



Qualified Person Education Course

Speakers:

Richard M. Bonner

Formerly with Eli Lilly and
Company Ltd., UK

Dr Christopher Burgess

Burgess Consultancy, UK

Dr Bernd Renger

Vetter Pharma-Fertigung GmbH,
Germany

Lance Smallshaw

Eli Lilly and Company Ltd., UK

John Taylor

MHRA, UK

Understand the Implications of Working as a QP

Berlin, Germany, 1-2 October 2008



Dr Bernd Renger

Dear Colleagues,

After the foundation of the Qualified Person Association, it became evident that there is a need for an education course for new and future Qualified Persons to address general compulsory and regulatory issues. This course 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
Director Quality Control
Vetter Pharma-Fertigung GmbH
Chairman, European QP 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, U.K., Qualified Person and European QP Association Board Member

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
- 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

- Risk Management and risk based decision making
 - QP's discretion in batch certification when a batch does not fully meet the requirements and specifications
 - QP's discretion in batch certification when a batch does not fully comply with marketing authorisation
- Problems, incidents and possible solutions

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

- 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

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

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

- Responsibilities
- OOS 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

Social Event



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

Speakers

Richard M. Bonner

Mr Bonner is currently located in the UK and works as a consultant to the Pharmaceutical Industry. He is a Qualified Person in Europe and member of the Qualified Person Association Advisory Board.

Dr Christopher Burgess

Dr Burgess 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 has recently been appointed to the Qualified Person Association Advisory Board.

Dr Bernd Renger

Dr Bernd Renger is Director of quality control at Vetter Pharma-Fertigung in Ravensburg, Germany. He started at Hoechst AG as a research and development chemist. Since then, he has held several quality positions at Mundipharma, Limburg, Altana Pharma, Constance, in Germany and Baxter AG in Austria. He is a member of the ECA Advisory Board and Chairman of the QP Association.

Lance Smallshaw

Lance Smallshaw is a Chartered Chemist and Fellow of the Royal Society of Chemistry. 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. Lance has 25 years experience in Analytical Development and QC Laboratories at Eli Lilly and Company.

John Taylor

John Taylor is Quality and Standards Manager of the UK Medicines and Healthcare products Regulatory Agency. He is a Chartered Chemist, a Fellow of the Royal Society of Chemistry and a member of the Qualified Person Association Advisory Board.

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 a 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 a Member of the QP Association?

The QP Association offers a free membership for the first 2 years after its foundation. In 2008 the Association's Board Members will decide if a regular membership fee is necessary to fulfil the tasks and objectives.

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%.

To become a Member please fill in the membership application form available at www.qp-association.eu.

Date

Wednesday, 1 October 2008, 9.00 – 18.00h

(Registration and coffee 8.30 – 9.00)

Thursday, 2 October 2008, 8.30 – 15.30 h

Venue

Steigenberger Hotel Berlin

Los Angeles Platz 1

D-10789 Berlin, Germany

Phone:+49 (0)30 2127 0, Fax:+49 (0)30 2127 117

Conference fees

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

QP Association Members € 1,521.- 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.

Accommodation

CONCEPT HEIDELBERG has reserved a limited number of rooms in the Steigenberger Hotel Berlin. Reservation should be made directly with the hotel not later than 30 August 2008. You will receive a room reservation form when you have registered for the course. Please use this form for your room reservation or be sure to mention "VA 5499 ECA Course" to receive the specially negotiated rate for the duration of your stay. Early reservation is recommended.

Registration

Via the attached reservation form, by e-mail to info@qp-association.eu or by fax to +49 6221 / 84 44 34 . Or you register online at www.qp-association.eu.

Conference language

The official conference language will be English.

Organisation / Contact

CONCEPT HEIDELBERG

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D-69007 Heidelberg, Germany

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For questions regarding content:

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:

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.

General Terms of Business

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 % of the registration fee.
- until 1 week prior to the conference 50 % of the registration fee.
- within 1 week prior to the conference 100 % of the registration fee.

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. You are not entitled to participate in the conference until we have received your payment (receipt of payment will not be confirmed)!

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

CONCEPT HEIDELBERG
Postfach 10 17 64
Fax 06221/84 44 34

D-69007 Heidelberg

Reservation Form (Please complete in full)

**Qualified Person Education Course –
Understand the Implications of Working as a QP**
Berlin, Germany, 1-2 October 2008

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)