



# Qualified Person Education Course

## Speakers:

### Susanne Ding

Boehringer Ingelheim, Germany

### Dr Ulrich Kissel

European QP Association

### Savvas Koulouridas

Fagron BV, The Netherlands

### Aidan Madden

FivePharma, Ireland

### Sue Mann

Sue Mann Consultancy, U.K.

### Rico Schulze

GMP Inspectorate, Local  
Authorities, Germany

### Lance Smallshaw

UCB, Belgium

### Brenda Van Assche

Janssen, Belgium

## Understand the Implications of Working as a QP

21/22 March 2019, Prague, Czech Republic

With an optional pre-course Session:

“Investigational Medicinal Products (IMP) QP Education Course”  
on 20 March 2019

#### Participants' comments on the last QP Education Courses

*“Everything was splendid.”*  
Nicoleta Mindrut, Zentiva, Romania  
*“Very enjoyable and engaging.”*  
Jason Fagg, Leyden Delta B.V., The  
Netherlands

*„Everything, course, lecture, workshops  
were great.”*  
Nisha Thadathil, Sun Pharmaceutical  
Industries Europe B.V., The Netherlands

*“Thanks for great opportunity for improving  
my knowledge and change experience!  
Excellent Organization!”*  
Iryna Martynchyk, JSC Pharmaceuticals



Dr Ulrich Kissel

Dear Colleagues,

The European Qualified Person Association (EQPA) has developed this Education Course for new and future Qualified Persons to address general compulsory and regulatory issues. It 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. 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

# Programme QP Education Course

## 21/22 March 2019

### 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

#### Workshop on Case studies:

#### Certification by a QP and Batch Release - to certify or not, that's the Question

- Batch release: degrees of freedom and limits
- The QP's discretion as defined in Annex 16
- Case Studies

### What the QP needs to know about Elemental Impurities

- What guidance is available
- What does it mean for the QP
- From Risk Analysis to Batch Certification and Release

#### Workshop:

#### 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
  - Batch certification and release
  - Laboratory investigations

## 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

### Workshop:

#### 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

## Social Event

At the end of the first day of the course you are invited to take part in an evening program in Prague (tour and Dinner). This is an excellent opportunity to share your experiences with the speakers and colleagues from other companies in a relaxed atmosphere.



## Speakers QP Education Course



### 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 Sue Mann Consultancy, 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.



### Rico Schulze GMP Inspectorate, Local Authorities Dresden, Germany

Rico Schulze is a Pharmacist and holds a degree in Economics. Since 2003, he is GMP and GDP Inspector at the Local Inspectorate in Dresden and performs inspections worldwide. From 2008 to 2011 he was working at the Saxon State Ministry of Social affairs.



### Lance Smallshaw UCB, Belgium

Lance Smallshaw is Director of Analytical and Quality Competitive Intelligence at UCB Biopharma, working in the Corporate Analytical Sciences Team. He is also Co-Chair of the Executive Board of ECA and Associate Director and European CMC Strategy Committee member for CaSSS Biopharm.

# Pre-course Session: “Investigational Medicinal Products (IMP) QP Education Course” on 20 March 2019

## Objectives

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This pre-course session provides a detailed overview of the specific characteristics in IMP manufacturing a QP must know to certify IMP batches for the release for clinical trials.

## Background

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The manufacture of investigational medicinal products (IMPs), including labelling, packaging, testing and certification, is carried out in accordance with the applicable GMP regulations. However, this is not a routine process, since, among other things, manufacturing and packaging procedures might be different for each and every clinical trial. The Qualified Person (QP) must therefore take into account these particularities and the GMP/GCP interface.

## Target Audience

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New colleagues becoming IMP QPs, QPs looking for continuous training and personnel of CROs and “non-commercial” IMP organisations.

## Moderator

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Dr Susanne Ding

## Programme

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### General introduction

- Different clinical phases I to IV, focus on patient safety
- Undefined processes (manufacture, fit for purpose control strategy, etc.)
- Why use risk assessments & how to apply – vital core of a IMP quality system
- Diversity: IMP manufacturers, start-ups, academia...

