



Qualified Person Education Course

Speakers:

Richard Bonner

EQPA, formerly with Eli Lilly, UK

Dr Christopher Burgess

EQPA, formerly with Glaxo, UK

Dr Bernd Renger

Chairman of the EQPA

Lance Smallshaw

UCB Pharma, Belgium

Edit Szöcs

National Institute of Pharmacy,
Hungary

Understand the Implications of Working as a QP

Budapest, Hungary, 4 – 5 October 2012



Dr Bernd Renger

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,

Dr Bernd Renger
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

Dr Christopher Burgess

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, EMA, EDQM)
- Professional tasks, duties and responsibilities
- What documents need to be signed by a QP?
- Additional duties in accordance with national legislation or administrative procedures

Case Studies

Certification by a QP and Batch Release – to certify or not, that's the Question

- EU Regulations
- The EMA Reflection Paper
- The QP's Discretion
- Case Studies

Workshop

Batch Disposition – What Actions should you take as the responsible QP?

What the QP needs to know regarding the Supply Chain

- Supplier qualification
- Contract laboratories and TPMs
- Storage
- Distribution
- Cold chain management
- Traceability and the recall process

What the QP should know about assuring Product Quality including Contracts for external Manufacturing and Laboratories

- Facility and equipment
- Environmental contamination aspects
- Cleaning validation
- Supply, Quality and Development Agreements
- The QP: ultimate responsibility for the supply-chain of a drug product
- QP's roles and responsibilities: audits, complaints, adverse events, contracting

Update on European Requirements

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

Speakers

The role of the QP in Supplier Qualification

- Auditing
- Documentation
- Duties and Responsibilities

Delegation of Duties and Responsibilities

- Possible scenarios according to Annex 16
- Mutual Recognition Agreements (MRA)
- Documentation review issues
- The QP in the quality system

Interactive Session

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

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

Being inspected: Inspection Administration

- The role of the QP in the different types of inspections
- Interaction with authorities/customers
- Preparation of an inspection
- Roles and duties
- Follow-up

Richard M. Bonner

Mr Bonner 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. Mr Bonner is a Qualified Person in Europe and member of the Qualified Person Association Advisory Board.

Dr Christopher Burgess

Chartered Chemist with more than 30 years experience in the pharmaceutical industry primarily with Glaxo in Quality Assurance and Analytical R & D. He is a Qualified Person and a qualified ISO Guide assessor and a member of the PDA (USA) Scientific Advisory Board on 'OOS Task Force'. He is also member of the Qualified Person Association Advisory Board.

Dr Bernd Renger

Dr Bernd Renger is a member of the ECA Advisory Board and Chairman of the European QP Association. Since 2011, is running his own consultancy business. Before that he was Director 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 positions at Mundipharma, Altana Pharma and Baxter.

Lance Smallshaw

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.

Edit Szöcs

Edit Szöcs is GMP Inspector at the National Institute of Pharmacy, Hungary. She has over 10 years of QA experience in pharmaceutical industry. Additionally, Edit Szöcs gained expertise in manufacturing, testing and packaging of pharmaceuticals, e.g. for Sanofi Pasteur and Abbott.



Social Event

At the end of the first day of the course you are invited to take part in an evening programme in Budapest. This is an excellent opportunity to share your experiences with the speakers and colleagues from other companies in a relaxed atmosphere.

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

Thursday, 4 October 2012, 9.00 – 18.00 h

(Registration and coffee 8.30 – 9.00 h)

Friday, 5 October 2012, 8.30 – 15.30 h

Venue

Hilton Budapest WestEnd

Váci út 1-3

1062 Budapest, Hungary

Phone +36 1 288 5500

Fax +36 1 288 5588

Accommodation

CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. Please make your reservation via the Personalised Online Group Page www.budapest-westend.hilton.com/ECA0310 where you also can modify/cancel your reservation until 22 August 2012 without any penalty (single room € 125,- per night incl. breakfast + 18% VAT + city tax). Early reservation is recommended.

Conference fees

QP Association Members € 1,490.- per delegate plus VAT.

Non-QP Association Members € 1,690.- per delegate plus VAT.

EU GMP Inspectorates € 845.- per delegate plus VAT.

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.

Organisation / Contact

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or per e-mail at w.schmitt@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc:

Marion Grimm (Organisation Manager) at +49 (0) 62 21 / 84 44 18,

or per e-mail at grimm@concept-heidelberg.de.

About CONCEPT HEIDELBERG

Founded in 1978, CONCEPT HEIDELBERG is the leading organiser of seminars on pharmaceutical production, quality control, quality assurance and GMP in Europe. This year more than 240 events will be organised by CONCEPT HEIDELBERG. The European QP Association/ ECA has entrusted CONCEPT HEIDELBERG with the organisation of its events.

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

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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 Budapest, Hungary, 4-5 October 2012

☐ 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)!