# Qualified Person Education Course

## Module A

## Understand the Implications of becoming a QP

12/13 November 2024, Live Online

**Speakers:**

**Julia Gudd**
Ministry of Justice and Consumer Protection, Hamburg, Germany

**Dr Ulrich Kissel**
European QP Association

**Savvas Koulouridas**
Fagron BV, The Netherlands

**Aidan Madden**
FivePharma, Ireland

**Sue Mann**
Qualified Person Assessor, U.K.

**Lance Smallshaw**
UCB, Belgium

Dr Ulrich Kissel

Dear Colleagues,

The European Qualified Person Association (EQPA) has developed two Education Course Modules for new, trainee and practising Qualified Persons to address general compulsory and regulatory issues. **This Module A** has been compiled by the EQPA Board of Directors to provide a general idea of the special tasks and responsibilities of a QP, but also to discuss and convey possible solutions to problems addressed in case studies and workshops. How to master the QP role in practice including interfaces and interactions is a central topic of **Module B**.
Further impacts of the latest developments, specific tasks and further discussions will be part of the **annual QP Forum** of the European Qualified Person Association.

Best regards,

Ulrich Kissel
Chairman of the European Qualified Person Association

## Objectives

Broaden and intensify your knowledge of the Qualified Person's duties and responsibilities. Experts from the EQPA Board of Directors, pharmaceutical industry and regulatory authority will share their experience on important issues of the QP's daily business and will give first-hand information on current and future expectations.

## Background

Over the last years the role and responsibilities of the Qualified Persons have been increasing considerably. As a key person in the company, the QP has to consider many issues and has to take up the challenges within its areas of responsibilities. Additionally, as laid out in Article 49 of the European Directive 2001/83/EC, the QP needs to be highly qualified and experienced. This education course is one important part to help the QP be on top of current developments in GMP and regulatory requirements.

## Target Audience

New and future Qualified Persons, QPs who are looking for ongoing training and personnel who want to get a detailed overview of the role and responsibilities of a QP.

## Moderator

Wolfgang Schmitt, on behalf of the EQPA

## Programme

**The Legal and Professional Duties of the Qualified Person**
- The Qualified Person within the EU legislation and regulation framework
- Professional tasks, duties and responsibilities
- Expectations of an EU GMP Inspector

**Update on European Requirements**
- EU GMP Guide Chapters
- EU GMP Guide Annexes
- Other important News
- What the QP needs to be aware of

**Delegation of Duties and Responsibilities**
- Possible scenarios according to Annex 16
- Mutual Recognition Agreements (MRA)
- Documentation review issues
- The QP in the quality system

**Case Studies: Certification by a QP and Batch Release (to certify or not)**
- Batch certification: degrees of freedom and limits
- Batch deviations and QP Certification
- **Examples**: To certify or not, that's the question

**Case Study: Deviations during the Manufacture of an API – What Actions should you take as the responsible QP?**

**What the QP needs to know regarding the Supply Chain (from Supplier Qualification to GDP)**
- The QP: ultimate responsibility for the supply-chain of a drug product?
  - What is the expected scope of supply chain oversight
  - Supply chain integrity
  - Active Pharmaceutical Ingredient, Excipients, Bulk and Finished Product
  - Shipping under quarantine, ship to label claim, importation testing
- The role of the QP in supplier qualification and auditing
- Written confirmation and QP Declaration
- GMP meets GDP: where does the responsibility end?
- The QP's involvement in the recall process

**How the QP fits into the Quality Systems**

- How much involvement is needed in systems like:
  - Product Quality Review
  - Inspection Management
  - Batch Record Review
  - CAPA
  - Change Control
  - Validation
  - Complaints and recalls

**Liability and Indemnification**

- Liability and indemnification of QPs
- Role and responsibility of head of production and head of quality control (when things go wrong)
- Role and responsibility of upper management (when things go wrong)
- Delimitation of responsibilities with QPs in the same company
- Delimitation of responsibilities with QPs at a contractor

**What the QP needs to know about Pharmacopoeias**

- The world of different Pharmacopoeias
- Pharmacopoeias are more than just Monographs
- How to deal with different methods

**Case Studies: What the QP needs to know about OOS/OOT**

- Involvement of the QP
- Role and responsibility of the Head of Quality Control
- Responsibility of the QP

