Qualified Person Education Course
Module A

Understand the Implications of becoming a QP

05/06 June 2024, Munich, Germany

– With an optional Pre-Course Session –
"Investigational Medicinal Products (IMP) QP Education Course"
on 04 June 2024

Speakers:

Dr Susanne Ding
Boehringer Ingelheim, Germany

Julia Gudd
GMP and GDP Inspector, Ministry of Justice and Consumer Protection, Hamburg, Germany

Patryk Jegorow
Takeda, Ireland

Dr Ulrich Kissel
European QP Association

Savvas Koulouridas
Fagron BV, The Netherlands

Aidan Madden
FivePharma, Ireland

Sue Mann
Sue Mann Consultancy, 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 QP Education Course Module A

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: QP Discretion and Batch Certification
- Batch certification: degrees of freedom and limits
- Batch deviations and QP Certification: To certify or not, that's the question

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

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

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

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

Social Event

On 05 June you are invited to take part in an evening programme. This is an excellent opportunity to share your experiences with the speakers and colleagues from other companies in a relaxed atmosphere.

Participants' Comments

"I learnt many things in the case study."
Naaz Dubash, ProPharma Group B.V.

"Being a senior professional, it has been very helpful for getting overview and confirming confidence in my professional judgment."
Marc Stegeman, ProPharma Group

"More than satisfied with the course!"
Dr. Pavla Holubova, TPI Norway

"Excellent course and perfect organization! Very practical and valuable case studies, good discussions and opinion sharing."
Vjaceslavs Krauklis, Boston Biopharma LT

"Thank you, the course program is set up really well. I have learned a lot!"
Hamza Leith, Rhythm Pharmaceuticals Netherlands B.V.

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
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 before founding her company in 2009.

Lance Smallshaw
UCB, Belgium
Lance Smallshaw is Global Analytical Expert (Global Pharmacopoeias Leader) within the Regulatory Intelligence Network (RIN) in the the UCB Site Quality Operations Team. He is also Co-Chair of the Executive Board of ECA and Chairman of the ECA Medical Cannabis Group.

Pre-course Session: "Investigational Medicinal Products (IMP) QP Education Course" on 04 June 2023

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 consider 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

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.

Patryk Jegorow
Takeda, Ireland
Patryk Jegorow is Qualified Person and Head of Quality Compliance and Systems at the Biologics Operating Unit and a Member 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 before founding her company in 2009.

Programme

Principles of Clinical Trials
- Introduction to Clinical Trials
- Principles involved in;
  - API and excipients
  - Bulk manufacturing
  - Packing and labelling
  - QP Certification and batch release
- Final Thoughts for the QP

Specific Legal Requirements for IMPs
- Definitions
- Clinical Trial Regulation 536/2014
- Clinical Trial Directive 2001/20/EC
- MD Regulation 2017/745
- IMP Guidelines (various)

GMP meets Clinical Trials – Differences between IMPs and Commercial Products
- Starting materials – Active pharmaceutical ingredient, excipient, diluent / reconstitution media
- Bulk
- Placebo
- Comparator
- Auxiliary Medicinal Product AxMP
- Trial design, randomization
- Order
- Blinding principles
- Packaging scenarios
- Labelling
- Exemptions from the manufacturing authorization for packaging & labelling
- Future concepts

IMP Batch Confirmation, QP Certification and IMP Release
- Definitions / Regulations / Guidelines
- IMP Release Process
- Distribution Concept / Controlled Shipment of IMPs

GMP/ GDP/ GCP Interface
- Reconstitution
- Pre-requisites for Randomisation and Blinding
- Distribution
- Stability and Shelf-Life extensions
- Trial Master File
- Site to site transfers
- Complaints and Recall
- End of Study
- Where does QP responsibility end?

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%.

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

Date Pre-course Session: IMP QP Education Course
Tuesday, 04 June 2024, 9.00 h – 17.45 h
(Registration and coffee 8.30 h – 9.00 h)

Date QP Education Course – Module A
Wednesday, 05 June 2024, 9.00 h – 18.00 h
(Registration and coffee 8.30 h – 9.00 h)
Thursday, 06 June 2024, 8.30 h– 15.30 h

Venue of both Events
HYPERION Hotel München
Truderinger Straße 13
81677 Munich (München), Germany
E-mail: hyperion.muenchen@h-hotels.com

Fees (per delegate plus VAT):

Pre-course Session: IMP QP Education Course
QP Association Members € 990
ECA Members € 990
Non-ECA/Non-QP Association Members € 1,190
EU GMP Inspectorates € 595

QP Education Course
QP Association Members € 1,690
ECA Members € 1,690
Non-ECA/Non-QP Association Members € 1,890
EU GMP Inspectorates € 945

Save money when booking both events
If you book the **QP Education Course** TOGETHER WITH the **Pre-course IMP QP Education Course**, the fee will be as follows (per delegate plus VAT):
QP Association Members € 2,190
ECA Members € 2,190
Non-ECA/Non-QP Association Members € 2,490
EU GMP Inspectorates € 1,245

The conference fee is payable in advance after receipt of invoice and includes dinner on Wednesday, lunch on all conference days and all refreshments. VAT is reclaimable.

Accommodation
CONCEPT HEIDELBERG 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.

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 for this event will be available for you to download and print before and after the event. Please note that no printed materials will be handed out on site and that there will not be any opportunity to print the presentations on site. After the event, you will automatically receive your certificate of participation.

Conference language
The official conference language will be English.

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
Phone +49 (0) 62 21/84 44-0
Fax +49 (0) 62 21/84 44 34
E-Mail 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
marion.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**
05/06 June 2024, Munich, Germany

☐ **Pre-course Session: IMP QP Education Course**
04 June 2024, Munich, Germany

☐ Mr ☐ Ms ☐ Mx

_____
Title, first name, surname

_____
Company Department

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

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Street / P.O. Box

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City Zip Code Country

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Phone/Fax

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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 %.
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 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 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.