### Specific legal requirements for IMPs

- Clinical Trial Regulation EU No. 536/2014 and the “old” Annex 13 and Directives 2001/20/EC and 2003/94/C
- The “new” ATMP regulation

### GMP meets clinical trials – Differences between IMPs and commercial Products

- Packaging & labeling
- Randomization
- Blinding / placebos
- Comparators
- NIMPs / AMPs
- Where to apply validation activities
- The Product Specification File (PSF)
- 3rd country manufacture of IMPs: import and the QP Declaration

### Registration

- IMPD, CTA, IND etc.
- Regulatory compliance and the two step release procedure

### GMP meets GCP

- Interaction with clinical sites
- Distribution
- IRT

## Speakers I

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### Dr Susanne Ding Boehringer Ingelheim, Germany

Susanne Ding is Qualified Person for IMPs at Boehringer Ingelheim, Member of the Board of Directors of the European Qualified Person Association (EQPA) and Chair of the IMP

Working Group within the EQPA.



### Sue Mann Sue Mann Consultancy, 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 Interna-

tional Quality Assurance at Shire Pharmaceuticals.



### Brenda Van Assche Janssen, Belgium

Brenda Van Assche is Director QA Clinical Supply Chain and Qualified Person for IMPs at Janssen. She is also a member of the IMP Working Group within the EQPA.

## About the European QP Association

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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?

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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?

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To become member please fill in the membership application form available at [www.qp-association.eu](http://www.qp-association.eu). Membership is free.


## What are the benefits of the membership?


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As a member of the European Qualified Person Association you can exchange your experience with other colleagues (e.g. by using the exclusive QP discussion forum), send comments on new Guidances and Directives to EU Authorities through the Association and join the annual QP Forum with a discount of 10%.



## Easy Registration

 **Reservation Form:**  
**CONCEPT HEIDELBERG**  
P.O. Box 10 17 64  
69007 Heidelberg, Germany

 **Reservation Form:**  
+ 49 6221 84 44 34

 **e-mail:**  
info@concept-heidelberg.de

 **Internet:**  
www.qp-association.eu

### Dates

#### Pre-course Session: IMP QP Education Course

Wednesday, 20 March 2019, 9.00 – 17.30 h  
(Registration and coffee 8.30 – 9.00 h)

#### QP Education Course

Thursday, 21 March 2019, 9.00 – 18.00h  
(Registration and coffee 8.30 – 9.00)  
Friday, 22 March 2019, 8.30 – 15.30 h

#### Venue for both events

Corinthia Hotel Prague  
Kongresova 1  
14069 Prague 4, Czech Republic  
Phone +(0) 420 261 191 111  
prague@corinthia.com

#### Fees (per delegate plus VAT)

Pre-course Session: IMP QP Education Course  
QP Association Members € 890  
ECA Members € 890  
Non-ECA Members € 990  
EU GMP Inspectorates € 495

### QP Education Course

QP Association Members € 1,490  
ECA Members € 1,490  
Non-ECA/ Non-QP Association Members  
€ 1,690  
EU GMP Inspectorates € 845

#### Save money when booking both events

If you book the QP Education Course TOGETHER WITH the Pre-course Session IMP QP Education Course, the fee will be as follows:

QP Association Members € 1,990  
ECA Members € 1,990  
Non-ECA Members € 2,290  
EU GMP Inspectorates € 1,145

#### Conference language

The official conference language will be English.

#### Accommodation

CONCEPT has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form/POG when you have registered for the course. Reservation should be made directly with the hotel. Early reservation is recommended.

### Organisation / Contact

CONCEPT HEIDELBERG  
P.O. Box 10 17 64  
D-69007 Heidelberg, Germany  
Phone +49 (0) 62 21/84 44-0  
Fax +49 (0) 62 21/84 44 34  
info@concept-heidelberg.de,  
www.concept-heidelberg.de

#### For questions regarding content please contact:

Mr Wolfgang Schmitt (Operations Director)  
at +49 (0) 62 21 / 84 44 39, or per e-mail at  
w.schmitt@concept-heidelberg.de.

#### For questions regarding reservation, hotel, organisation, etc please contact:

Ms Marion Grimm (Organisation Manager)  
at +49 (0) 62 21 / 84 44 18, or per e-mail at  
grimm@concept-heidelberg.de.

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

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CONCEPT HEIDELBERG  
P.O. Box 10 17 64  
Fax +49(0)6221/84 44 34

69007 Heidelberg  
Germany

### Reservation Form (Please complete in full)

- Qualified Person Education Course – Understand the Implications of Working as a QP**  
21-22 March 2019, Prague, Czech Republic
- Pre-course Session: IMP QP Education Course**  
20 March 2019, Prague, Czech Republic

Mr  Ms

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

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 2 weeks prior to the conference 10 %  
■ until 1 weeks prior to the conference 50 %  
■ within 1 week 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 January 2012).

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/ecca\\_privacy.html](http://www.gmp-compliance.org/ecca_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.