ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Pharmaceutical Development Manager

Speakers


Sandra Blim
AbbVie


Dr Gundula Born
Sanofi-Aventis


Inge De Meyer
J&J Innovative Medicine


Rita Hattemer-Apostel
Verdandi


Ian Holloway
former GMP/GCP/GDP Inspector at MHRA


Patryk Jegorow
Takeda


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

Live Online Training from 27–29 February 2024

Get the Updates on the New Clinical Trials Regulation 536/2014!

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
- Case Studies

Objectives

During this Live Online Training 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 regulations will lead to satisfactory results. **GMP and GCP requirements need to be considered and understood** from all parties involved.

Since 31 January 2022, the **Clinical Trials Regulation** 536/2014 (CTR) is applicable. This is followed by a consecutive transition period of three years, during which both the contents of the CTR and the previous legislation on clinical trials will apply.

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 Live Online Training Course has been designed by the ECA to enhance and broaden your knowledge and to **consolidate the various aspects** which need to be considered 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.

Participants' comments from the March 2023 and March 2022 Live Online Training Courses

"Very informative with lots of information. Lots of food for thought. I enjoyed participating in the questions. Good discussion was promoted."
Dr Jennifer Bell, Ekrity Ltd., Ireland (March 2023)

"Very professional set up. Different aspects in IMP were very good."
Esmee Kester, Ecraid, The Netherlands (March 2023)

"Case studies make it really interesting and interactive."
Dr Annelies Jorritsma-Smit, Celgene Distribution B.V. - a Bristol Myers Squibb Company, The Netherlands (March 2022)

"This dynamic session on case studies was really very informative. Thanks."
Dr Florence Philippoz, Switzerland (March 2022)

Programme Day 1

A first Case Study: How things can go wrong

Interface between GMP and GCP

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

Legislation related to Investigational Medicinal Products (IMPs)

- Legislation impacting IMP QPs
- New & upcoming regulations and guidance
- Other topics – within and outside the EU

Q&A Session 1

Packaging and Labelling of IMPs

- Blinding aspects in packaging
- Packaging technology
- Unblinding risks during packaging
- Just-in-time labelling
- Relabeling
- Reconstitution

Distribution of IMP Supplies

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

Challenges from a CTS Coordinators Perspective

- Supply Chain Planning
- Comparators: selection, procurement, pedigree
- Blinding
- NIMPs
- Shelf-life assignment
- Outsourcing

Q&A Session 2

Programme Day 2

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

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

Case Study:
QP Tasks and Challenges in Clinical Trials

Q&A Session 3

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

Contracts and Agreements in the Management of Clinical Trials

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

Q&A Session 4

Programme Day 3

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

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

Case Study on GCP Aspects:
Handling IMPs at the Investigator's Site

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

Q&A Session 5

Speakers

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 (Manager Clinical Packaging / Clinical Supply Management).

Dr Gundula Born, Sanofi-Aventis, Germany
Dr Gundula Born is a pharmacist and Qualified Person (QP), with a more than 25 years track record in the pharmaceutical industry. She has filled roles in quality control and quality assurance. Her QP experience covers both commercial and investigational medicinal products. Most recently, she is working as a QP for Sanofi-Aventis since May 2019.

Inge De Meyer, J&J Innovative Medicine, 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 since 2001. She assists clients in developing QM systems and conducts audits/mock inspections on a global level. She has worked in Pharma and CRO industry since 1991 and in QA since 1994. 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).

Ian Holloway, former GMP/GDP/GCP Inspector at MHRA, UK
Ian Holloway was GMP/GDP/GCP inspector at the MHRA. Before that, he was Head of the Defective Medicines Report Centre at MHRA.

Patryk Jegorow, Takeda, Ireland
Patryk Jegorow is Qualified Person and Head of Quality Compliance and Systems, Biologics Operating Unit (Global Quality), at Takeda.

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).

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Reservation Form (Please complete in full)

GMP meets GCP
Live Online Training from 27-29 February 2024

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:
- Cancellation until 4 weeks prior to the conference 10 %,
- Cancellation until 3 weeks prior to the conference 25 %,
- Cancellation until 2 weeks prior to the conference 50 %,
- Cancellation within 2 weeks 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 July 2022).
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 https://www.gmp-compliance.org/privacy-policy). 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.

Date of the Live Online Training

Tuesday, 27 February 2024, 9.00 h – 17.00 h
Wednesday, 28 February 2024, 9.00 h – 17.00 h
Thursday, 29 February 2024, 9.00 h – 13.00 h

All times mentioned are CET.

Technical Requirements

We use Webex for our live online training courses and webinars. At https://www.gmp-compliance.org/training/online-training-technical-information you will find all the information you need to participate in our trainings and you can check if your system meets the necessary requirements to participate. If the installation of browser extensions is not possible due to your rights in the IT system, please contact your IT department. Webex is a standard nowadays and the necessary installation is fast and easy.

Fees (per delegate, plus VAT)

ECA Members € 2,090
EQPA Members: € 2,090
APIC Members € 2,190
Non-ECA Members € 2,290
EU GMP Inspectorates € 1,145

The conference fee is payable in advance after receipt of invoice.

Registration

Via the attached reservation form, by e-mail or by fax message. Or you register online at www.gmp-compliance.org.

Presentations/Certificate

The presentations will be made available to you prior to the Live Online Training as PDF files. After the event, you will automatically receive your certificate of participation.

Conference language

The official conference language will be English.

You cannot attend the Live Event?

We also offer many of the training courses and conferences as recordings. This means that you can watch the videos of the event „on demand" – whenever it suits you – on our web server. It is quite uncomplicated and doesn't require any software – you simply watch the video on your browser. You can find all recorded events at www.gmp-compliance.org/recordings.

Organisation and Contact

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