Speakers from Authorities and Public Health Organisations:

Dr Stefan Almeling
EDQM
Riekert Bruinink
Dutch Health Care Inspectorate, Member of the EMA GDP Drafting Group
Dr Herbert Schmidt
WHO
Edit Szőcs
Hungarian Drug Inspectorate

Speakers from the Industry:

Richard M. Bonner
Chairman of the EQPA, form with Eli Lilly
Dr Christopher Burgess
EQPA, form. with Glaxo
Véronique Davoust
Pfizer
Dr Alexander J.J. Debets
MSD
Dr Susanne Ding
Boehringer Ingelheim
Karin Hoogendoorn
Janssen Biologics
Dr Afshin Hosseiny
Tabriz Consulting
Dr Ulrich Kissel
Roche Pharma
Dr Jean-Denis Mallet
NNE Pharmaplan
Sue Mann
Sue Mann Consultancy
Ann McGee
McGee Pharma International form. Senior Inspector of the Irish Medicines Board
Katie Mortier
Janssen Pharmaceutica
Clodagh Owens
Genzyme
Frank Raisch
GlaxoSmithKline
Dr Bernd Renger
Immediate Past Chairman of the EQPA
Gillian Renouf
Eli Lilly
Hazel Sarosi
Covance
Dr Björn Seidel
Team Connex
Lance Smallshaw
UCB Pharma
Niina Taylor
Pfizer
Philippe Van de Hofstadt
B&C Group
Dr Dirk Theodoor Witte
Abbott Logistics

Invitation
to the

QP ASSOCIATION

Qualified Person Forum 2013

Lisbon, Portugal 28 – 29 November 2013

With three Pre-Conference Sessions
on 27 November 2013:

Investigational Medicinal Products

The Role of the QP in a global System in a multinational Company

What the QP needs to know about Virtual Companies

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 2013 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 three pre-conference sessions 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,

Richard M. Bonner
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

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 Lisbon. **Note: there will be no print-outs available during the conference.**

Pre-Conference Sessions

27 November 2013

Full Day Pre-Conference Session

Specific Requirements for IMPs
Facilitated by the IMP Working Group

- New legislation impacting IMP QPs
- Presentation of Working Groups
  - GMP concept in various Development Stages
  - Future trends in Clinical Trials
  - IMP certification process
  - QP release in Investigator-Sponsored Trials
- Advanced therapy medicinal products: what's it about?
- Interactive case studies – decision making of IMP QPs

1/2 Day Pre-Conference Session

The Role of the QP in a global System in a multinational Company
Facilitated by:
Véronique Davoust / Ian Holloway / Dr Ulrich Kissel / Frank Raisch

- Responsibilities and delineation
- Interaction and delegation
- How ICH Q10 and EU-GMP Chapter 1 lead the way
- Case studies

1/2 Day Pre-Conference Session

What the QP needs to know about Virtual Companies
Facilitated by:
Dr Afshin Hosseiny / Ann McGee / Dr Jean-Denis Mallet

- What the QP in a virtual company needs to know and consider
- What a QP at a contract manufacturer needs to know and consider when co-operating with virtual companies

Programme QP Forum

28 – 29 November 2013

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

- What is important for the QP?
- Outcome interest party meetings
  - ➲ Dr Bernd Renger

Annex 16: How the Stakeholders see the Changes – A moderated Q&A Session

- ➲ Dr Christopher Burgess, Dr Ulrich Kissel, Edit Szőcs

What the QP needs to know about GDP
a) GMP/GDP Interface: the Authority's Perspective

- Why the new GDP Guide was necessary
- How inspectorates are dealing with the new requirements
- Main concerns of inspectorates
  - ➲ Riekert Bruinink

b) GMP/GDP Interface: the Industry's Perspective

- The role of the QP and its interface to the Responsible Person
- Challenges in practice
  - ➲ Dr Dirk Theodoor Witte

The Impact of Mergers on Pharmaceutical Industry and the QP

- The challenges in the interaction of the operational business with QPs
- Workload and process-change challenges
- The Swiss QP point of view and the interaction with the EU
  - ➲ Dr Alexander J.J. Debets

What the QP needs to know about EDQM

- Current situation and future trends
- European Pharmacopoeia Reference Standards
- Examples of other activities
  - ➲ Dr Stefan Almeling