**Question and Answer Sessions**

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

## Participants' Comments on the last Live Online QP Education Courses

*"Great speakers, up to date, with practical cases assessed"*
*Dr Marion Chomet, NRG Nuclear Research & Consultancy Group, The Netherlands*

*"Good to understand, many examples, not only theory"*
*Dr Anke Cwiklicki, Klosterfrau Berlin GmbH, Germany*

*"Very interesting topics, well explained, interaction with questions is superb"*
*Charlotte Van den Berk, Sharp, Belgium*

*"Well prepared presentations and good presenters. I also like the way of asking questions"*
*Alexandra Weidler, Hookipa Biotech GmbH, Austria*

*„Everything interesting"*
*Sonia Vanheeghe, Winmed, Denmark*

## Speakers

**Julia Gudd**
**GMP and GDP Inspector, Ministry of Justice and Consumer Protection, Hamburg, Germany**
In addition to national and international inspections of pharmaceutical and API manufacturers, Julia Gudd's tasks also include ministry work in the area of pharmaceutical and pharmacy law.

**Dr Ulrich Kissel**
**European QP Association**
Ulrich Kissel is Qualified Person and Chairman of the Board of Directors of the European Qualified Person Association (EQPA). 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.

**Savvas Koulouridas**
**Fagron BV, The Netherlands**
Savvas Koulouridas is Global Innovations Director. He is a lawyer in profession and has also worked as a consultant on pharmaceutical law (GMP regulations and Pharmaceutical Contracts).

**Aidan Madden**
**FivePharma, Ireland**
Aidan Madden is CEO of FivePharma, a Quality Services Company founded in 2003. Aidan held senior quality positions in Wyeth Pharmaceuticals, Baxter Healthcare and Fort Dodge Laboratories.

**Sue Mann**
**Qualified Person Assessor, U.K.**
Sue Mann is a Qualified Person and a QP Assessor in the U.K. working on behalf of the MHRA, representing the Royal Pharmaceutical Society. She was Vice President of International Quality Assurance at Shire Pharmaceuticals before founding her company Sue Mann Consultancy Ltd (SMC) in 2009.

**Lance Smallshaw**
**UCB, Belgium**
Lance Smallshaw is Head of Compendial Affairs, Global Knowledge and Analytical – Industrialization and Network Programs Team. He is also Co-Chair of the Executive Board of ECA and Associate Director and European CMC Strategy Committee member for CaSSS Biopharm.

If the bill-to-address deviates from the specification to the right, please fill out here:

CONCEPT HEIDELBERG
P.O. Box 10 17 64
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69007 Heidelberg
Germany

## Reservation Form (Please complete in full)

### Qualified Person Education Course – Understand the Implications of Working as a QP
12/13 November 2024, Live Online

Title, first name, surname

Company Department

**Important: Please indicate your company's VAT ID Number and your PO Number**

Street / P.O. Box

City Zip Code Country

Phone/Fax

Email ( 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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**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.

## 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.

## Who can become member of the QP Association?

Only registered Qualified Persons in Europe can become regular members of the QP Association. Details about the registration of the QP will be required in the application form. Interested persons who want to become a Qualified Person can apply for an associate membership.

## How to become member of the QP Association?

To become member please fill in the membership application form available at **www.qp-association.eu.**
Membership is free.

## Organisation/ Contact

EQPA has entrusted Concept Heidelberg with the organisation of this event.
CONCEPT HEIDELBERG | P.O. Box 10 17 64 | D-69007 Heidelberg | Germany
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**For questions regarding content:**
Wolfgang Schmitt (Director Operations) at +49 (0) 62 21 / 84 44 39,
or per e-mail at w.schmitt@concept-heidelberg.de
**For questions regarding organisation:**
Marion Grimm (Organisation Manager) at +49 (0) 62 21 / 84 44 18,
or per e-mail at marion.grimm@concept-heidelberg.de

## Conference language

The official conference language will be English.

## 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 message. Or you register online at www.gmp-compliance.org.

## Fees (per delegate plus VAT)

**QP Education Course**
QP Association Members € 1,690.-
ECA Members € 1,690.-
Non-ECA/ Non-QP Association Members € 1,890.-
EU GMP Inspectorates € 945.-
The conference fee is payable in advance after receipt of invoice.

## 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.

## Date

Tuesday, 12 November 2024, 9.00 – 17.45 h CET
Wednesday, 13 November 2024, 8.30 – 16.30 h CET