

GMP meets GCP

Management, Supply and Quality Assurance of Clinical Trials

15 – 17 October 2019, Hamburg, Germany

SPEAKERS



DR GUNDULA BORN



INGE DE MEYER
Janssen Pharmaceutica NV



SILJA DU MONT
GCP/GDP Inspector



RITA HATTEMER-APOSTEL
Verdandi AG



DR CLAUDIO LORCK
AbbVie



DR ANDREAS SCHWINN
Roche Pharma



DR LENKA TAYLOR
University Hospital of Heidelberg

Update on Changes in the Regulatory Landscape of Clinical Trials!

HIGHLIGHTS:

Rules and Regulations	<ul style="list-style-type: none"> - Applicable legislation and GMP/GCP interfaces - Duties and responsibilities - Typical inspection findings
Supply Management	<ul style="list-style-type: none"> - Packaging, labelling, distribution - Shelf-life extensions - Handling of comparators - GMP requirements at the investigational site - Trials outside the EU
Study Management	<ul style="list-style-type: none"> - Key tasks and responsibilities - The role of the hospital pharmacy - IMP-related documentation
The Role of the QP in Clinical Trials	<ul style="list-style-type: none"> - When does the QP responsibility end? - Oversight of the supply chain
International Contracts and Agreements	
Workshops and Case Studies	

Co-sponsored by
European QP Association



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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. Especially, in regard of trials performed in UK after the Brexit.

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

Interfaces between GMP and GCP

- Clinical trials Phase I – III, Investigator-Initiated Trials and Pre-Approval Access to IMPs

Changes in the Regulatory Landscape of Clinical Trials

- Comparison of Directive 2004/93/EC and Commission Delegated Regulation 2017/1569
- GMP Changes
- Current status of the implementation progress of EMA's Portal and Data base

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

Interface between GMP and GCP

- Challenges in the initiation and conduct of *Compassionate Use*
 - Single-patient
 - Multi-patient (cohorts)
- Who is responsible in regard of GMP?
- Who is responsible in regard of GCP?

GCP/GMP Inspections

- The inspection and monitoring process
- Typical and recurrent compliance issues (regarding IMPs)
- Typical issues at the interfaces
- Inspections in Europe and beyond

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

Contracts and Agreements in the Management of Clinical Trials

- Applicable law and jurisdiction
- Contractual partners and QP participation
- Contract concepts
- Typical building blocks

A last Case Study - how things can go wrong

- How would you have reacted?

Speakers

DR GUNDULA BORN, Germany



Dr Gundula Born is a pharmacist and Qualified Person (QP), with a more than 20 years track record in the pharmaceutical industry. She has filled roles in quality control and quality assurance. Her QP responsibilities cover both commercial and investigational medicinal products.

INGE DE MEYER, Janssen Pharmaceutica NV (part of Johnson & Johnson), Belgium



Inge De Meyer 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 contact for New Product Introduction and concomitant release activities.

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.

SILJA DU MONT, GDP/GCP Inspector, Germany



Since 2010 Silja du Mont is working as GCP/GDP Inspector for medicinal products / medical devices at the district authority of Freiburg (Regierungspräsidium Freiburg). She is Head of the German GCP Inspectors Expert Group at ZLG, European Expert GCP IWG EMA and also responsible for Pharmacy Surveillance.

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).

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

Tuesday, 15 October 2019, 9.00 h – 17.30 h
(Registration and coffee 8.30 h – 9.00 h)
Wednesday, 16 October 2019, 8.30 h – 17.30 h
Thursday, 17 October 2019, 8.30 h – 15.30 h

Venue

Barcelo Hamburg
Ferdinandstr. 15
20095 Hamburg, Germany
Tel. +49 (0) 40 22 63 62 0
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hamburg@barcelo.com

Fees (per delegate plus VAT)

ECA Members € 1,790
EQPA Members € 1,790
APIC Members € 1,890
Non-ECA Members € 1,990
EU GMP Inspectorates € 995

The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on all three days and all refreshments. 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/POG when you have registered for the conference. 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
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D-69007 Heidelberg, Germany
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For questions regarding content please contact:

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. please contact:

Mr Niklaus Thiel (Organisation Manager) at
+49-62 21/84 44 43, or per e-mail at
thiel@concept-heidelberg.de.

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

Reservation Form (Please complete in full)

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Mr Ms

Title, first name, surname

Company

Department

Important: Please indicate your company's VAT ID Number

Purchase Order Number, if applicable

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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 %
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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)

German law shall apply. Court of jurisdiction is Heidelberg.

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.