Qualified Person Education Course

Understand the Implications of Working as a QP

08-09 October 2015, Barcelona, Spain

Speakers:

Richard Bonner
Chairman of the EQPA, formerly with Eli Lilly, UK

Sue Mann
Sue Mann Consultancy, UK

Ann McGee
McGee Pharma International, form. Senior Inspector of the Irish Medicines Board (now HPRA)

Dr Bernd Renger
Immediate Past Chair of the EQPA

Rico Schulze
GMP Inspectorate, Germany

Lance Smallshaw
UCB Pharma, Belgium

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.

Moderator

Richard M. Bonner

Programme

The Legal and Professional Duties of the Qualified Person

- The Qualified Person within the EU legislation and regulation framework
- Different European authorities (e.g. EU Commission, DG Enterprise, EMEA, EDQM)
- Professional tasks, duties and responsibilities
- Interface and delimitation to the QPPV (Qualified Person for Pharmacovigilance)

Update on European Requirements

- EU GMP Guide Chapters
- EU GMP Guide Annexes
- Other important News

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

- EU Regulations
- Annex 16
- The QP's Discretion
- 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
  - QP handshakes
- 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 Advisory 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, UK
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 30 years experience in the Pharmaceutical Industry, mainly in Quality Assurance, Clinical Trials supply and production support

Ann McGee, McGee Pharma International, form. Senior Inspector of the Irish Medicines Board (now HPRA)
Ann McGee has extensive experience both in the pharmaceutical industry and as a regulator. She is a former Senior Inspector of the Irish Medicines Board (now being called HPRA – Health Products Regulatory Authority), Chief Executive of the Pharmaceutical Society of Ireland and Deputy Chair of PIC/S. Ann McGee also has many years "hands –on" experience in industry.

Dr Bernd Renger, ECA
Dr Bernd Renger is a member of the ECA Advisory Board and was Chairman 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 affaires. 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, having more than 25 years experience in Analytical Development and QC Laboratories. He is one of the original conception members of the UK Pharmaceutical Analytical Science Group (Pasg) Biopharm. Working Group and currently is their honorary secretary.

Easy Registration

Reservation Form:
CONCEPT HEIDELBERG
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69007 Heidelberg
Germany

Reservation Form:
+ 49 6221 84 44 34

e-mail:
info@concept-heidelberg.de

Internet:
www.qp-association.eu

Date
Thursday, 08 October 2015, 9.00 – 18.00 h
(Registration and coffee 8.30 – 9.00 h)
Friday, 09 October 2015, 8.30 – 15.30 h

Venue
Barceló Sants Hotel
Plaça dels Països Catalans, s/n
Estació de Sants
08014 Barcelona, Spain
Tel. +34 (93) 503 53 00
Fax +34 (93) 490 60 45

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
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D-69007 Heidelberg, Germany
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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 programme in Barcelona. 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:

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Reservation Form (Please complete in full)

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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 %.

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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.
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).

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