GMP meets GCP
Management, Supply and Quality Assurance of Clinical Trials

21 – 23 November 2017, Berlin, Germany

HIGHLIGHTS:

- Rules and Regulations
  - Applicable legislation and GMP/GCP interfaces
  - Duties and responsibilities
  - Typical inspection findings
- Supply Management
  - Packaging, labelling, distribution
  - Shelf-life extensions
  - Handling of comparators
  - GMP requirements at the investigational site
  - Trials outside the EU
- Study Management
  - Key tasks and responsibilities
  - The role of the hospital pharmacy
  - IMP-related documentation
- The Role of the QP in Clinical Trials
  - When does the QP responsibility end?
  - Oversight of the supply chain
- International Contracts and Agreements
- Workshops and Case Studies

Speakers

Brigitte Bastyns
Johnson & Johnson

Rita Hattemer-Apostel
Verdandi AG

Andreas Jungk
Lawfirm Jungk

Dr. Anne Lewerenz
GMP/GDP/GCP Inspector, Landesdirektion Sachsen (Local Authority), Leipzig, Germany

Dr. Claudio Lorck
AbbVie

Dr. Andreas Schwinn
Roche Pharma

Dr. Lenka Taylor
University Hospital of Heidelberg

Delegated Regulation 2017/1569 „GMP for IMPs“ published – facing the new EU Guidelines for IMPs of September 2017!

This course is recognised for the ECA GMP Certification Programme „Certified Pharmaceutical Development Manager“.
Please find details at www.gmp-certification.eu
Objectives

During this course, well-experienced specialists will share their expert knowledge about important aspects of IMP Supplies and the Management of Clinical Trials. Hear essential aspects about the organisation and management of the supplies, their distribution, things to consider during the study and learn how the various regulations lead the way. During this event, the important interfaces between GMP and GCP will be elaborated.

Background

In the development of new pharmaceutical products, it is a challenge to design and initiate sound and appropriate studies. Compliance with GMP and GCP regulations is mandatory. A prerequisite for a successful study is the thorough planning of the clinical trial supplies. Beginning with the order, the manufacturing and supply of the IMPs, an efficient study management and full compliance with applicable rules and regulation will lead to satisfactory results. GMP and GCP requirements need to be considered and understood from all parties involved.

Trials outside the EU and contracts and agreements are two other aspects which require particular attention.

This event has been designed by the ECA to enhance and broaden your knowledge and to consolidate the various aspects which need to be taken into account for an efficient management of clinical trials.

Target Audience

Specialists, managers and executives from R&D dealing with the various aspects of IMP supply and clinical trial management. It addresses representatives from IMP manufacturing, packaging, QP certification and supply as well as from the study design and management and the respective Quality Assurance units. It is also directed to CROs and members of inspectorates and authorities.

Social Event

In the evening of the first conference 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.

Programme

Case Studies

- How things can go wrong

Interface between GMP and GCP

- Examples of why GMP and GCP do have an impact on what happens during clinical trials

CTS Planning

- Supply Chain Planning
- Comparators: selection, procurement, pedigree
- Blinding
- NIMPs
- Shelf-life assignment
- Outsourcing
- IRT: Pros and Cons to use for a particular study

Packaging and Labelling of IMPs

- Blinding aspects in packaging
- Packaging technology
- Unblinding risks during packaging
- Just-in-time labelling
- Relabeling
- Reconstitution
QC Aspects
- CMC Aspects of comparator modifications
  - Comparative dissolution, Stability, BE studies
  - Shelf-life Assignment for Comparators
- Stability concepts for comparator studies
- Shelf-life Assignment
- Assessment of temperature deviations
- Mean kinetic temperature
- QC approach for site transfer

Clinical Trials with Advanced Therapy Investigational Medicinal Products (ATIMPs): GMP-GCP- Interface Management
- ATIMPs: Examples and Definitions
- Legal Requirements and Specifics for ATIMPs
- Traceability: Responsibilities of Manufacturer and Sponsor
- Adverse Events: Responsibilities of Manufacturer and Sponsor
- Inspection Findings