Under Pressure

- Are the day to day business pressures adversely affecting the QPs ability to carry out their duties properly?
  - ➲ Richard Bonner

Parallel Sessions

Working on Case Studies

1) Outsourced Activities: Impact from the Update to Chapter 7 of the EU GMP Guide
- Challenges and possible solutions
  - ➲ Ann McGee and Clodagh Owens

2) New GMP requirements with relevance for the QP
- Some practical case studies
  - ➲ Dr Bernd Renger and Dr Jean-Denis Mallet

3) QP Scenarios: Would you know what to do? Make decisions based on real-life situations
- What "risk" is acceptable
- Responsibilities
  - ➲ Sue Mann and Gillian Renouf

4) The Role of the QP in an R&D Environment: End to End Visibility of the IMP Supply Chain
- How to achieve complete visibility and quality oversight over the IMP Supply Chain
- High level summary of the IMP Pre-conference
  - ➲ IMP Working Group

5) The changing Role of the Pharmacopoeia and what's the Impact on Batch Release
  - ➲ Dr Christopher Burgess, Dr Herbert Schmidt and Lance Smallshaw

6) Communication as the Key
- How to get all necessary information a QP needs
- Conflict solving
- How to be tough on the subject
  - ➲ Dr Afshin Hosseiny and Dr Björn Seidel

You will be able to attend three 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 28 November, you are cordially invited to a social event in Lisbon. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

Special Offer with Lufthansa – Discounted Travel

Lufthansa
Official Airline

As an ECA course or conference attendee, you will receive up to 20% discounted travel fares (according to availability). And as Lufthansa German Airlines offers a comprehensive global route network linking major cities around the world you will most likely be able to benefit from these special prices and conditions.

And this is how it works: Once you registered for a course or conference you will receive a link together with your registration confirmation. Opening that link will take you to the Mobility Partner Program website where you can enter a code in the "Access to Event Booking" area you will also receive. This will take you into an online booking platform that will automatically calculate the discount offered or provide you with an even better offer if another promotional fare is available.

Speakers

Speakers from Authorities and Public Health Organisations:

Dr Stefan Almeling, *EDQM, France*
Head of Analytical Chemistry Division; European Directorate for the Quality of Medicines & Healthcare (EDQM), Council of Europe.

Riekert Bruinink, *Dutch Health Care Inspectorate, Netherlands*
Group Chairman of the PIC/S GDP Working Group, Member of the European Medicines Agency (EMA) GDP Drafting Group.

Dr Herbert Schmidt, *WHO, Switzerland*
Technical Officer at the World Health Organization, Quality Assurance and Safety: Medicines.

Edit Szőcs, *Hungarian Drug Inspectorate, Hungary*
Inspector at the Hungarian Drug Inspectorate, National Institute of Pharmacy (NIP).

Speakers from the Industry:

Richard M. Bonner, *Chairman of the EQPA*
Qualified Person, Chairman of the Qualified Person Association, formerly with Eli Lilly.

Dr Christopher Burgess, *formerly with Glaxo, U.K.*
Qualified Person, Advisory Board member of the Qualified Person Association. Visiting Professor at the Strathclyde Institute of Pharmacy and Biomedical Sciences (SIPBS).

Véronique Davoust, *Pfizer, France*
PGS Global Quality Operations, Quality Strategy.

Dr Alexander J.J. Debets, *MSD Werthenstein BioPharma, Switzerland*
Site Head.

Dr Susanne Ding, *Boehringer Ingelheim, Germany*
Qualified Person for Investigational Medicinal Products.

Karin Hoogendoorn, *Janssen Biologics Europe, Netherlands*
Associate Director Global CMC Regulatory Affairs.

Dr Afshin Hosseiny, *Tabriz Consulting, U,K.*
Qualified Person and Managing Director.

Dr Ulrich Kissel, *Roche Pharma AG, Germany*
Qualified Person and Advisory Board member of the Qualified Person Association.

Dr Jean-Denis Mallet, *NNE Pharmaplan, France*
Formerly Head of the French Pharmaceutical Inspection Department (AFSSAPS). Member of the Advisory Board of the ECA Foundation.

Sue Mann, *Sue Mann Consultancy Ltd. U.K.*
Qualified Person and QP Assessor working on behalf of the MHRA, representing the Royal Pharmaceutical Society.

