

Speakers



Sandra Blim
AbbVie, Germany



Dr Gundula Born
Sanofi-Aventis,
Germany



Inge De Meyer
Janssen, Belgium



Rita Hattemer-Apostel
Verdandi, Switzerland



Ian Holloway
former GMP/GCP/GDP
Inspector at MHRA,UK



Patryk Jegorow
Takeda, Ireland



Dr Lenka Taylor
University Hospital
of Heidelberg, Germany

GMP meets GCP

Management, Supply and Quality Assurance of Clinical Trials



Live Online Training from 07-09 March 2023



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

Co-sponsored by the
European QP Association



An ECA Foundation Interest Group

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.

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.

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 2022 Live Online Training Course

"I really enjoyed discussions about these cases."
Cécile Cler, Ceva Sante Animale SA, France

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

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

"Very interesting cases."
Dr Fabio Carchedi, Italy

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, 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 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 7-9 March 2023

Title, first name, surname

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Date of the Live Online Training

Tuesday, 7 March 2023, 9.00 h – 17.00 h

Wednesday, 8 March 2023, 9.00 h – 17.00 h

Thursday, 9 March 2023, 9.00 h – 13.00 h

All times mentioned are CET.

Technical Requirements

We use Webex Events 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 € 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.

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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