QP ASSOCIATION

Speakers from Authorities and International Organisations:

Frede Dreier
Danish Medicines Agency
Anthony Gould
World Health Organisation (WHO)
Dr Susanne Keitel,
EDQM, France
Dr Jean-Denis Mallet
Formerly Head of the French Pharmaceutical Inspection Department
Benoît Rime
United States Pharmacopeia (USP)
Dr Fergus Sweeney
European Medicines Agency (EMA)
John Taylor
MHRA, U.K.
Rudolf Völler
Head of a German Inspectorate

Speakers from the Industry:

Lynne Byers
GSK, U.K., RX-360 Representative
Dr Christopher Burgess
Burgess Consultancy, U.K.
Dr Georg Goestl
Baxter AG, Austria
Dr Afshin Hosseiny
Tabriz Consulting, U.K.
Dr Ines Janssen
Baxter AG, Austria
Dr Line Lundsberg-Nielsen
NNE Pharmaplan, U.K.
Kati Mortier
Johnson & Johnson, Belgium
Dr Bernd Renger
Vetter Pharma-Fertigung GmbH, Germany
Gillian Renouf
Eli Lilly, U.K.
Jakob Sandersen
Astellas Pharma, Danmark
Dr Annemiek Stijnen
Kinesis Pharma, Netherlands
Anthony Storey
Pfizer, U.K., APIC Representative
Beam Suffolk
IPEC Europe, Belgium
Martine Tratsaert
Johnson & Johnson, Belgium

Invitation
to the

Qualified Person Forum 2010

London, U.K., 25 – 26 November 2010

1/2 Day Pre-Conference Workshop

Specific Requirements for IMPs on 24 November 2010

Full Day Pre-Conference Session

The GMP Auditing Conference on 24 November 2010

Welcome

Dear Colleagues,

The European QP Association Forum has been becoming a major event for European Qualified Persons. Speakers from EMA and various national authorities as well as QPs have been sharing their view of roles and responsibilities of the Qualified Person.

Hoping to continue the success of the QP Forum, the Advisory Board of the QP Association has set up the programme at hand for the 2010 Forum to give you an update about recent developments and important matters to consider. Representatives from the authorities as well as QPs and well-known experts will present latest issues and share their point of view. During the two pre-conference workshops and the six parallel sessions at the Forum, various case studies will be presented and discussed to come up with possible solutions.

Make use of this event by exchanging experiences with your colleagues and by establishing informal contact and networking.

I would like to invite you to this unique opportunity, and I look forward to meeting you.

Best regards,

Dr Bernd Renger
Chairman of the Qualified Person Association

Background

Over the past few years the role and duties of the Qualified Person keep increasing in significance and scope. Being the key person in the quality function of a pharmaceutical company, the QP has to consider many issues to fulfil the responsibilities and to comply with the European legislation.

Objective

This Conference is designed by QPs for QPs as an International Expert Forum with focus on sharing information and experience and on discussing the critical areas of the QP's daily work.

Target Group

The Forum is designed for all Qualified Persons and aspiring Qualified Persons. It also addresses upper management functions and authority representatives who want to be informed about the latest development regarding the duties and responsibilities of Qualified Persons.

Forum Moderator

Dr Christopher Burgess

1/2 Day Pre-Conference Workshop

Specific Requirements for IMPs (London, U.K., 24 November 2010)

"To Release or not to Release.." – Decision making process during Certification and Release of Investigational Medicinal Products

- Legislation
- Patient safety
- Impurities
- Deviations
- Risk-based approach
- Case studies
  - ➲ Facilitated by the IMP Working Group

Full Day Pre-Conference Session:

The GMP Auditing Conference (London, U.K., 24 November 2010)

How to use external sources of compliance information and to share information between QPs

- The QP's responsibility in supplier qualification in a global environment
  - ➲ Dr Bernd Renger
- WHO Prequalification of Medicines Programme
  - ➲ Anthony Gould
- Integration of APIC Audit Programme in Supplier Qualification – what is the QP's role
  - ➲ Tony Storey
- Integration of Rx-360 initiative in Supplier Qualification – what is the QP's role?
  - ➲ Lynne Byers
- Certified Excipients? Is the upcoming certification based on IPEC/EFFC the solution for the complex Excipient market?
  - ➲ Beam Suffolk
- EDQM Database - How to obtain information about withdrawn and suspended CEPs
  - ➲ Dr Susanne Keitel
- USP view: USP verified programme for APIs and Excipients
  - ➲ Benoît Rime

