ECA Certified Biotec Manager Course*

Photo: Courtesy Rentschler Biotechnologie, Laupheim, Germany

cGMP Compliance for Biopharmaceuticals

Regulatory Requirements and Practical Implementation

3 – 5 November 2010, Berlin, Germany

SPEAKERS:

Dr Markus Fido
Vela Laboratories, Austria

Dr Andreas Nechansky
Vela Laboratories, Austria

Dr Falk Klar
IDT Biologika, Germany

Jolande Schoemaker
Schoemaker Consultancy, The Netherlands

Dr Klaus B. Schoepe
Rentschler Biotechnology, Germany

Axel H. Schroeder
CONCEPT HEIDELBERG, Germany

Dr Christian Schröter
Merck, Germany

Dr Jürg Sommer
Head of Regional Medicines Inspectorate of North-Western Switzerland

HIGHLIGHTS:

- Regulatory Requirements Applying to Development and Manufacturing in Clinical Phases I-III
- Control of Process Changes Through Development and Comparability
- Qualification or Validation of Analytical Methods
- Design and Implementation of a Multi Purpose Facility for Biotechnological Manufacturing
- Quality Assurance for Biopharmaceuticals
- Requirements to Rooms, Equipment and Staff
- Cleaning Validation
- GMP-conform Process Development and Qualification
- Process Validation in Clinical Phases I-III
- GMP Inspections in Biopharmaceutical Production
- Manufacturing of Cell Banks

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

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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, and, in addition, the experiences during the building of new production sites.

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 those 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

Regulatory GMP Requirements Applying to Development and Manufacturing in Clinical Phases I-III

- Relevant Swiss laws and EU guidelines
- Authority inspections with focus on IMPs
- Specific inspection findings

Control of Process Changes Through Development and Comparability

- When to start change control
- Planning of upscaling
- Comparability protocol
- When is a product comparable?

Qualification or Validation of Analytical Methods for Biopharmaceuticals

- Relevant guidelines
- Phases of product development / testing requirements
- Method portfolio/method development / method qualification / method validation

Process Validation in Clinical Phases I-III

- Definition of Validation
- Validation in early clinical phase
- Validation in late clinical phase
- Validation Documentation
- Guidelines

GMP Inspections in Biopharmaceutical Production

- Relevant Swiss laws and EU guidelines
- Authority inspections with focus on pharmaceuticals derived from recombinant organisms
- Specific inspection findings

Manufacturing of Cell Banks (MCB,WCB) and their Characterization

- Cell bank characterization
- Safety testing
- US, European and ICH guides

Quality Assurance in Biotechnology

- 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

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

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

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

Case study: Process Transfer from Development to Commercial Manufacturing

- What is the difference between development and commercial manufacturing?
- What does that mean for process transfers?
- Which problems does development have with commercial manufacturing?
- Which problems does commercial manufacturing face with development products?

Single-use Equipment during Transfer of Development Products - a Case Study

- What are the issues transferring development products into production?
- How can single use equipment help?
- What are the issues with single use equipment?

Cleaning and Disinfecting Aspects in biopharmaceutical Production

- Regulatory Background
- Efficacy of Disinfectants
- Criteria for selection
- Practical examples for Deviations by incorrect use

Case Study: Failures and successes in outsourcing manufacturing

- A project that failed, a project that succeeded
- Reasons for success and failure
- Lessons learned

Design and Implementation of a Multi-Purpose Facility for Biotechnological Manufacturing

- Regulatory requirements
- Planning of Process Technologies, Reactor Scale and Configuration
- Further Requirements
- Qualification Steps
- Optimising Costs and Time schedule

Speakers

Dr Markus Fido, *Vela, 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 preclinical 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 Falk Klar, *IDT Biologika GmbH, Germany*
In his recent position as Chief Compliance Officer at IDT Biologika GmbH Dr Klar is responsible for all quality assurance and compliance aspects in the branches human vaccines, contract manufacturing of biopharmaceuticals and animal health.

