ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Pharmaceutical Development Manager

Speakers


Sandra Blim
AbbVie, Germany


Dr Gundula Born
Sanofi-Aventis, Germany


Inge De Meyer
Janssen, Belgium


Silja Du Mont
GCP/GDP Inspector, Germany


Rita Hattemer-Apostel
Verdandi, Switzerland


Patryk Jegorow
Takeda, Ireland


Dr Lenka Taylor
University Hospital of Heidelberg, Germany

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 29–31 March 2022

New Clinical Trials Regulation 536/2014 applies as of 31 January 2022 - Get the Updates!

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 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.

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

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 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 Day 1

Provisional timetable, the actual schedule may vary depending on the situation

09.00 - 09.15 h Welcome/Introduction

09.15 - 09.45 h **A first Case Study - How things can go wrong**

09.45 - 10.15 h Interface between GMP and GCP

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

10.15 - 10.30 h Break

10.30 - 11.30 h Legislation related to Investigational Medicinal Products (IMPs)

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

11.30 - 12.00 h **Q&A Session 1**

12.00 - 13.00 h Break

13.00 - 14.00 h Packaging and Labelling of IMPs

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

14.00 - 15.00 h Distribution of IMP Supplies

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

15.00 - 15.15 h Break

15.15 - 16.15 h Challenges from a CTS Coordinators Perspective

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

16.15 - 17.00 h **Q&A Session 2**

Programme Day 2

09.00 - 10.00 h GCP/GMP Inspections

- The inspection and monitoring process
- Typical and recurrent compliance issues
- Typical issues at the interfaces
- Inspections findings

10.00 - 10.45 h 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

10.45 - 11.00 h Break

11.00 - 12.00 h **Case Study: QP Tasks and Challenges in Clinical Trials**

12.00 - 12.45 h **Q&A Session 3**

12.45 - 13.45 h Break

13.45 - 15.15 h 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

15.15 - 15.30 h Break

15.30 - 16.30 h Contracts and Agreements in the Management of Clinical Trials

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

16.30 - 17.00 h **Q&A Session 4**

Programme Day 3

08.30 - 09.15 h 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

09.15 - 10.15 h 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

10.15 - 10.30 h Break

10.30 - 11.30 h **Case Study on GCP Aspects: Handling IMPs at the Investigator's Site**

11.30 - 12.00 h **A last Case Study: How things can go wrong**
- How would you have reacted?

12.00 - 12.30 h **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, 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.

Silja Du Mont, GCP/GDP 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.

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).

Patryk Jegorow, Takeda, Ireland
Patryk Jegorow is Qualified Person and Head of Quality Strategy and Business Operations / Biologics, Product Quality and Incident Management in the Global Quality Unit 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 29-31 March 2022

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

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German law shall apply. Court of jurisdiction is Heidelberg.

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Date of the Live Online Training

Tuesday, 29 March 2022, 9.00 h – 17.00 h
Wednesday, 30 March 2022, 9.00 h – 17.00 h
Thursday, 31 March 2022, 8.30 h – 12.30 h

All times mentioned are CEST.

Technical Requirements

For our Live Online Training Courses and Webinars, we use Cisco WebEx, one of the leading suppliers of online meetings. At http://www.webex.com/test-meeting.html you can check if your system meets the necessary requirements for the participation at a WebEx meeting and at the same time install the necessary plug-in. Please just enter your name and email address for the test. If the installation is not possible because of your rights for the computer 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 € 1,990
EQPA Members: € 1,990
APIC Members € 2,090
Non-ECA Members € 2,190
EU GMP Inspectorates € 1,095

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.

Ordering Recordings

Independent from the Live Online Training Courses, you can also order recordings of selected Live Online Training Courses at the same conditions – at www.gmp-compliance.org/recordings. These recordings will be provided on our media server. All you need to watch it is an Internet browser – no additional software.

Organisation and Contact

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

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