vaccines and Biomedicines*
Dr Ralf Sanzenbacher works at the Sectionof Somatic Cell Therapy and Tissue Engineering at the Paul-Ehrlich-Institut. He is an expert for quality and preclinical aspects within the scope of manufacturing license, clinical trials and marketing authorisation.

Axel H. Schroeder, *Concept Heidelberg, Germany*
Axel Schroeder got his degree in Biology at Ruprecht-Karls University Heidelberg. From 1994 to 2000 he was Territory Manager for Hygiene and Medical Devices at HenkelEcolab GmbH. From 2000 to 2005 he was Key Account Manager for Industrial Hygiene and Contamination Control at Ecolab GmbH, Düsseldorf, and from 2003 to 2005, Member of the International Cleanroom-Team of Ecolab. Between 2005 and 2008 he was engaged at Basan GmbH as Key Account Manager for Pharmaceuticals and Biotechnology. Since 2008 he is operation director at Concept Heidelberg for microbiology and biotechnology.

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

Reservation Form (Please complete in full)

+ 49 6221 84 44 34

☐ **GMP Compliance for Biopharmaceuticals,** 10 -11 October 2012, Heidelberg, Germany
☐ **Workshop: GMP for Advanced Therapy Medicinal Products (ATMP),** 12 October 2012, Heidelberg, Germany

☐ 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

Phone/Fax

E-Mail (please fill in)

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

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GERMANY

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 %.

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 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 2012)

Date

GMP Compliance for Biopharmaceuticals
Wednesday, 10 October 2012 , 09.00 h – 17.00 h
(Registration and coffee 08.30 h – 09.00 h)
Thursday, 11 October 2012, 08.30 h – 16.30 h

Workshop GMP for ATMP
Friday 12 October 2012, 09.00 – 16.30 h
(Registration and coffee 08.30 h – 09.00 h)

Venue

Heidelberg Marriott Hotel
Vangerowstraße 16
69115 Heidelberg, Germany
Phone 0049 6221 908 0
Fax 0049 6221 908 698

Fees

GMP Compliance for Biopharmaceuticals
ECA Members EUR 1,490.- per delegate plus VAT
APIC Members EUR 1,590.- per delegate plus VAT
(does not include ECA Membership)
Non-ECA Members EUR 1,690.- per delegate plus VAT
EU GMP Inspectorates EUR 845.- per delegate plus VAT
Academic Scientists/ Students EUR 845.- per delegate plus VAT

Workshop: GMP for Advanced Therapy Medicinal Products (ATMP)
ECA Members EUR 790.- per delegate plus VAT
APIC Members EUR 840.- per delegate plus VAT
(does not include ECA Membership)
Non-ECA Members EUR 890.- per delegate plus VAT
EU GMP Inspectorates EUR 445.- per delegate plus VAT
Academic Scientists/ Students EUR 445.- per delegate plus VAT

GMP Compliance for Biopharmaceuticals AND Workshop GMP for ATMP
ECA Members EUR 1,980.- per delegate plus VAT
APIC Members EUR 2,080.- per delegate plus VAT
(does not include ECA Membership)
Non-ECA Members EUR 2,180.- per delegate plus VAT
EU GMP Inspectorates EUR 1,090.- per delegate plus VAT
Academic Scientists/ Students EUR 1,090.- per delegate plus VAT

Accommodation

CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form when you have registered for the event. Please use this form for your room reservation or be sure to mention "1126345" to receive the specially negotiated rate (single room € 135,- per night, incl. brekfast) for the duration of your stay. Reservation should be made directly with the hotel not later than 9 September 2012. 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.**

wa/versl/22022012