Speakers from Authorities and Public Health Organisations:

Klaus Eichmüller
German GMP Inspectorate
Dr Rainer Gnibl
Government of Upper Franconia
Paul Hargreaves
MHRA and PIC/S Chairman
Mag.pharm. Andreas Kraßnigg
Austrian Agency for Health and Food Safety (AGES)
Mag. Dr Christina Meissner
Austrian Agency for Health and Food Safety (AGES)
Gillian Renouf
Royal Pharmaceutical Society QP Assessment Panel

Speakers from the Industry:

Justin Barry
Midatech Pharma España
Richard M. Bonner
Chairman of the EQPA, form. with Eli Lilly
Dr Susanne Ding
Boehringer Ingelheim
DI Georg Göstl
Baxter AG
Tor Gråberg
AstraZeneca
Tricia Harbinson
Pfizer
Dr Afshin Hosseiny
Tabriz Consulting
Dr Ulrich Kissel
Roche Pharma
Dr Line Lundsberg-Nielsen
NNE Pharmaplan
Aidan Madden
FivePharma
Dr Jean Denis Mallet
Form Head of the French Pharmaceutical Inspection Department
Sue Mann
Sue Mann Consultancy
Ann McGee
McGee Pharma International form. Irish Health Products Regulatory Authority
Marie O'Callaghan
Genzyme
Dr Bernd Renger
Immediate Past Chairman of the EQPA
Markus Roemer
comes compliance services
Dr Andreas Schwinn
Roche Pharma
Niina Taylor
Pfizer
Andrew Teasdale
AstraZeneca
Brenda Van Assche
Janssen Pharmaceutica NV
Philippe Van der Hofstadt
B&C Group

Invitation
to the

QP ASSOCIATION

Qualified Person Forum 2016

Madrid, Spain 1 – 2 December 2016

With three Pre-Conference Sessions
on 30 November 2016:

Investigational Medicinal Products (full day)

The new Annex 16: Quality Risk Management for QPs (1/2 day)

Supply Chain Challenges (1/2 day)

Welcome

Dear Colleagues,

In the last ten years, the European QP Association Forum has been becoming a major event for European Qualified Persons.

Speakers from EMA, FDA 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 this unique Forum, the Advisory Board of the QP Association has set up the programme at hand for the 11th QP 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 outstanding event, and I look forward to meeting you.

Best regards,

Richard M. Bonner
Chairman of the Qualified Person Association

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

Aidan Madden

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

Pre-Conference Sessions

30 November 2016

Full Day Pre-Conference Session

Specific Requirements for IMPs
Facilitated by:
IMP Working Group

- New legislation impacting IMP QPs
- Revised Annex 16 – lessons learned
- Advanced Therapy Medicinal Products (ATMPs): regulatory requirements, GMP and the grey zones
- Quality Assurance Agreement / QP to QP agreement for clinical trial manufacture
- Interactive sessions
- Q & A sessions

1/2 Day Pre-Conference Session

The new Annex 16: Quality Risk Management for QPs
Facilitated by:
Richard M. Bonner / Aidan Madden

The term "quality risk management" is used throughout the new Annex 16. But how could the QP use this tool? In this session you will get some practical advice!

1/2 Day Pre-Conference Session

The Falsified Medicines Directive (FMD): Supply Chain Challenges and Solutions for QPs

Facilitated by:
Georg Göstl / Afshin Hosseiny / Andreas Kraßnigg / Sue Mann

- What the QP needs to know to allow successful implementation of the FMD requirements
- Preparing for transition of the verification process
- What is the QP's role in preparation, implementation and validation of the product verification systems
- What systems do we need to have in place to manage issues with the Supply Chain

Programme QP Forum

1 – 2 December 2016

What the QP needs to know about the new Annex 15
- The influence on the work and responsibility of the QP
- Expectation of an inspector
  - ➲ Klaus Eichmüller

What the QP needs to know about Serialisation
- Implementation of the FMD: influence on batch documentation and certification
- Challenges for industry and especially the QP
  - ➲ Jean-Denis Mallet

The Detection of falsified Medicines
- The protection of the public and how the QP could support this
  - ➲ Paul Hargreaves

What the QP should know about Out of Stock Situations
- Reasons
- Management
- Co-operation with the authorities
  - ➲ Tor Gråberg

Case Study on the QP Declaration
- Challenges and possible solutions
- Experiences made
  - ➲ Ulrich Kissel

Elemental Impurities: global Approaches and possible Solutions
- What are the global challenges (different expectations, different directions?)
- What is the role and responsibility of the QP?
- Case study
  - ➲ Andrew Teasdale

Parallel Sessions

Working on Case Studies

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

2) The QP and ICH Q8/ Q12
- The link to PAT and Real Time Release
- Batch documentation and batch certification: things to consider for QPs
  - ➲ Line Lundsberg-Nielsen and Afshin Hosseiny

3) QP Scenarios – How serious could they be?
- Make decisions based on real-life situations
  - ➲ Sue Mann and Gillian Renouf

4) Quality Oversight of IMP QPs in global Supply Chains
- Maintaining quality oversight at relevant interfaces
- Testing of IMPs in various scenarios (importation, intercompany-, intracompany shipments)
- QP GMP declaration for 3rd country IMP manufacture
  - ➲ IMP Working Group

5) Data Integrity: Why it is so important for QPs
- How can the QP be sure about the integrity of data: what to focus on, what to check
  - ➲ Markus Roemer and N.N. (speaker invited)

6) Quality Metrics vs. Quality Parameters
- What are the different expectations in the EU and the US
- What is important for QPs
- How to interpret data
- How the QP can use quality data reviews for their daily work
  - ➲ Ann McGee and Marie O'Callaghan

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 you can post your questions on a bulletin board. Expert speakers will then provide answers in a dedicated session. This session will also be published in the members' area of the EQPA website.