Distribution of IMP Supplies
- Distribution concept and prerequisites
- IRT
- Temperature controlled shipments
- Temperature deviations
- Site transfer
- Depots
- Customs

GCP Aspects to Consider for IMPs
- Roles and responsibilities: Sponsor, CRA, Investigator
- ICH GCP
- Storage of IMPs
- Reconstitution
- Accountability and Reconciliation
- Sponsor: Achieving and Maintaining the Blind
- IMP return and destruction
- IMP related documentation

The Role of the QP in Clinical Trials
- When does the QP responsibility end?
- Dealing with deviations during distribution
- How to handle deviations at investigator’s site
- Extension of shelf-life
- Oversight of distribution and transport
- The responsibility for comparators

Three Workshops on Case Studies
Evaluate and discuss with the other delegates and the speakers case studies on:

1. Study Planning: Challenges from a CTS coordinators perspective
2. Case Studies: Open Discussion of QP Tasks and Challenges in Clinical Trials
3. GCP Aspects: Handling IMPs at the Investigator’s Site

You will be able to attend all 3 workshops.

Handling IMPs at a Hospital Pharmacy
- The role of the hospital pharmacy: manufacturing, organisation, consultancy
- The interface of manufacturing IMPs at a hospital pharmacy and the daily work
- Investigator-Initiated Trials (IITs)
- FAQs: things you need to consider
- Challenges and problem solving
International Contracts and Agreements in the Management of Clinical Trials

- Applicable law and jurisdiction
- Representations and warranties
- Indemnification and liability
- Frequently asked questions

A last Case Study - how things can go wrong
- How would you have reacted?

Speakers

BRIGITTE BASTYNS, Janssen Pharmaceutica NV (part of Johnson & Johnson), Belgium
Brigitte Bastyns is Manager QA of the Clinical Supply Chain and delegate QP. She is releasing IMPs for J&J sponsored clinical trials globally. In her role, she is also first point of GMP contact for GCP issues, escalations, inspections and process improvements.

RITA HATTEMER-APOSTEL, Verdandi AG, Switzerland
Rita Hattemer-Apostel is founder and CEO of Verdandi AG, an independent Quality Management Consultancy for GCP/QA. She has worked in Pharma and CRO industry and has many years of clinical QA experience. She has been President of SPAQA, the Swiss Professional Association of Quality Assurance and Editor-in-Chief of the Quality Assurance Journal.

ANDREAS JUNGK, Lawfirm Jungk, Germany
Andreas Jungk worked as an attorney-at-law at a German-French law office focusing on civil law, international sale and purchase contracts and arbitration. In 1998 he founded his own law office focusing on medicines law, medical devices law and contracts in the field of clinical research.

DR ANNE LEWERENZ, GMP/GDP/GCP Inspector, Landesdirektion Sachsen (Local Authority), Leipzig, Germany
Dr Lewerenz is GMP, GDP and GCP Inspector at the Local Inspectorate in Leipzig, Germany. Before that, she held the positions of Clinical Research Associate at a Contract Research Organization specialized in oncological clinical trials located in Germany and Scientific Associate Quality Control/CMC at a mid-sized pharmaceutical company in Germany. She is a member of the Expert Circle EFG 05 “Clinical Trials” of the Central Authority of the Laender for Health Protection with regard to Medicinal Products and Medical Devices (ZLG).

DR CLAUDIO LORCK, AbbVie Deutschland GmbH, Germany
Claudio Lorck is QP Lead for Clinical Product Supply EU. Before that he was Head of the Business Unit ‘Clinical Trial Materials’ and Qualified Person (QP) at Temmler. He was also working in Pharmaceutical Development, as Quality Control Manager, Quality Manager R&D, QP for IMPs and Head of Clinical Trial Materials at various pharmaceutical companies.

DR ANDREAS SCHWINN, Roche Pharma AG, Germany
Dr Andreas Schwinn is Qualified Person for IMP Release and Head of the Release Preparation Group. Before that he was Director Clinical Supplies and QP at Nuvisan Pharma Services, where he has developed a group to provide Clinical Packaging, Manufacturing and Pharmaceutical Development Services for the Pharmaceutical Industry.

