Speakers from Authorities, Inspectorates and Associations:

Dr Daniela Allhenn
German Medicines Manufacturers' Association (BAH)
Dr Rainer Gnibl
Government of Upper Bavaria
Mag.pharm. Andreas Kraßnigg
Austrian Agency for Health and Food Safety (AGES)
Martine Powell
Medicines and Healthcare Products Regulatory Agency (MHRA), U.K.
Gillian Renouf
Royal Pharmaceutical Society QP Assessment Panel
Dr Sabine Sereinig
Austrian Agency for Health and Food Safety (AGES)
Paul Sexton
Irish Health Products Regulatory Authority (HPRA)

Speakers from the Industry:

Justin Barry
J&JB Consulting
Richard M. Bonner
Immediate Past Chairman of the EQPA
David Cockburn
EQPA
Sipi Dhaliwal
Merck Sharp & Dohme
Dr Susanne Ding
Boehringer Ingelheim
DI Georg Göstl
Shire
Tor Gråberg
AstraZeneca
Dr Afshin Hosseiny
Tabriz Consulting
Dr Ulrich Kissel
EQPA
Cristina De Simoni Klitgaard
Novo Nordisk
Aidan Madden
FivePharma
Sue Mann
Sue Mann Consultancy
Ann McGee
PharmaLex
Dr Maria Polley
Roche
Dr Bernd Renger
Immediate Past Chairman of the EQPA
Andreas Schwinn
Roche Pharma
Niina Taylor
Pfizer
Brenda Van Assche
Janssen
Philippe Van der Hofstadt
Clinical Supplies Management
Gunter Van Hoof
Clinical Supplies Management
Guy Villax
Hovione
Jan Voß
Medac

Invitation to the

Qualified Person Forum 2018

Prague, Czech Republic, 29-30 November 2018

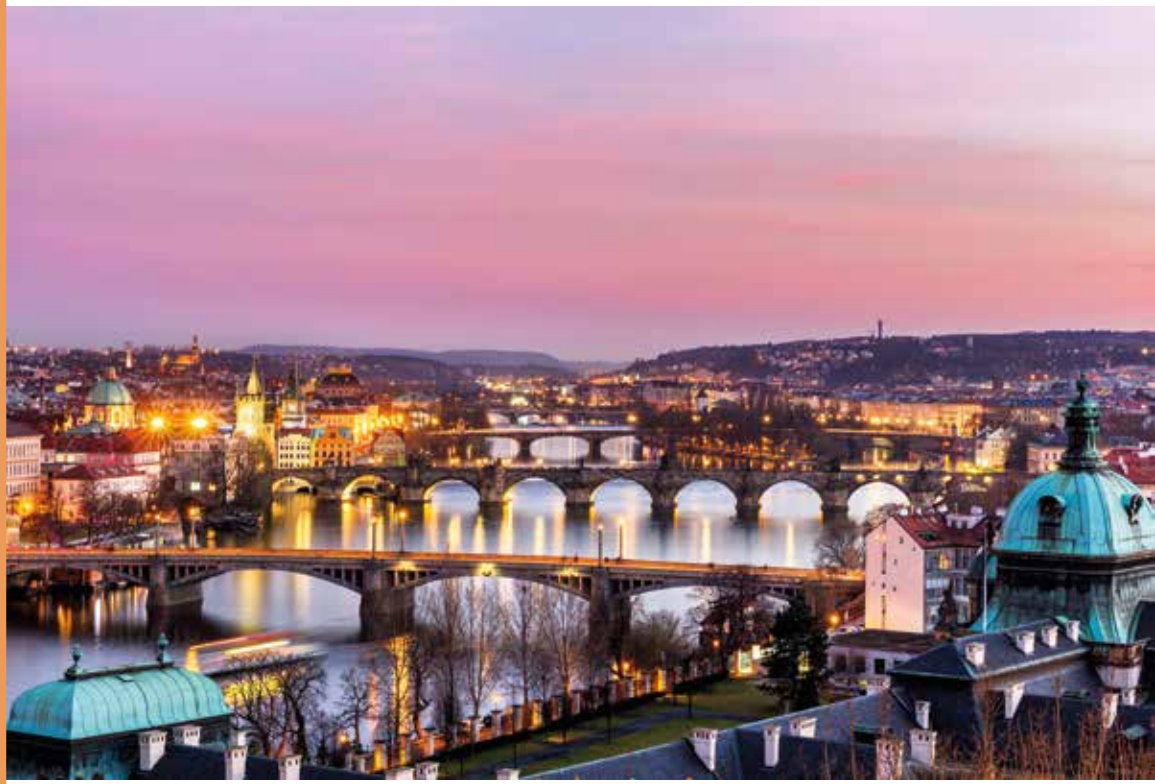
With three Pre-Conference Sessions

on 28 November 2018:

Specific Requirements for Investigational Medicinal Products (full day)

Surviving and excelling as a new QP (1/2 day)

Serialisation: What is important for the QP (1/2 day)



QP ASSOCIATION

Welcome

Dear Colleagues,

In the last twelve years, the QP Forum of the European QP Association 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 this programme for the 13th 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 consider possible solutions.