Social Event

On 1 December you are cordially invited to a social event in Madrid. 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:

Klaus Eichmüller, *Regional Competent Authority, Germany*
Head of the Inspectorate for Drug Products, APIs, Blood Products and Tissues in Hesse.

Dr Rainer Gnibl, *Government of Upper Bavaria, Germany*
GMP Inspector for the District Government and the EMA, Advisory Board member of the Qualified Person Association.

Paul Hargreaves, *Medicines & Healthcare Products Regulatory Agency (MHRA), U.K.*
Expert Medicines Inspector and PIC/S Chairman.

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

Mag. Dr Christina Meissner, *Austrian Agency for Health and Food Safety (AGES), Austria*
GMP Inspector.

Gillian Renouf, *Royal Pharmaceutical Society QP Assessment Panel, U.K.*
Chair of the RPS QP Assessment Panel.

Speakers from the Industry:

Justin Barry, *Midatech Pharma España, Spain*
Managing Director.

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

Dr Susanne Ding, *Boehringer Ingelheim, Germany*
Qualified Person for Investigational Medicinal Products, Advisory Board member of the Qualified Person Association.

DI Georg Göstl, *Baxter AG, Austria*
Qualified Person and Chair of the Austrian QP Association aqpa.

Tor Gråberg, *AstraZeneca, Sweden*
Head of External Advocacy, Global Quality, Operations, Advisory Board member of the Qualified Person Association. Former Head of the Drug Inspectorate at the Swedish Medical Products Agency and former PIC/S Chair.

Tricia Harbinson, *Pfizer, U.K.*
Qualified Person for IMPs.

Dr Afshin Hosseiny, *Tabriz Consulting, U.K.*
Managing Director and Qualified Person, Co-Chair of the ECA Executive Board and Chair of the ECA GDP Group.

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

Dr Line Lundsberg-Nielsen, *NNE Pharmaplan., U.K.*
Senior QbD & PAT Consultant; Chair of the ISPE PQLI Control Strategy Team.

Aidan Madden, *FivePharma, Ireland*
Managing Director and Senior Consultant

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

Dr Jean Denis Mallet, *NNE Pharmaplan, France*
Former Head of the French Pharmaceutical Inspection Dpt. AFSSAPS (now ANSM), Chair of the ECA Validation Group.

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

Marie O'Callaghan, *Genzyme (a Sanofi Company), Ireland*
Quality Systems & Compliance Team Leader.

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

Markus Roemer, *comes compliance services, Germany*
Managing Director.

Dr Andreas Schwinn, *Roche Pharma AG, Germany*
Qualified Person for IMP Release and Head of the Release Preparation Group.

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

Dr Andrew Teasdale, *AstraZeneca, U.K.*
Chair of AstraZeneca Impurities Advisory Group.

Brenda Van Assche, *Janssen Pharmaceutica NV, Belgium*
Qualified Person.

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

Other speakers invited

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 2016,** Madrid, Spain, 1-2 December 2016
Please choose **three of the six** parallel sessions:
☐ Session 1: Update on GMP-relevant topics: what QPs are expected to do
☐ Session 2: The QP and ICH Q8/ Q12
☐ Session 3: QP Scenarios – How serious could they be?
☐ Session 4: Quality Oversight of IMP QPs in global Supply Chains
☐ Session 5: Data Integrity: Why it is so important for QPs
☐ Session 6: Quality Metrics vs. Quality Parameters

☐ **Optional Pre-Conference Session**, Madrid, Spain, 30 November 2016
Please choose **one of the following**:
☐ Full Day Session "Investigational Medicinal Products"
☐ 1/2 Day Session "The new Annex 16: Quality Risk Management for QPs"
☐ 1/2 Day Session "The Falsified Medicines Directive (FMD): Supply Chain Challenges and Solutions 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.

Date Full Day Pre-Conference Session:
Specific Requirements for IMPs
Wednesday, 30 November 2016, 9.30 – 18.00
(Registration and coffee: 9.00 – 9.30)

Date ½ Day Pre-Conference Session:
The new Annex 16: Quality Risk Management for QPs
Wednesday, 30 November 2016, 13.00 – 17.45
(Registration, snacks and coffee: 12.30 – 13.00)

Date ½ Day Pre-Conference Session:
FMD: Supply Chain Challenges and Solutions for QPs
Wednesday, 30 November 2016, 13.30 – 18.00
(Registration, snacks and coffee: 13.00 – 13.30)

Welcome Reception for all participants
Wednesday, 30 November 2016, 18.00 – 19.00

Date QP Forum
Thursday, 01 December 2016, 9.00 – 18.00
(Registration: Wednesday, 30 November 18.00 – 19.00 and
Thursday 01 December, 08.00 – 9.00)
Friday, 02 December 2016, 8.30 – 14.30

Venue
Meliá Castilla
Capitán Haya 43
28020 Madrid
Spain
Tel.: +34 91 567 50 77
Fax: +34 91 567 50 66

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 new Annex 16: Quality Risk Management 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.

Fees for ½ Day Pre-Conference Session:
FMD: Supply Chain Challenges and Solutions 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 155,- Euros per night incl. breakfast, excl. 10% tax) for the duration of your stay. Reservation should be made directly with the hotel not later than 15 October 2016. 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
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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.