Speakers from Authorities and Public Health Organisations:

Dara Corrigan
U.S. Food & Drug Administration (FDA)
Dr Rainer Gnibl
District Government of Upper Bavaria
Mag.pharm. Andreas Kraßnigg
Austrian Agency for Health and Food Safety (AGES)
Kevin O'Donnell
Irish Health Products Regulatory Authority (HPRA) (form. IMB)
Edit Szőcs
Hungarian Drug Inspectorate, National Institute of Pharmacy (NIP)
Maria Wängelin
Swedish Medical Products Agency (MPA)

Speakers from the Industry:

Justin Barry
Midatech Biogune
Richard M. Bonner,
Qualified Person, Chairman of the Qualified Person Association, form. with Eli Lilly
Dr Christopher Burgess
EQPA, form. with Glaxo
Dr Dagmar Chase
European CRO Federation
Dr Susanne Ding
Boehringer Ingelheim
Dr Oskar Enzersberger
Baxter
Dr Afshin Hosseiny
Tabriz Consulting
Dr Ulrich Kissel
Roche Pharma
Sue Mann
Sue Mann Consultancy
Ann McGee
McGee Pharma International, form. Senior Inspector of the Irish Medicines Board
Geneviève Meeus
Johnson & Johnson
Dr Gabriele Oleschko
Merck KGaA
Frank Raisch
GSK
Dr Rolf Ratke
AbbVie
Stefan Reintgen
Team Connex
Dr Bernd Renger
Immediate Past Chairman of the EQPA
Gillian Renouf
InterMune
Niina Taylor
Pfizer
Philippe Van de Hofstadt
B&C Group

Invitation
to the

QP ASSOCIATION

Qualified Person Forum 2014

Vienna, Austria 27 – 28 November 2014

With three Pre-Conference Sessions
on 26 November 2014:

Investigational Medicinal Products

Risk Management in the Supply Chain

OOS and OOT: What's important for QPs

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 2014 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

26 November 2014

Full Day Pre-Conference Session

Specific Requirements for IMPs
Facilitated by:
IMP Working Group

- New legislation impacting IMP QPs
- GMP in different clinical phases
- The Product Specification File - PSF
- Interactive case studies – decision making of IMP QPs

1/2 Day Pre-Conference Session

Risk Management in the Supply Chain
Facilitated by:
Richard M. Bonner / Afshin Hosseiny / Edit Szőcs

- What the QP needs to know about Supply Chain Risk Management
- What inspectors expect from the QP

1/2 Day Pre-Conference Session

OOS and OOT: What's important for QPs
Facilitated by:
Christopher Burgess / Bernd Renger

- How the QP can rely on the Quality System
- How to handle IPC results impacting the product's final quality

Programme QP Forum

27 – 28 November 2014

The QP in a Global Environment: a positive Picture; Reflections about Perceptions
- Perceptions and self-understanding
- Roles of QPs in a global environment
  - ➲ Rolf Ratke

Current and future Activities of the FDA
- EU Mutual Reliance Drug Quality Initiative
- Pharmaceutical Quality for the 21st Century
- Lifecycle Quality Risk Management
  - ➲ Dara Corrigan

The Role of the QP in Product Recalls
- EU-GMP Chapter 8
- Critical Defects and Risk Management
- Rapid Alert and communication between National Authorities and the QP
  - ➲ Edit Szőcs

What the QP needs to know about Quality by Design
- Know your process
- Risk Management
- Exceptional Release
  - ➲ Oskar Enzersberger

Law and Order
- Liability
- Indemnification
- Insurance
  - ➲ Frank Raisch

What the QP needs to know about Excipient Quality
- Transparency and the control of the supply chain
- Key criteria input
- Definition of standards
  - ➲ Gabriele Oleschko

The Written Confirmation and the QP: What Inspectors expect
- Role and responsibilities of the QP
- Interface with supplier qualification and the Quality System
  - ➲ Rainer Gnibl

Parallel Sessions

Working on Case Studies

1) Update on GMP-relevant topics and what QPs are expected to do
- Discussion, questions, answers
  - ➲ Bernd Renger and Rainer Gnibl

2) Annex 16 – how to live with it
- Discussion, questions, answers
  - ➲ Ulrich Kissel and Andreas Kraßnigg

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

4) The Role of the QP in an R&D Environment
- Challenges with NCEs & Biotech bulk drug substances
- Comparator sourcing and handling
  - ➲ IMP Working Group

5) How to interpret the PQR
- What the QP can and should get out of it
  - ➲ Ann McGee and Kevin O'Donnell

6) How to deal with Time Pressure
- Key tools to plan, organise and set priorities to get the right things done, every day.
  - ➲ Afshin Hosseiny and Stefan Reintgen

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 web-site.