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

I would like to invite you to this outstanding event, and I look forward to meeting you.

Best regards,

Dr Ulrich Kissel
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 one week before and after the conference.
Note: there will be no print-outs available during the conference.

Pre-Conference Sessions

28 November 2018

Full Day Pre-Conference Session on IMPs: Transitioning to new IMP GMPs

Specific Requirements for IMPs

Facilitated by:

Justin Barry / Susanne Ding / Martine Powell / Niina Taylor / Brenda Van Assche / Philippe Van der Hofstadt / Andreas Schwinn / Gunter van Hoof

- New legislation impacting IMP QPs
- The IMP order
- Interactive sessions and case studies – decision making of IMP QPs
- Survey results "To delegate or not to delegate"
- The inspector's view
- Q&A sessions

1/2 Day Pre-Conference Session

Surviving and excelling as a new QP

Facilitated by:

Sue Mann / Sipi Dhaliwal / Maria Polley / Jan Voß

- Knowledge Management – how to get involved
- Soft skills needed
- Change Management: how to initiate and implement necessary system changes
- Where to look for help
- Case studies: how to discuss deviations with a senior production manager; how to deal with out-of-date traditions; senior management tries to overrule decision – what to do

1/2 Day Pre-Conference Session

Serialisation: What is important for the QP

Facilitated by:

Ulrich Kissel / Daniela Allhenn / Afshin Hosseiny / Andreas Kraßnigg

- Delegated Act for the Safety Features: the impact for the QP
- securPharm: Experiences made and what to learn from them
- Challenges and possible solutions

Programme QP Forum

29-30 November 2018

Being a QP - why do I have the best Job in the World? Key Note

- Why I was choosing to become a QP
- What is behind being a QP
- Enjoy your job!

Aidan Madden

Update on International Developments and their possible Impact on GMP and Manufacturers

- Brexit
- MRA with FDA and other MRAs

David Cockburn

GMP Update Session

New Regulations and Guidance and their relevance for the QP

- Annex 1
- ICH Q12
- Others

Rainer Gnibl and Tor Gråberg

How to report serious GMP Deviations and Fraud

- EMA Policy Guide 0072 on "Handling of information from external sourcing disclosing alleged improprieties"
- Deviations/fraud at subcontractors and/or raw material suppliers
- Deviation/fraud at own premises
- What are the obligations of the QP in serious cases

Martine Powell

Data Integrity: Examples why Data Governance is important for QPs

- Examples why Data Governance is important for QPs
- What to look for

Rainer Gnibl

Quality Culture is what allows me (and the QP) to sleep well at Night

- Compliance versus Quality
- Why does the tone need to be set at the top
- What is evidence of a quality culture
- When things go wrong: what matters is how you deal with it

Guy Villax

Parallel Sessions

Working on Case Studies

1) How to deal with post-marketing Issues
- There is more than just Complaint and Recall Handling
- How to react as a QP?
- To notify or not?

Richard Bonner, Georg Göstl and Sabine Sereinig

2) KPIs and Quality Metrics for QPs
- Meaningful KPIs for QPs and what to learn from them
- How KPIs can create wrong behaviour
- Involvement of the QP
- Examples for good KPIs for QPs

Ulrich Kissel and Cristina De Simoni Klitgaard

3) QP Scenarios – How serious could they be?
- Make decisions based on real-life situations

Sue Mann and Gillian Renouf

4) Changes at the GMP-GCP Interface

Continuing to shed light on grey zones and sharing experiences

IMP Working Group

5) Supply Chain Diagram and Overview
- How to implement chapter 1.7.2 of Annex 16
- Why Supply Chain overview is more than just a diagram
- The GDP interface

Afshin Hosseiny and Bernd Renger

6) CMO Oversight – the QP Perspective
- What does Quality Oversight mean for a QP
- How to deal with the various quality and documentation systems at different CMOs
- Management of significant cGMP compliance problems (is there a "warning system"?)
- Information and communication
- Maintenance and monitoring

Paul Sexton and Ann McGee

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, delegates can post their questions. The answers will be given by the expert speakers in a dedicated session and/or published in the members' area of the EQPA website.

