ECA | QP ASSOCIATION
An ECA Foundation Interest Group

QUALIFIED PERSON FORUM 2020

BENEFIT FROM UP TO 400 € DISCOUNT FOR REGISTRATIONS UNTIL 31 AUGUST

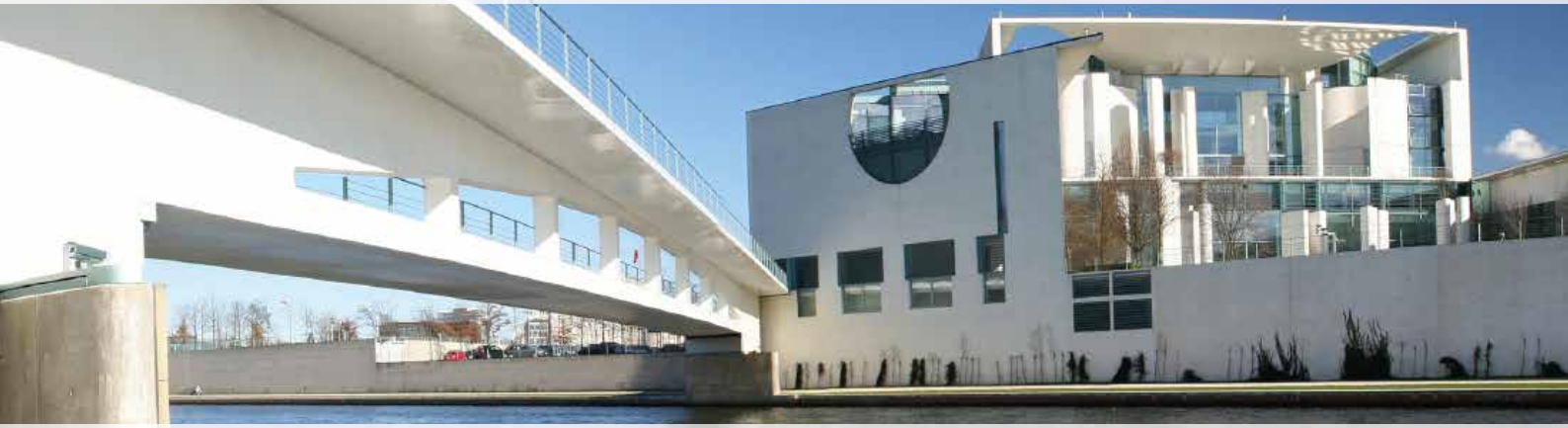
26-27 NOVEMBER 2020

Face-to-Face: BERLIN, GERMANY | Remotely: LIVE ONLINE

PRE-CONFERENCE SESSIONS ON 25 NOVEMBER 2020

Specific Requirements for IMPs (full day) | Human Error (1/2 day) | Serialisation re-revisited (1/2 day)

QP FORUM APP* | Scan Code for Installation



Speakers from Authorities, Inspectorates and Associations:

Dr Rainer Gnibl
Government of Upper Bavaria, Germany
Anne Hayes
Irish Health Products Regulatory Authority (HPRA) and PIC/S
Mag.pharm. Andreas Kraßnigg
Austrian Agency for Health and Food Safety (AGES)
Catherine Neary
Irish Health Products Regulatory Authority (HPRA)
Gillian Renouf
Royal Pharmaceutical Society QP Assessment Panel, U.K.

Speakers from Industry:

Richard M. Bonner
former Chairman of the EQPA
David Cockburn
EQPA
Cristina De Simoni Klitgaard
Novo Nordisk
Sipi Dhaliwal
Merck Sharp & Dohme
Dr Fabienne Diekmann
Diekmann Lawyers
Dr Susanne Ding
Boehringer Ingelheim
DI Georg Göstl
Takeda
Tor Gråberg
AstraZeneca
Dr Afshin Hosseiny
ECA
Patryk Jegorow
Takeda
Dr Ulrich Kissel
EQPA
Karsten Lollike
Novo Nordisk
Aidan Madden
FivePharma
Sue Mann
Sue Mann Consultancy
Dr Peer Schmidt
AbbVie
Dr Wolfgang Schumacher
form. F. Hoffmann-La Roche
Dr Andreas Schwinn
Roche
Kristina Smith Hansen
Leman
Niina Taylor
Pfizer
Brenda Van Assche
Janssen

(other speakers invited)

WELCOME

Dear Colleagues,

This year is a special year and will be remembered for a long time. The **Covid-19 pandemic** is shaping our professional environment as well as our private lives. But life goes on and we, especially as QPs, need and want to educate ourselves.