Ann McGee, *McGee Pharma International, Ireland*
Managing Director and Principal Consultant. Former Senior Inspector of the Irish Medicines Board and Deputy Chair of PIC/S.

Kati Mortier, *Janssen Pharmaceutica NV, Belgium*
Associate Program Director Clinical Supply Chain.

Clodagh Owens, *Genzyme Ireland Ltd., a Sanofi Company*
Qualified Person.

Frank Raisch, *GlaxoSmithKline, Germany*
Attorney-at-Law and Legal Counsel.

Dr Bernd Renger, *EQPA*
Immediate Past Chairman of the Qualified Person Association.

Gillian Renouf, *Eli Lilly, U.K.*
Qualified Person and Regulatory and Quality Consultant EMACM.

Hazel Sarosi, *Covance Laboratories Limited, U.K.*
GMP QA Manager and Qualified Person

Dr Björn Seidel, *Team Connex, Germany*
Certified Trainer and Systemic Coach. Formerly with Fraunhofer Institute for Molecular Biology.

Lance Smallshaw, *UCB Pharma, Belgium*
Global Director Analytical Strategy.

Niina Taylor, *Pfizer, U.K.*
Qualified Person and Director Quality Assurance.

Philippe Van de Hofstadt, *B&C Group, Belgium*
CEO of B&C, a Clinical Research Packaging & Logistics Organisation.

Dr Dirk Theodoor Witte, *Abbott Logistics, Netherlands*
Head of the Quality Unit.

Date Full Day Pre-Conference Session:
Specific Requirements for IMPs
Wednesday, 27 November 2013, 9.30 – 18.00
(Registration and coffee: 9.00 – 9.30)

Date ½ Day Pre-Conference Session:
The Role of the QP in a global System in a multinational Company
Wednesday, 27 November 2013, 13.00 – 18.00
(Registration, snacks and coffee: 12.30 – 13.00)

Date ½ Day Pre-Conference Session:
Virtual Companies
Wednesday, 27 November 2013, 13.30 – 18.00
(Registration, snacks and coffee: 13.00 – 13.30)

Welcome Reception for all participants
Wednesday, 27 November 2013, 18.00 – 19.00

Date QP Forum
Thursday, 28 November 2013, 9.00 – 18.00
(Registration: Wednesday, 27 November 18.00 – 19.00 and
Thursday 28 November 2013, 08.00 – 9.00)
Friday, 29 November 2013, 8.30 – 14.30

Venue
Corinthia Hotel
Av. Columbano Bordalo Pinheiro, 105
1099-031 Lisbon
Portugal
Tel.: +351 21 723 6300
Fax: +351 21 723 6364

Fees for QP Forum
QP Association Members € 1.590,- 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.

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

Fees for ½ Day Pre-Conference Session:
The Role of the QP in a global System in a multinational Company
€ 590,- 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 ½ Day Pre-Conference Session:
Virtual Companies
€ 590,- 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.

Saving opportunity:

Book both the QP Forum and a Pre-Conference Session:
Delegates who attend the QP Forum and a Pre-Conference 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. You will receive a room reservation form when you have registered for the event. Please use this form for your room reservation or be sure to mention QP Association to receive the specially negotiated rate (single room 150,- Euros per night incl. breakfast) for the duration of your stay. Reservation should be made directly with the hotel not later than 26 September 2013. 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-forum.org.

Conference Language
The official conference language will be English.

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 2013,** Lisbon, Portugal, 28-29 November 2013
Please choose **three of the six** parallel sessions:
☐ Session 1: Outsourced Activities: Impact from the Update to Chapter 7 of the EU GMP Guide
☐ Session 2: New GMP requirements with relevance for the QP
☐ Session 3: QP Scenarios: Would you know what to do? Make decisions based on real-life situations
☐ Session 4: The Role of the QP in an R&D Environment: End to End Visibility of the IMP Supply Chain
☐ Session 5: The changing Role of the Pharmacopoeia and what's the Impact on Batch Release
☐ Session 6: Communication as the Key

☐ **Optional Pre-Conference Session**, Lisbon, Portugal, 27 November 2013
Please choose **one of the following**:
☐ Full Day Session "Investigational Medicinal Products"
☐ 1/2 Day Session "The Role of the QP in a global System in a multinational Company"
☐ 1/2 Day Session "What the QP needs to know about Virtual Companies "

☐ 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.