Social Event

On 29 November, you are cordially invited to a social event in Prague (city tour and Dinner). This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

Lufthansa Official Airline

Special Offer with Lufthansa – Discounted Travel

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, Inspectorates and Associations:

Dr Daniela Allhenn, *German Medicines Manufacturers' Association BAH, Germany*
Manager Pharmaceutical Technology/ GMP

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

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

Martine Powell, *Medicines and Healthcare Products Regulatory Agency (MHRA), U.K.*
GMDP Inspector, Inspection, Enforcement and Standards Division

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

Dr Sabine Sereinig, *Austrian Agency for Health and Food Safety (AGES), Austria*
Assessor

Paul Sexton, *Health Products Regulatory Authority (HPRA), Ireland*
GMP Inspector

Speakers from the Industry:

Justin Barry, *J&JB Consulting, Spain*
Qualified Person and member of the EQPA IMP Working Group Board

Richard M. Bonner
Immediate Past Chairman of the EQPA and of the ECA Foundation

David Cockburn, *European Qualified Person Association (EQPA)*
Member of the EQPA Board of Directors. Former Chair of the EMA GMP/ GDP IWG

Sipi Dhaliwal, *Merck Sharp & Dohme Ltd., U.K.*
Qualified Person and Associate Director Development Quality

Dr Susanne Ding, *Boehringer Ingelheim, Germany*
Qualified Person for Investigational Medicinal Products and member of the EQPA Board of Directors

DI Georg Göstl, *Shire, Austria*
Qualified Person, Chair of the Austrian QP Association aqpa and member of the EQPA Board of Directors

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

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

Dr Ulrich Kissel, *European Qualified Person Association (EQPA)*
Qualified Person and Chairman of the EQPA Board of Directors

Cristina De Simoni Klitgaard, *Novo Nordisk A/S, Denmark*
Director Quality Assurance and Qualified Person

Aidan Madden, *FivePharma, Ireland*
CEO

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, *PharmaLex, Ireland*
Managing Director and form. Senior Inspector of the Irish Medicines Board (now HPRA)

Dr Maria Polley, *Roche Pharma AG, Germany*
Qualified Person

Dr Bernd Renger, *European Qualified Person Association (EQPA)*
Immediate Past Chairman of the EQPA

Andreas Schwinn, *Roche Pharma AG, Germany*
Head PQIP, Qualified Person

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

Brenda Van Assche, *Janssen Pharmaceutica NV, Belgium*
Director Quality Assurance Clinical Supply Chain and Qualified Person

Philippe Van der Hofstadt, *Clinical Supplies Management, Belgium*
EU President

Gunter Van Hoof, *Clinical Supplies Management, Belgium*
Vice President EU Operations

Guy Villax, *Hovione, Portugal*
CEO

Jan Voß, *Medac GmbH, Germany*
Qualified Person

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 2018,** Prague, Czech Republic, 29-30 November 2018
Please choose **three of the six** parallel sessions:
☐ Session 1: How to deal with post-marketing Issues
☐ Session 2: KPIs and Quality Metrics for QPs
☐ Session 3: QP Scenarios – How serious could they be?
☐ Session 4: IMP QPs implementing Annex 16 and the new IMP GMP regulation
☐ Session 5: Supply Chain Diagram and Overview
☐ Session 6: CMO Oversight – the QP Perspective

☐ **Optional Pre-Conference Session**, Prague, Czech Republic, 28 November 2018
Please choose **one of the following**:
☐ Full Day Session "Specific Requirements for IMPs"
☐ 1/2 Day Session "Surviving and excelling as a new QP"
☐ 1/2 Day Session "Serialisation: What is important for the QP"

☐ 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 300 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, 28 November 2018, 9.00 – 18.00
(Registration and coffee: 8.30 – 9.00)

Date ½ Day Pre-Conference Session:
Surviving and excelling as a new QP
Wednesday, 28 November 2018, 13.30 – 18.00
(Registration, snacks and coffee: 13.00 – 13.30)

Date ½ Day Pre-Conference Session:
Serialisation: What is important for the QP
Wednesday, 28 November 2018, 13.00 – 18.00
(Registration, snacks and coffee: 12.30 – 13.00)

Welcome Reception for all participants
Wednesday, 28 November 2018, 18.00 – 19.00

Date QP Forum
Thursday, 29 November 2018, 9.00 – 18.00
(Registration: Wednesday, 28 November 18.00 – 19.00 and
Thursday, 29 November, 08.00 – 9.00)
Friday, 30 November 2018, 8.30 – 14.30

Venue
InterContinental Praha
Pařížská 30
110 00 Praha 1
Czech Republic
Tel: +420296631111 / Fax: +420224811216
Email: prague@icprague.com

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:
Surviving and excelling as a new QP
€ 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:
Serialisation: What is important for the QP
€ 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.

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 145,- Euros per night incl. breakfast, excl. 15% VAT) for the duration of your stay. Reservation should be made directly with the hotel not later than 6 October 2018. Early reservation is recommended.

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.

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.