**Speakers from Authorities and Public Health Organisations:**

**Dr Christian Hösch**
*Ministry of Health and Consumer Protection, Hamburg, Germany*
**Frithjof Holtz**
*IPEC Europe*
**Riccardo Luigetti**
*European Medicines Agency (EMA)*
**Anne Junttonen**
*Finnish Medicines Agency, Finland*
**Dr Pierre Poitou**
*Ordre National des Pharmaciens, France*
**Edit Szőcs**
*Hungarian Drug Inspectorate*
**Rudolf Völler**
*GMP Inspectorate Darmstadt, Germany*

**Speakers from the Industry:**

**Richard M. Bonner**
*EQPA, formerly with Eli Lilly, U.K*
**Dr Christopher Burgess**
*EQPA, formerly with Glaxo, U.K.*
**Dr Pierre-Jean Consalvi**
*Merial, France*
**Dr Susanne Ding**
*Boehringer Ingelheim, Germany*
**Georg Göstl**
*Baxter BioScience, Austria*
**Johannes Heusler**
*Roche Pharma AG, Germany*
**Dr Afshin Hosseiny**
*Tabriz Consulting, U.K.*
**Dr Ulrich Kissel**
*Roche Pharma AG, Germany*
**Henny Koch**
*qimp Management Systems B.V., Netherlands*
**Aidan Madden**
*FivePharma, Ireland*
**Dr Jean-Denis Mallet**
*SNC Lavalin, France*
**Sue Mann**
*Sue Mann Consultancy, U.K.*
**York Moeller**
*J.A.Moeller Chongqing, China*
**Dr Dr Dierk Rebeski**
*Lohmann Animal Health, Germany*
**Stefan Reintgen**
*Team Connex, Germany*
**Dr Bernd Renger**
*Chairman of the EQPA*
**Gillian Renouf**
*Eli Lilly, U.K.*
**Dr Stephan Rönninger**
*F. Hoffmann-La Roche, Switzerland*
**Lance Smallshaw**
*UCB Pharma, Belgium*
**Dr Annemiek Stijnen**
*Kinesis Pharma, Netherlands*
**Martine Tratsaert**
*Johnson & Johnson, Belgium*
**Philippe Van de Hofstadt**
*B&C Group, Belgium*

Invitation
to the

QP ASSOCIATION

# Qualified Person Forum 2012

**Hamburg, Germany 22 – 23 November 2012**

With three Pre-Conference Sessions
**on 21 November 2012:**

Investigational Medicinal Products

The changing Role of the QP in a changing Environment

QP Challenges in the Veterinary Industry

# 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 2012 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,

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

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

# Pre-Conference Sessions

21 November 2012

## Full Day Pre-Conference Session

**Specific Requirements for IMPs**
Facilitated by the IMP Working Group
- New Legislation impacting IMP QPs
- Concept of eLabels
- Product Specification File
- Interactive Response Technologies (IRT)
- Decision making of IMP QPs

## 1/2 Day Pre-Conference Session

**QP Challenges in the Veterinary Industry**
Facilitated by:
- ➲ Dr Pierre-Jean Consalvi / Dr Afshin Hosseiny / Dr Dr Dierk Rebeski
- GMP fitness for purpose
- Pharmacovigilance
- Routine batch release

## 1/2 Day Pre-Conference Session

**The changing Role of the QP in a changing Environment: Training, Organisation, new Challenges**

**The Roche Pharma AG Training Programme for QPs**
- ➲ Johannes Heusler

**The QP Declaration Paper and its Implementation in a global Company**
- ➲ Dr Ulrich Kissel

**Combination Products: new Challenges for QPs**
- ➲ Henny Koch

**The QP in a virtual Company – what both sides need to know**
- ➲ Aidan Madden

**GDP: how the QP is involved**
- ➲ Aidan Madden

**The role of the Responsible Pharmacist in French Pharma Companies**
- ➲ Dr Pierre Poitou

# Programme QP Forum

22 – 23 November 2012

**Keynote and Welcome by Ministry of Social- and Family Affairs, Health and Consumer Protection, Hamburg, Germany**
- ➲ Dr Christian Hösch

**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

**The "flavour of the month" syndrome - is public Attention overruling scientific Risk Assessment in Quality Management?**
- Industry and authorities: do we have the same basic requirements?
- QRM: risk acceptance vs. no-risk expectation
- Is industry willing to accept new requirements?
  - ➲ Georg Göstl

**The Falsified Medicines Directive and the new GDP Guide**
- ➲ Riccardo Luigetti

**What the QP needs to know about Unique Identifiers acc. Directive 2011/62 and other new Packaging Technologies**
- ➲ Dr Jean-Denis Mallet

**The Revision of Annex 16**
- ➲ Anne Junttonen

**EXCiPACT - the new Certification Scheme for Excipients**
- How QPs can make use of the certification scheme as part of supplier qualification
  - ➲ Frithjof Holtz

**Quality Cultures in the World**
- ➲ Richard Bonner

## Parallel Sessions

**Working on Case Studies**

**1. What the QP needs to know about Supplies from China**
- Challenges and possible solutions
  - ➲ York Moeller and Rudolf Völler

**2. The QP and Risk Management**
- Statistical tools used in QRM
- Case studies and examples
  - ➲ Richard Bonner, Dr Stephan Rönninger and Edit Szőcs

**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**
- Outsourcing of the manufacturing, control & release of IMPs – how far do we go with the delegation of responsibilities?
  - ➲ IMP Working Group

**5. The changing Role of the Pharmacopoeia and what's the Impact on Batch Release**
  - ➲ Dr Christopher Burgess and Lance Smallshaw

**6. Work Organisation and Time Management for QPs**
  - ➲ 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 22 November, you are cordially invited to a social event in Hamburg. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

**Special Offer with Lufthansa –**
**Discounted Travel for Qualified Person Forum 2012 Attendees**

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 Christian Hösch,** *Ministry of Health and Consumer Protection, Hamburg, Germany*
GMP inspector and member of the ZLG Expert Groups Quality Assurance and Inspections.

