



Qualified Person Education Course

Speakers:

Richard M. Bonner

EQPA

Sue Mann

Sue Mann Consultancy, U.K.

Dr Bernd Renger

EQPA

Rico Schulze

GMP Inspectorate, Local
Authorities Dresden, Germany

Lance Smallshaw

UCB, Belgium

Dr Jurgen van Turnhout

Pelfort Pharma Consultant B.V,
The Netherlands

Understand the Implications of Working as a QP

18-19 October 2017, Prague, Czech Republic

Participants' comments on the last QP Education Course:

"Everything was splendid."
Nicoleta Mindrut, Zentiva, Romania

*„Everything, course, lecture, workshops
were great."*
Nisha Thadathil, Sun Pharmaceutical
Industries Europe BV, The Netherlands

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



Richard M. Bonner

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.

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 Parliament 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.

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, that's the Question

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

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 v 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

Speakers

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

Parallel Sessions:

1) What the QP needs to know about Laboratory Operations to ensure correct Decision Making

- Responsibilities
- OOS, OOT and OOE results
- Failure Investigation
- Method validations

2) What the QP needs to know about Investigational Medicinal Products (IMPs)

- EU GMP and QP requirements for the release of Investigational Medicinal Products
- GMP-GCP Interface
- QP oversight and being a QP in a global environment
- Liability of the IMP QP
- Case studies

You will be able to attend one of these parallel sessions. Please choose the one you like to attend when you register for the Course.



Richard M. Bonner, EQPA

Mr Bonner is a Qualified Person in Europe and Chairman of the Qualified Person Association Advisory Board and of the ECA Executive Board. He is currently located in the UK and works as a consultant to the Pharmaceutical Industry. Previous to his current role he was a Senior Quality Adviser for Eli Lilly and Company. He had 31 years experience within the pharmaceutical industry working in production, technical services and both Quality Control and Quality Assurance functions.



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.



Dr Bernd Renger, EQPA

Dr Bernd Renger is the former Chair of the European QP Association. Since 2011 he is running his own consultancy business. Before that he was VP of Quality Control at Vetter Pharma-Fertigung. He started his career at Hoechst AG as a research and development chemist. Since then, he has held several quality management positions at Mundipharma, Altana Pharma and Baxter BioScience.



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. From 2008 to 2011 he was working at the Saxon State Ministry of Social affairs. He is also the Head of the German Authorities' Radiopharmaceuticals Working Group.



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 and sole shareholder 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.

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

Wednesday, 18 October 2017, 9.00 – 18.00h
(Registration and coffee 8.30 – 9.00)
Thursday, 19 October 2017, 8.30 – 15.30 h

Venue

Corinthia Hotel Prague
Kongresova 1
14069 Prague 4, Czech Republic
Phone +420 (261) 191 111
Fax +420 (261) 225 011

Conference fees (per delegate plus VAT)

QP Association Members € 1,490
ECA Members € 1,490
Non-ECA/Non-QP Association Members € 1,690
EU GMP Inspectorates € 845
The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on both days and all refreshments.
VAT is reclaimable.

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,
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info@concept-heidelberg.de,
www.concept-heidelberg.de

For questions regarding content:

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:

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

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.

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

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 18-19 October 2017, Prague, Czech Republic

Please choose ONE Parallel Session:

- What the QP needs to know about Laboratory Operations to ensure correct Decision Making
 What the QP needs to know about Investigational Medicinal Products (IMPs)

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).

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.