Qualified Person Education Course

Understand the Implications of Working as a QP

25/26 March 2020, Berlin, Germany

With an optional pre-course Session:
“Investigational Medicinal Products (IMP) QP Education Course”
on 24 March 2020

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
State Ministry of Social Affairs and Consumer Protection, Saxony, Germany

Lance Smallshaw
UCB, Belgium

Brenda Van Assche
Janssen, Belgium

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!”
Iryna Martynychyk, JSC Pharmaceuticals

“Excellent Organization!”

Nicoleta Mindrut, Zentiva, Romania
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

25/26 March 2020

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

Experiences made with the MRA and post-Brexit

- Inspections, GMP certificates, importation, acceptance of US CoAs…
- What we have experienced
- Problems occurred and solutions found

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

On 25 March 2020, you are invited to take part in an evening program in Berlin (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
State Ministry of Social Affairs and Consumer Protection, Saxony, Germany
Rico Schulze is a Pharmacist and holds a degree in Economics. Before working for the State Ministry, he was GMP and GDP Inspector at the Local Inspectorate in Dresden and performed inspections worldwide.

Lance Smallshaw
UCB, Belgium
Lance Smallshaw Regulatory Intelligence and External Advocacy (Quality, Analytical and Pharmacopeia) at UCB Biopharma. He is also Co-Chair of the Executive Board of ECA and Associate Director and European CMC Strategy Committee member for CaSSS Biopharm.
Objectives

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

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

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

Moderator

Dr Susanne Ding

Programme

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/ GDP/ GCP Interface
- Interaction with clinical sites
- Distribution
- IRT

Speakers IMP QP Education Course

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 International 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

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.

What are the benefits of the membership?

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%.
## 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 within 1 week prior to the conference: 100%.
   - Cancellation until 1 week prior to the conference: 50%.
   - Cancellation until 2 weeks prior to the conference: 10%.
   - Cancellation after 2 weeks prior to the conference: 0%.

### Important:
- 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.
- 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 any extra costs incurred due to a cancellation.
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- 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.

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