DR LENKA TAYLOR, Pharmacy of the University Hospital Heidelberg, Germany
Dr Lenka Taylor is a Pharmacist, working at the Clinical Trial Department within the Pharmacy of the University Hospital Heidelberg. She is managing clinical trials within InPhaSol, the production unit of the University Hospital, as well as commercial clinical studies. She is also lecturer at the University of Freiburg (Pharmacy).
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.

What are The ECA Foundation and the ECA Academy?
The European Compliance Academy Foundation (ECA Foundation) is an independent professional organisation chaired by a Scientific Advisory Board with members from the pharmaceutical industry and regulatory authorities. The ECA Foundation’s goal is to support the Pharmaceutical Industry and Regulators to move towards a harmonised set of GMP and regulatory guidelines by providing information and interpretation of new or updated guidances. The ECA Academy offers professional basic and advanced education (training) programmes. All services offered by the ECA Academy and with regard to ECA Academy Memberships are solely managed by Concept Heidelberg (a leading European training and information services provider). The ECA Foundation is conceptual sponsor of the ECA Academy.

How Do You Become a Member of ECA?
By participating in one of the ECA Academy Conferences or Courses you will automatically become a ECA Academy Individual Member for two years - free of charge. More information about ECA Academy can be obtained on the Website http://www.gmp-compliance.org

What Are the Benefits of ECA?
During the membership, you enjoy

- free access to the members’ area where you always find the latest update of the "GMP Guideline Manager" online version – allowing you to access a GMP tree with guidelines sorted by topics or by authority. It lets you find relevant guidelines quick and easy. And as member you can also get to this detailed tree with the GMP WebApp on your smartphone or tablet PC.

- a 200,- Euro rebate for any ECA course and conference, plus the opportunity to complete the GMP Certification Programme with an internationally recognised certificate.

GMP/GDP Certification Programme

This seminar is recognised within the GMP Certification Programme Module "Pharmaceutical Development Manager". By attending selected seminars, the participant can acquire an additional certificate. We offer the following certification 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
- ECA GMP Auditor
- ECA GDP Compliance Manager
- ECA Packaging Manager
- ECA Data Integrity 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.
Date
Tuesday, 21 November 2017, 9.30 h – 17.30 h
(Relaxation and social networking 18.00 h – 21.00 h)
Wednesday, 22 November 2017, 8.30 h – 17.30 h
Thursday, 23 November 2017, 8.30 h – 15.30 h

Venue
Steigenberger Hotel Berlin
Los-Angeles-Platz 1
10789 Berlin, Germany
Phone +49 (0)30 2127 - 0
Fax +49 (0)30 2127 - 117
Email berlin@steigenberger.de

Fees (per delegate plus VAT)
- ECA Members € 1,790
- EQPA Members € 1,790
- APIC Members € 1,890
- EU GMP Inspectorates € 1,995
- Non-ECA Members € 1,990

The conference fee is payable in advance. The registration fee will be refunded in case of cancellation or non-appearance. VAT is reclaimable.

Accommodation
CONCEPT HEIDELBERG 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 conference. Please use this form for your room reservation to receive the specially negotiated rate for the duration of your stay. 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.

Organisation and Contact
ECA has entrusted Concept Heidelberg with the organisation of this event.

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

For questions regarding content:
Dr Andrea Kühn-Hebecker (Operations Director) at +49-62 21/84 44 35, or per e-mail at kuehn@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc.:
Mr Niklaus Thiel (Organisation Manager) at +49-62 21/84 44 43, or per e-mail at thiel@concept-heidelberg.de.

Reservation Form (Please complete in full)

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Title, first name, surname
Company
Department

Important: Please indicate your company’s VAT ID Number
Purchase Order Number, if applicable

Street / P.O. Box
City Zip Code
Country
Phone / Fax
E-Mail (Please fill in)

General terms and conditions
1. We are happy to welcome a substitute colleague at any time.
2. If you can attend the conference you have two options:
   1. You have to cancel the event immediately. 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)!
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   3. This is a binding registration and above mentioned cancellation fee will apply. If you cancel the event within 10 days after receipt of invoice and cancellation fee, a full refund of fees paid will be made.

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). 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.

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