European GMPs and the Role of the Qualified Person (QP)

The Impact of EU Legislation on the Supply Chain

Live Online on 10-12 February 2025

Live Online with Q&A Sessions or as a Recording on demand

Speakers

David Cockburn
form. European Medicines Agency (EMA)

Dr Susanne Ding
Boehringer Ingelheim

Dr Rainer Gnibl
EU-GMP Inspectorate

Dr Ulrich Kissel
European QP Association

Highlights

- **Understand European GMPs**
  - EU GMPs you should know
  - Who will come and inspect/ audit?
  - Brexit Implications
- **The Role of the QP**
  - Batch Certification and Release for the EU
  - Duties and Responsibilities
- **Supply Chain**
  - Export and Import
  - Distribution in the EU
- **Clinical Trial Supplies (optional on day three)**
  - Revision of the EU Legislation
  - IMP Handling in Europe and the Role of the QP

A Live Online Conference organised by the European Compliance Academy ECA and the European QP Association

ECA Academy Your GMP/GDP Information Source

QP ASSOCIATION

Welcome

The Pharmaceutical Industry has become more global due to international collaborations, mergers and acquisitions and more complex supply chains require companies to have a greater understanding of pharmaceutical legislation throughout the world. This is becoming increasingly evident by the number of non-EU professionals contacting the European Compliance Academy and the Qualified Persons Association asking for more and more detailed information about the European GMPs and the unique role and responsibility of the EU QP.

The ECA Academy and the European QP Association, recognising this need for further professional knowledge development, intend to support the pharmaceutical industry outside Europe in understanding the EU approach and legal framework in this respect. Therefore, the QP Association has set up the programme at hand on European GMP requirements and the role of the QP.

In light of the establishment of a Mutual Recognition Agreement between US and EU and the parallel move out of Great Britain from the EU, representatives from the authorities as well as QPs and well-known experts will talk about the current issues and share their point of view.

I would like to invite you to this unique opportunity, and I look forward to meeting you.

Best regards,
Dr Ulrich Kissel
Chairman of the European Qualified Person Association

Objectives

This event is designed by QPs and international Experts as a forum with focus on sharing information and experience and on discussing the critical areas of European GMPs and the QP's daily work.

Target Audience

The Conference has been designed for non-EU QA and QCU personnel, upper management functions and authority representatives who want to be informed about European GMPs and the duties and responsibilities of Qualified Persons.

Moderator

Wolfgang Schmitt, on behalf of the European QP Association

Programme Part 1:

Understand European GMPs 10/11 February 2025

The EU Pharmaceutical Legislation and the respective Inspection System

- EU legislation and relevant guidance documents (overview)
- The EU inspection system
- Non-compliance with EU-GMP and authority actions
- EU Manufacturing Authorisation & EU-GMP Certificate
- MRA: impact for industry
- Exchange on GMP-information between US and EU

Export and Import of Medical Products

- Annex 21 of the EU-GMP Guidelines
- Import of Medicinal Products and APIs into the European Union
- Which types of materials do fall under EU import legislation?
- Regulatory requirements for import
- Which documents are needed for import activities of medicinal products and APIs
- Regulatory procedure to get an import licence
- Procedure if a non-EU company imports to different EU Member States

The Role and Responsibilities of the QP

- Batch certification and release for the EU Market
- Directive 2001/83/EC; Article 49 – "conditions of qualification"
- Annex 16 of the EU-GMP Guidelines
- The role of the QP within the pharmaceutical quality System
- What the QP is responsible for
- The QP's margin of discretion when certifying batches with deviations
- Supply Chain oversight and supply chain diagram
- QP Declaration

Distribution in the EU

- GDP requirements
- Importers, brokers, local affiliates, pre-wholesalers, wholesalers, parallel import
- Serialisation
- Virtual companies

Brexit: Consequences for the pharmaceutical industry

- UK and EU Point of View
- The Northern Ireland Protocol
- Impact on the roles and responsibilities of the QP
- What companies outside Europe need to be aware of
- Examples of complications

When things go wrong

- Complaint and recall handing
- The QP and the QPPV
- When to contact the authorities

Programme Part 2:

Clinical Trial Supplies (optional)
12 February 2025

Clinical Trial Supplies: IMP Handling in Europe and the Role of the QP

- Current and future EU-GMP and QP requirements
- Certification and release of Investigational Medicinal Products (IMPs) for studies in the EU
- Specific aspects of IMP supply chains
- GMP-GCP Interface
- QP oversight and being a QP in a global environment

Question and Answer Sessions

When attending live online, a set of live Q&A Sessions will give you the possibility to interact with the speakers and get answers to your questions.