Programme QP Forum

London, U.K., 25 – 26 November 2010

Keynote and Welcome by EMA

- ➲ Dr Fergus Sweeney

Update on GMP-relevant topics and what QPs are expected to do

- EMA and FDA co-operation
- API initiative
- Supply chain concerns; counterfeits & adulteration
- Revised Variations process
  - ➲ Dr Bernd Renger

Process Analytical Technology (PAT) for QPs

- In-process testing vs end product testing
- Process mapping
- Control and process monitoring
- Towards parametric release
  - ➲ Dr Christopher Burgess

What the QP should know about CEPs and GMP Certificates

- What the QP is obliged to do when a supplier of raw materials was found to be non-compliant or not valid
  - ➲ Frede Dreier

How to interpret the Variations Regulation

- Do and tell
- How far back should the QP be involved
- Impact on QP Discretion
  - ➲ Jakob Sandersen

ICH Q8, Q9, Q10: how to implement and the role of the QP

- What impact will QbD have on product control and batch release
- Practical examples of QbD implementation with and without Real-Time Release Testing
- What impact will QbD have on the role of the QP
  - ➲ Dr Line Lundsberg-Nielsen

Outcome interest party meetings

- ➲ EQPA Representative

Parallel Sessions

Working on Case Studies

1. Risk Management Session: different approaches the QP should know and should know how to apply

➲ Dr Christopher Burgess & Rudolf Völler

2. QP Scenarios: Would you know what to do ? Make decisions based on real-life situations

- What "risk" is acceptable
- Where do your responsibilities end
- What are the legal responsibilities of a QP

➲ Gillian Renouf

3. Root cause analysis and troubleshooting techniques for QPs

- Cause Mapping and first Steps
- Problem Solving Methods & Risk Management
- Pareto, Ishigawa, the 5 Whys, FMEA, Fault tree analysis…
- Soft Skill – how to motivate your team

➲ Dr Bernd Renger & Jean-Denis Mallet

4. The role of the QP in an R&D Environment

- Sourcing and Handling of Comparators
- IMP Transfers and Returns

➲ IMP Working Group

5. What is the role of the QP in cycle time reduction/ business process strategies without corrupting legal and GMP requirements

➲ Dr Georg Goestel & Dr Ines Janssen

6. Define and secure your supply chain

- To learn how to process map your supply chain
- Risk assessment and defining the product critical steps in the supply chain
- Risk mitigation and action planning for critical steps

➲ Dr Afshin Hosseiny & John Taylor

You will be able to attend 2 of these parallel sessions. Please choose the ones you like to attend when you register for the Forum.

Q&A Session

During the 2 days of the Forum a bulletin board will be set up where delegates can post their question cards. The answers will be given by the expert speakers in this dedicated session and published in the members' area of the EQPA website.

Social Event

On 25 November, you are cordially invited to a social event in London. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

Speakers

Speakers from Authorities and International Organisations:

Frede Dreier, Danish Medicines Agency
Medicines Inspector.

Anthony Gould, World Health Organisation (WHO)
Manager of the Medicines Prequalification Program

Dr Susanne Keitel, EDQM, France
Director of the EDQM in Strasbourg.

Dr Jean-Denis Mallet
Formerly Head of the French Pharmaceutical Inspection Department.

Benoît Rime, United States Pharmacopeia (USP)
Senior International Account Manager USP Europe/Middle East/Africa.

Dr Fergus Sweeney, European Medicines Agency (EMA)
Head of Compliance and Inspections at the European Medicines Agency.

John Taylor, MHRA, U.K.
Quality and Standards Manager Acting and Group Manager, Enforcement and Intelligence.

Rudolf Völler, Head of a German Inspectorate
Director of the GMP Inspections Department of Hessen, Germany.

Speakers from the Industry:

Lynne Byers, GlaxoSmithKline, U.K.
Head of Supplier Quality Shared Service and Vice Chair of RX 360.

Dr Christopher Burgess, Burgess Consultancy, U.K.
Qualified Person, Consultant to the Pharmaceutical Industry and Advisory Board member of the Qualified Person Association.

Dr Georg Goestl, Baxter AG, Austria
Qualified Person and Head of Quality Assurance.

Dr Afshin Hosseiny, Tabriz Consulting, U.K.
Managing Director of Tabriz Consulting.

Dr Ines Janssen, Baxter AG, Austria
Quality Control, Baxter BioScience.

Dr Line Lundsberg-Nielsen, NNE Pharmaplan, U.K.
Senior QbD & PAT Consultant.

Kati Mortier, Johnson & Johnson, Belgium
Manager & Qualified Person, Global Qualified Person Group.

Dr Bernd Renger, Vetter Pharma-Fertigung GmbH, Germany
Director of Quality Control and Chairman of the QP Association Advisory Board.