Dr Andreas Nechansky, *Vela Laboratories, Austria*
Andreas Nechansky is Co-founder and CEO of Vela Laboratories and is also responsible for the Department of Analytical Development & Validation and for Business Development. He previously held the position of Head Assay Development at Igeneon / Aphton Biopharma.

Jolande Schoemaker, *Schoemaker Consultancy, The Netherlands*
Jolande is currently located in The Netherlands and works as a consultant to the pharmaceutical industry. Previous to her current role she was the Director Quality Affairs at Crucell and was involved in many regulatory inspections, including some conducted by the US FDA, the Canadian and the British Inspectorate.

Dr Klaus B. Schoepe, *Rentschler Biotechnologie, Germany, Senior Vice President Projects*
Klaus B. Schoepe started his career in the pharmaceutical industry with Boehringer Mannheim. He subsequently worked for Hoffmann La Roche AG, ASTA Medica AG – which later became Baxter Oncology GmbH – and Merckle. In 2005 he joined Rentschler Biotechnologie. In 2007 he was appointed to his current position with responsibility for Project Management, Regulatory Affairs and Quality Assurance.

Axel H. Schroeder, *Concept Heidelberg*
Mr Schroeder was Territory Manager for Hygiene and Medical Devices at HenkelEcolab, Key Account Manager for Industrial Hygiene and Contamination Control at Ecolab and Member of the International Cleanroom-Team of Ecolab. He also was engaged at Basan as Key Account Manager for Pharmaceuticals and Biotechnology. Since 2008 he is operations director at Concept Heidelberg for microbiology and biotechnology.

Dr Christian Schröter, *Director of Liquid Manufacturing, Merck KGaA, Darmstadt, Germany*
Dr Schröter is currently Director of Liquid Manufacturing responsible for making, filling and packaging of sterile and non-sterile liquids. Before commercial manufacturing, he was working in various positions in pharmaceutical development.

Dr Jürg Sommer, *Head of the Regional Medicines Inspectorate of North-Western Switzerland (RHI)*
Since 2003 head of the Regional Medicines Inspectorate in Basel, Switzerland. Based on Swiss law and EU GMP/GDP guidelines the Regional Medicines Inspectorate examines up to 470 pharmaceutical companies (manufacturers, wholesalers) and 600 self dispensing physicians in its region.

Social Event

On 3rd November 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.

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

Date

Wednesday, 3 November 2010 , 09.00 h – 17.00 h
(Registration and coffee 08.30 h – 09.00 h)
Thursday, 4 November 2010, 9.00 h – 16.30 h
Friday, 5 November 2010, 9.00 - 13.30 h

Venue

NH Hotel Berlin Mitte
Leipziger Str. 106-111
10117 Berlin, Germany
Phone +49(0)30 - 2062070
Fax +49(0)30 - 206207600

Fees

Non-ECA Members € 1,890.- per delegate plus VAT
ECA Members € 1,701.- per delegate plus VAT
APIC Members € 1,745.- per delegate plus VAT
(does not include ECA Membership)
EU GMP Inspectorates € 945.- per delegate plus VAT
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.

Accommodation

CONCEPT has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form when you have registered for the course. Please use this form for your room reservation or be sure to mention "VA 6521 ECA Event" to receive the specially negotiated rate for the duration of your stay. Reservation should be made directly with the hotel not later than 3 October 2010. Early reservation is recommended.

Organisation and Contact

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69007 Heidelberg, Germany,
Phone ++49-62 21/84 44-0
Fax ++49-62 21/84 44 84
info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content:
Axel H. Schroeder (Operations Director) at
+49-62 21/84 44 10 or per e-mail at
schroeder@concept-heidelberg.de.
For questions regarding reservation, hotel, organisation etc.:
Marion Weidemaier (Organisation Manager) at
+49-62 21/84 44 46 or per e-mail at
weidemaier@concept-heidelberg.de.

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 10 % 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 http://www.gmp-compliance.org

GMP Certification Programme

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

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

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

CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49 (0) 62 21/84 44 34

D-69007 Heidelberg
GERMANY

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. Number (if applicable)**

Street/P.O. Box

City Zip Code Country

Phone/Fax

E-Mail (please fill in)

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)!