About the ECA

The **ECA Foundation** was set up to provide support to the Pharmaceutical Industry and Regulators to promote the move towards a harmonised set of GMP and regulatory guidelines by providing information and interpretation of new or updated guidance. the ECA Foundation comprises a number of so called interest and working groups. These groups focus on different GMP compliance aspects such as QP regulation, Validation, IT Compliance, Good Distribution Practice and other topics – and, e.g., provide good practice papers which are intended to help industry and authorities to implement GMP in an effective manner. In addition, the Foundation comprises the ECA Academy as its educational organisation.

The ECA Academy is the educational organisation established by the ECA Foundation. It develops and organises a wealth of international education courses, conferences and webinars around GMP and regulatory compliance, picking up emerging GMP challenges and currently discussed subjects (www.gmp-compliance.com)

As the Foundation does not employ own staff all services offered by the ECA Academy and with regard to ECA Academy Memberships are solely managed by Concept Heidelberg, a leading professional European training and information services provider in the pharmaceutical industry environment.

About the European QP Association

The European Qualified Person (QP) Association was founded in July 2006 by the European Compliance Academy's (ECA) Advisory Board Members. With this unique association the ECA wants to provide QPs in Europe with a platform allowing them to exchange their experience, discuss the latest regulatory requirements, to identify and address difficulties and challenges and to support a harmonised European approach. www.qp-association.eu

Speakers

David Cockburn, form. EMA, U.K.

David Cockburn was Principal Scientific Administrator at the European Medicines Agency and Chair of the EMA GMP/GDP Inspectors Working Group (IWG). In his role he was also EU technical lead for the EU-US Mutual Reliance Initiative. He is also member of the Board of Directors of the European Qualified Person Association.

Dr Susanne Ding
Boehringer Ingelheim, Germany

As Qualified Person for IMPs at Boehringer Ingelheim Pharma, Susanne Ding is in charge of certifying clinic trial samples for the use in clinical studies worldwide since 2005. Prior to that she worked in Analytical Development including the responsibility as Head of Quality Control. Susanne Ding is chair of the EQPA IMP Working Group and member of the Board of Directors of the European Qualified Person Association.

Dr Rainer Gnibl
Government of Upper Bavaria, Germany

Dr Rainer Gnibl is EU-GMP inspector in Germany and performs GMP inspections worldwide also on behalf of the European Medicines Agency (EMA). He is also member of the Board of Directors of the European Qualified Person Association.

Dr Ulrich Kissel, European QP Association

Ulrich Kissel is Qualified Person and Chair of the Board of Directors of the European Qualified Person Association. He works as a GMP consultant and contract QP to the Pharmaceutical Industry. Previous to his current role he held leadership positions in Quality and Supply Chain and served for many years as QP for Roche.


CERTIFICATE

Your Benefits
Internationally Acknowledged Certificate from ECA Academy

The EU GMP Guide requires: „... All personnel should be aware of the principles of Good Manufacturing Practice that affect them and receive initial and continuing training,...". This is why you receive an acknowledged participant certificate, which lists the contents of the seminar in detail and with which you document your training.

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GERMANY

Reservation Form (Please complete in full and tick in the box)

☐ European GMPs and the Role of the QP | 10/11 February 2025
☐ European GMPs and the Role of the QP | 10/11 February 2025 + course „Clinical Trial Supplies“ on 12 February 2025
☐ Course „Clinical Trial Supplies“ on 12 February 2025

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 %.

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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 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.

Date of the Live Online Training
Monday, 10 February 2025, 14.00 – 19.00h CET
Tuesday, 11 February 2025, 14.00 – 18.00h CET
Optional Day 3 on IMPs: Wednesday, 12 February 2025, 14.00 – 18.00h CET

Technical Requirements
We use Webex for our live online training courses and webinars. At www.gmp-compliance.org/training/online-training-technical-information you will find all the information you need to participate in our events 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)

European GMPs and the Role of the Qualified Person (QP)
10/11 February 2025:
QP Association Members EUR 1,390.-
ECA Members EUR 1,390.-
Non-ECA/ Non-QP Association Members EUR 1,590.-
Optional Day three on IMPs only – 12 February 2025:
QP Association Members EUR 590.-
ECA Members EUR 590.-
Non-ECA Members EUR 790.-
Save money when booking all three days:
QP Association Members EUR 1,790
ECA Members EUR 1,790.-
Non-ECA Members EUR 1,990.-

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

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.

Registration
Via the attached reservation form, by e-mail or by fax - or search and register directly at www.gmp-compliance.org under the numbers 21691, 21692 or 21693. To avoid incorrect information, please give us the exact address and full name of the participant.

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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