Gillian Renouf, Eli Lilly, U.K.
QP and Regulatory and Quality Consultant EMACM.

Jakob Sandersen, Astellas Pharma, Denmark
Regulatory Affairs Manager, Nordic Operations.

Dr Annemiek Stijnen, Kinesis Pharma, Netherlands
Director Chemistry, Manufacturing & Control and Senior Consultant.

Anthony Storey, Pfizer, U.K.
Contract Operations Quality Assurance and Vice President APIC/CEFIC.

Beam Suffolk, IPEC Europe, Belgium
IPEC Europe Chair.

Martine Tratsaert, Johnson & Johnson, Belgium
Department head of the Global Qualified Person Group (GQPG), center of excellence for QP certification of IMPs.

Date ½ Day Pre-Conference Workshop:
Specific Requirements for IMPs
Wednesday, 24 November 2010, 13.30 – 18.00
(Registration and coffee: 13.00 – 13.30)

Date Full Day Pre-Conference Session:
The GMP Auditing Conference
Wednesday, 24 November 2010, 9.00 – 18.00
(Registration and coffee: 8.30 – 9.00)

Welcome Reception for all participants
Wednesday, 24 November 2010, 18.00 – 19.00

Date QP Forum
Thursday, 25 November 2010, 9.00 – 17.30
(Registration: Wednesday, 24 November 2010, 18.00 – 19.00 and
Thursday, 25 November 2010, 08.00 – 9.00)
Friday, 26 November 2010, 8.30 – 15.00

Venue
Hilton London Metropole
Edgware Road
London W2 1JU , U.K.
Tel .: +44 (0)20 7402 4141, Fax : +44 (0)20 7724 8866

The Hilton London Metropole is just 20 minutes from Heathrow Airport via the Heathrow Express to Paddington Station (5min to hotel). Closest underground station is Edgware Road.

Fees for ½ Day Pre-Conference Workshop
Specific Requirements for IMPs
€ 590,- per delegate plus VAT.
The fee is payable in advance after receipt of invoice and includes electronic conference documentation, lunch welcome reception and all refreshments. VAT is reclaimable.

Fees for Full Day Pre-Conference Session
The GMP Auditing Conference
€ 890,- per delegate plus VAT.
The fee is payable in advance after receipt of invoice and includes electronic conference documentation, welcome reception and all refreshments. VAT is reclaimable.

Fees for QP Forum
QP Association Members € 1.609,- per delegate plus VAT.
EU GMP Inspectorates € 895,- per delegate plus VAT.
Non-QP Association Members € 1.790,- per delegate plus VAT.
The conference fee is payable in advance after receipt of invoice and includes electronic conference documentation, welcome reception, dinner on the first day, lunch on both days and all refreshments. VAT is reclaimable.

Saving Opportunity!
Book both the QP Forum and a Pre-Conference Workshop/ Session: Delegates who attend the QP Forum and a Pre-Conference Workshop/ Session will get a **discount of 200€** on the QP Forum.

Accommodation
CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. Please make your reservation via the Personalised Online Group Page POG where you also can modify your reservation until 22 October 2010. 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.

Important Information!
The presentations of the QP Forum and the Pre-Conference Workshop/ Session will be available for download and your print-out 1 week before the conference. You will also receive a USB memo stick when you register in London. **Note: there will be no print-outs available during the conference.**

Organisation / Contact
CONCEPT HEIDELBERG
P.O. Box 10 17 64
D-69007 Heidelberg, Germany
Phone +49 (0) 62 21/84 44-0, Fax +49 (0) 62 21/84 44 34
E-mail: info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content:
Mr Wolfgang Schmitt (Operations Director) at +49-62 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.

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 Forum 2010,** London, U.K., 25 – 26 November 2010
Please choose **two of the six** parallel sessions:
☐ Session 1 ☐ Session 4
☐ Session 2 ☐ Session 5
☐ Session 3 ☐ Session 6

☐ **Optional Pre-Conference Workshop/Session,** London, U.K., 24 November 2010
Please choose **one of the following**:
☐ 1/2-Day Workshop "Specific Requirements for Investigational Medicinal Products"
☐ 1 Full Day Session "The GMP Auditing Conference"

☐ Mr ☐ Ms

Title, first name, surname

Company Department

Important: Please indicate your company's VAT ID Number

P.O Number (if applicable)

Street / P.O. Box

City Zip Code Country

Phone / Fax

E-mail (Please fill in)

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)!

About the European QP Association
The European Qualified Person (QP) Association was founded on 7 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.

More information about the QP Association and a membership application form are available at www.qp-association.eu.

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 has entrusted CONCEPT HEIDELBERG with the organisation of its events.