Social Event

On 27 November, you are cordially invited to a social event in Vienna. 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 web-site 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:

Dara Corrigan, *FDA, USA*
Assistant Commissioner for Global Regulatory Policy.

Dr Rainer Gnibl, *District Government of Upper Bavaria, Germany*
GMP Inspector for the District Government and the EMA.

Mag.pharm. Andreas Kraßnigg, *Austrian Agency for Health and Food Safety (AGES), Austria*
Head Pharmaceutical Inspections and Member of Annex 16 Drafting Group.

Kevin O'Donnell, PhD, *Irish Health Products Regulatory Authority (HPRA) (form. IMB), Ireland*
Market Compliance Manager.

Edit Szőcs, *Hungarian Drug Inspectorate, National Institute of Pharmacy (NIP), Hungary*
Inspector at the Hungarian Drug Inspectorate, National Institute of Pharmacy (NIP), Advisory Board member of the Qualified Person Association.

Maria Wängelin, *Medical Products Agency (MPA), Sweden*
GDP/GMP Inspector.

Speakers from the Industry:

Justin Barry, *Midatech Biogune, Spain*
Managing Director.

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).

Dr Dagmar Chase, *European CRO Federation (EUCROF)*
Vice President EUCROF and Managing Director of Clinrex GmbH.

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

Dr Oskar Enzersberger, *Baxter AG, Austria*
Qualified Person.

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.

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.

Geneviève Meeus, *Janssen Pharmaceutica NV (part of Johnson & Johnson), Belgium*
Director QA Clinical Supply Chain/ IMP QP.

Dr Gabriele Oleschko, *Merck KGaA, Germany*
Qualified Person and Senior Manager Quality Operations.

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

Dr Rolf Ratke, *AbbVie Biotechnology, Germany*
Qualified Person and Director Biologics Quality Assurance.

Stefan Reintgen, *Team Connex, Germany*
Trainer and Coach, formally working for BASF and Celanese

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

Gillian Renouf, *InterMune, U.K. and Ireland*
Qualified Person and Senior Director Quality.

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.

Date Full Day Pre-Conference Session:
Specific Requirements for IMPs
Wednesday, 26 November 2014, 9.30 – 18.00
(Registration and coffee: 9.00 – 9.30)

Date ½ Day Pre-Conference Session:
Risk Management in the Supply Chain
Wednesday, 26 November 2014, 13.00 – 18.00
(Registration, snacks and coffee: 12.30 – 13.00)

Date ½ Day Pre-Conference Session:
OOS and OOT: what's important for QPs
Wednesday, 26 November 2014, 13.30 – 18.00
(Registration, snacks and coffee: 13.00 – 13.30

Welcome Reception for all participants
Wednesday, 26 November 2014, 18.00 – 19.00

Date QP Forum
Thursday, 27 November 2014, 9.00 – 18.00
(Registration: Wednesday, 26 November 18.00 – 19.00 and
Thursday 27 November 2014, 8.00 – 9.00)
Friday, 28 November 2014, 8.30 – 14.30

Venue
Austria Trend Hotel Park Royal Palace Vienna
Schlossallee 8
1140 Vienna
Austria
Tel.: +43 1 8911 0
Fax:+43 1 8911 9050

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:
Risk Management in the Supply Chain
€ 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:
OOS and OOT: What's important for QPs
€ 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 opportunities:

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 link when you have registered for the event. Please use this link for your room reservation or be sure to mention QP Association to receive the specially negotiated rate (single room 125,- Euros per night incl. breakfast) for the duration of your stay. Reservation should be made directly with the hotel not later than 5 October 2014. 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 2014,** Vienna, Austria, 27-28 November 2014
Please choose **three of the six** parallel sessions:
☐ Session 1: Update on GMP-relevant topics and what QPs are expected to do
☐ Session 2: Annex 16 – how to live with it
☐ Session 3: QP Scenarios: Would you know what to do?
☐ Session 4: The Role of the QP in an R&D Environment
☐ Session 5: How to interpret the PQR
☐ Session 6: How to deal with Time Pressure

☐ **Optional Pre-Conference Session**, Vienna, Austria, 26 November 2014
Please choose **one of the following**:
☐ Full Day Session "Investigational Medicinal Products"
☐ 1/2 Day Session "Risk Management in the Supply Chain"
☐ 1/2 Day Session "OOS and OOT: What's important for QPs "

☐ 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.