ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Pharmaceutical Development Manager

Speakers


Inge De Meyer
Janssen Pharmaceutica NV


Rita Hattemer-Apostel
Verdandi AG


Dr Gundula Born


Mandy Budwal-Jagait
Senior GCP Inspector,
MHRA (invited)


Dr Claudio Lorck
AbbVie


Sandra Blim
AbbVie


Dr Lenka Taylor
University Hospital
of Heidelberg

Co-sponsored by the
European QP Association

ECA QP ASSOCIATION
An ECA Foundation Interest Group

GMP meets GCP

Management, Supply and Quality Assurance of Clinical Trials

3 – 5 November 2020, Barcelona, Spain

Highlights

- Rules and Regulations
  - Applicable legislation and GMP/GCP interfaces
  - Duties and responsibilities
  - Data Integrity
  - 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

Update on Changes in the Regulatory Landscape of Clinical Trials!

Objective

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 course 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.

Programme

Case Studies

- How things can go wrong

Interface 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 relevant Changes (including ICH E6(R2))
- 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

Data (and Study) Integrity in Clinical Trials

- Responsibilities of investigator, sponsor and monitor
- Vendors and contractors of electronic systems: Considerations and pitfalls
- Why do we need an Audit Trail (Review)?
- Inspection findings

GCP/GMP Inspections

- The inspection and monitoring process
- Typical and recurrent compliance issues
- 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 sites
- 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

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 18+ years of clinical QA experience. She has been President of SPAQA, the Swiss Professional Association of Quality Assurance (2003-2009) and Editor-in-Chief of the Quality Assurance Journal (2001-2011).

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.

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 started his career in Pharmaceutical Development, and became Quality Control Manager at Klinge Pharma. Later he was Quality Manager R&D and QP for IMPs at Fujisawa and Head of Clinical Trial Materials and QP at Astellas.

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 in Heidelberg, as well as commercial clinical studies. Within InPhaSol, Dr Taylor is appointed Head of Quality Control. She is also lecturer at the University of Freiburg (Pharmacy).

Mandy Budwal-Jagait (invited), Senior GCP Inspector, MHRA, UK

Mandy Budwal-Jagait is a Senior GCP inspector with the MHRA (Medicines and Healthcare products Regulatory Agency) and joined the Agency in April 2014. Mandy conducts a variety of GCP inspections in commercial and non-commercial organizations. Prior to joining the Agency, Mandy has held Clinical Research and Quality Assurance roles in the Pharmaceutical Industry.

Sandra Blim, AbbVie Deutschland GmbH, Germany

Sandra Blim studied pharmacy at the Johannes-Gutenberg-University in Mainz and joined AbbVie Deutschland GmbH in 2012 as Qualified Person (QP) Trainee in R&D Quality Assurance. From 2014 to 2018 Sandra was responsible as QP in R&D QA. Since 2018 she is Head of Production for IMP Packaging/Labelling.

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GERMANY

Reservation Form (Please complete in full)

GMP meets GCP, 3 – 5 November 2020, Barcelona, Spain

Title, first name, surname

Department | Company

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

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:
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- Cancellation until 1 weeks prior to the conference 50 %
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Terms of payment: Payable without deductions within 10 days after receipt of invoice.
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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.

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Date

Tuesday, 3 November 2020, 9.00 h – 17.30 h.
(Registration and coffee 8.30 h – 9.00 h).
Wednesday, 4 November 2020, 8.30 h – 17.30 h.
Thursday, 5 November 2020, 8.30 h – 15.30 h.

Venue

Barcelo Sants Hotel
Pl. Països Catalans, s/n
08014 Barcelona, Spain
Phone +34(0)93 503 53 00
Email sants@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.

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.

Accommodation

CONCEPT HEIDELBERG 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 course. 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.
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WA/27012020