Qualified Person Education Course

Understand the Implications of Working as a QP

22-23 February 2018, Barcelona Spain

With an optional pre-course Session:
Investigational Medicinal Products (IMP) QP Education Course on 21 February 2018

Speakers:
- Susanne Ding
  Boehringer Ingelheim, Germany
- Dr Ulrich Kissel
  European QP Association
- 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
- Dr Jurgen van Turnhout
  Pelfort Pharma Consultant B.V, The Netherlands

Participants’ comments on the last QP Education Courses:

“Everything was splendid.”
Nicoleta Mindrut, Zentiva, Romania

“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!”
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Iryna Martynychyk, JSC Pharmaceuticals
Dear Colleagues,

The Qualified Person Association has developed this Education Course for new and future Qualified Persons to address general compulsory and regulatory issues. It has been compiled by the QP Association Advisory Board members 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 Qualified Person Association.

Best regards,
Richard M. Bonner
Chairman of the Qualified Person Association

Objectives

Broaden and intensify your knowledge of the Qualified Person’s duties and responsibilities. Experts from the QP Association Advisory Board, 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

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
- IMP vs. Commercial products
- 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
Outsourcing: what the QP should know about assuring Product Quality

- Understanding the scope of your outsourced activities
  - More than Contract Laboratories and CMOs
- Communications and relationships with your outsourced partners
  - Product Quality Review
  - Quality Risk Management
  - Knowledge Management
- Selection, approval and ongoing oversight of outsourced partners
  - When to get involved
  - How much oversight is enough – taking a risk based approach to oversight
  - Metrics and KPIs
- Contracts – Development, Maintenance and ensuring adherence
  - Supply, Quality and Development Agreements
- QP’s roles and responsibilities: audits, complaints, adverse events, change control

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

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 Barcelona (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 Member 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.

Aidan Madden, FivePharma, Ireland
Aidan Madden is CEO of FivePharma, a Quality Services Company founded in 2003. Prior to setting up FivePharma Aidan held senior quality positions in Wyeth Pharmaceuticals, Baxter Healthcare and Fort Dodge Laboratories. Aidan holds a BS Degree in Biochemistry and an MS Degree in Immunochemistry as well a Higher Diploma in Pharmaceutical Manufacturing Technology and a Professional Teaching Qualification.

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 affaires.

Lance Smallshaw, UCB, Belgium
Lance Smallshaw is Global Director of Analytical Strategy for NBEs at UCB in Belgium. Before that he was Senior Scientist at Eli Lilly and Company. He is also a member of the Executive Board of ECA.

Dr Jurgen van Turnhout, Pelfort Pharma Consultant B.V, The Netherlands
Jurgen van Turnhout is Managing Director of Pelfort Pharma Consultant B.V. As a Qualified Person he supports and advises the pharmaceutical industry, related healthcare industry and hospital pharmacies in respect of quality related subjects. He is a Doctor of Pharmacy with a 5 years experience in hospital pharmacy and over 15 years experience as head of different Quality organisations within several companies.
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.

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 meets GCP
- Interaction with clinical sites
- Distribution
- IRT

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.

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 and has more than 35 years experience in the Pharmaceutical Industry, mainly in Quality Assurance, Clinical Trials supply and production support.

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%.
Date Pre-course Session:
IMP QP Education Course
Wednesday, 21 February 2018, 9.30 – 17.00 h
(Registration and coffee 9.00 – 9.30 h)

Date QP Education Course
Thursday, 22 February 2018, 9.00 – 18.00h
(Registration and coffee 8.30 – 9.00)
Friday, 23 February 2018, 8.30 – 15.30 h

Venue for both events
Barcelo Sants Hotel
Pl. Països Catalans, s/n
08014 Barcelona, Spain
Phone +34 93 503 53 00
Fax +34 93 4906045
Email sants@barcelo.com

Fees (per delegate plus VAT)
Pre-course Session: IMP QP Education Course
- QP Association Members € 890
- ECA Members € 890
- Non-ECA/ Non-QP Association Members € 990
- EU GMP Inspectorates € 495

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 without notice or to cancel an event.
   - To notify us of your withdrawal before 10 days after receipt of invoice.
   - Important: This is a binding registration and above fees are due in case of cancellation or non-attendance. 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.

Terms of payment: Payable without deductions within 10 days after receipt of invoice.
Important: The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on Thursday, lunch on all conference days and all refreshments. VAT is reclaimable.

Conference language
The official conference language will be English.

Reservation Form (Please complete in full)

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- Pre-course Session: IMP QP Education Course
  21 February 2018, Barcelona, Spain

Mr □ Ms □
Title, first name, surname

Company
Department

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

Street / PO Box
City Zip Code Country

Phone/Fax
E-mail (Please fill in)

General terms and conditions
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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/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.