**Frithjof Holtz,** *IPEC Europe*
Vice Chair of the International Pharmaceutical Excipients Council Europe and Director Advocacy Pharm Chemicals Solutions at Merck KGaA.

**Anne Junttonen,** *Finnish Medicines Agency, Finland*
Senior Pharmaceutical Inspector and leader of the EMA GDP/GMP IWG revising Annex 16.

**Riccardo Luigetti, European Medicines Agency (EMA), U.K.**
Senior Scientific Administrator

**Dr Pierre Poitou,** *Ordre National des Pharmaciens, France*
Member of the Industry Section Board of the 'Ordre National des Pharmaciens', corresponding Member of the French National Academy of Pharmacy.

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

**Rudolf Völler,** *GMP Inspectorate Darmstadt, Germany*
Director of the GMP Inspections Department of Hessen, Germany.

**Speakers from the Industry:**

**Richard M. Bonner,** *formerly with Eli Lilly, U.K.*
Qualified Person, Advisory Board member of the Qualified Person Association.

**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 Pierre-Jean Consalvi,** *Merial, France*
Qualified Person for veterinary products.

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

**Georg Göstl,** *Baxter BioScience, Austria*
Qualified Person and Head of Quality Assurance.

**Johannes Heusler,** *Roche Pharma AG, Germany*
Qualified Person in Training.

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

**Dr Ulrich Kissel,** *Roche Pharma AG, Germany*
Qualified Person.

**Henny Koch**
qimp Management Systems B.V., Netherlands
Managing Director.

**Aidan Madden,** *FivePharma, Ireland*
Director and Senior Consultant. Formerly with Wyeth, Baxter and Fort Dodge Laboratories.

**Dr Jean-Denis Mallet,** *SNC Lavalin, France*
Director Pharma Europe, formerly Head of the French Pharmaceutical Inspection Department (AFSSAPS). Member of the Advisory Board of the ECA Foundation.

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

**York Moeller,** *J.A.Moeller Chongqing, China*
Located in China to support European and US companies to deal with government authorities, plants and distributors in China.

**Dr Dr Dierk Rebeski,** *Lohmann Animal Health, Germany*
Qualified Person Vaccines.

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

**Dr Bernd Renger,** *EQPA*
Chairman of the QP Association Advisory Board.

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

**Dr Stephan Rönninger,** *F. Hoffmann-La Roche, Switzerland*
Head of External Collaboration Europe/Japan/CEMA at F. Hoffmann-La Roche and deputy topic leader for EFPIA in the ICH Q–IWG.

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

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

**Martine Tratsaert,** *Johnson & Johnson, Belgium*
Senior Director Market Quality EMEA.

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

**Date Full Day Pre-Conference Session:**
Specific Requirements for IMPs
Wednesday, 21 November 2012, 9.30 – 18.00
(Registration and coffee: 9.00 – 9.30)

**Date ½ Day Pre-Conference Session:**
The changing Role of the QP in a changing Environment
Wednesday, 21 November 2012, 13.00 – 18.00
(Registration, snacks and coffee: 12.30 – 13.00)

**Date ½ Day Pre-Conference Session:**
QP Challenges in the Veterinary Industry
Wednesday, 21 November 2012, 13.30 – 18.00
(Registration, snacks and coffee: 13.00 – 13.30)

**Welcome Reception for all participants**
Wednesday, 21 November 2012, 18.00 – 19.00

**Date QP Forum**
Thursday, 22 November 2012, 9.00 – 18.00
(Registration: Wednesday, 21 November 18.00 – 19.00 and
Thursday 22 November 2012, 08.00 – 9.00)
Friday, 23 November 2012, 8.30 – 15.00

**Venue**
Sofitel Hamburg Alter Wall
Alter Wall 40
20457 Hamburg
Germany
Tel.: +49 (0)40 36950 0

**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 changing Role of the QP in a changing Environment**
€ 690,- 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:**
**QP Challenges in the Veterinary Industry**
€ 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 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 € 180,- per night incl. breakfast) for the duration of your stay. Reservation should be made directly with the hotel not later than 20 September 2012. 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:

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

D-69007 Heidelberg

## Reservation Form (Please complete in full)

☐ **Qualified Person Forum 2012,** Hamburg, Germany, 22-23 November 2012
Please choose **three of the six** parallel sessions:
☐ Session 1: What the QP needs to know about Supplies from China
☐ Session 2: The QP and Risk Management
☐ 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
☐ Session 5: The changing Role of the Pharmacopoeia and what's the Impact on Batch Release
☐ Session 6: Work Organisation and Time Management for QPs

☐ **Optional Pre-Conference Session,** Hamburg, Germany, 21 November 2012
Please choose **one of the following**:
☐ Full Day Session "Investigational Medicinal Products"
☐ 1/2 Day Session "The changing Role of the QP in a changing Environment"
☐ 1/2 Day Session "QP Challenges in the Veterinary Industry"

☐ 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.