Therefore the EQPA Board has decided to **offer this year's QP Forum as both a face-to-face meeting in Berlin and as a live online conference**. All lectures and sessions will be held consecutively and can be attended either directly on site in Berlin or live online at your screen at home.

You can benefit from the Early Bird offer and register for the QP Forum now and decide later how you will participate.

Make use of this event and continue with your ongoing training and further improve your skills and knowledge.

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 challenging parts of the QP's daily work.

The Focus this year will be on interfaces and interaction with other functions.

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 Sessions will be available for download and your print-out one week before and after the conference.

*QP FORUM APP (available from September 2020)

Just download the QP Forum app to your smartphone or tablet and have everything at hand: agenda, presentations, speaker backgrounds, notifications and more... To install the app, please scan the QR code or search for "Pharma Events" in the Apple or the Google Play Store.

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

PRE-CONFERENCE SESSIONS

25 November 2020

FULL DAY PRE-CONFERENCE SESSION

Specific Requirements for IMPs

Facilitated by:
Susanne Ding / Patryk Jegorow / Catherine Neary / Andreas Schwinn / Niina Taylor / Brenda Van Assche

- New legislation impacting IMP QPs
- Interactive sessions and case studies – decision making for IMP QPs
- Phase appropriate GMP
- IMP QP involvement in Compassionate Use, Named Patient Use and Early Access Programs
- Use of comparators in clinical studies and IMP QP involvement
- Identification of potential risks for IMP QPs and their mitigation strategies
- Q&A sessions

1/2 DAY PRE-CONFERENCE SESSION

Human Error

Facilitated by:
Sue Mann / Kristina Smith Hansen

- What is behind "Human Error"?
- Considering human behaviours
- Is Human error avoidable?
- Tips for reducing human errors

1/2 DAY PRE-CONFERENCE SESSION

Serialisation re-revisited

Facilitated by:
Afshin Hosseiny / Ulrich Kissel

More than twenty months after implementation and still challenging: Discuss occurring challenges and the impact on the QP's daily life and find answers and solutions.

PROGRAMM QP FORUM

26-27 November 2020

Key Note: Quality Culture

Kristina Smith Hansen

- Why the focus on Quality Culture?
- Why is it important for QPs?
- Who creates culture and how?
- The role of the QP within the company's culture

The PIC/S GMP Inspection Reliance Initiative

Anne Hayes

- How PIC/S and ICMRA aim to maximise inspection resources for GMP compliance of overseas facilities
- The possibility of desk-top assessments of GMP compliance of overseas facilities
- Benefits for both Industry and Regulatory Authorities

QP between Import and Export – the Impact from Annex 21 and Brexit

Tor Gråberg and Sipi Dhaliwal

- Applicable and new Guidance
- Current and future role of the QP in import and export activities
- Necessary QP Supply Chain oversight
- The QP/RP interface
- Practical examples

The Role of the QP in the Company (A Code of Practice for QPs)

Richard M. Bonner, Georg Göstl and Ulrich Kissel

- Various interfaces
- Hierarchy and discretionary power
- Organisation-chart and job description
- How to foster decision making and autonomy
- How to fulfil QP duties in a global environment

Challenges for IMP QPs

IMP Working Group

- Relationship between Sponsor and IMP QPs
- Brexit considerations

QP Scenarios – How serious could each Issue be?

Sue Mann and Gillian Renouf

- Discuss real-life situations involving QPs
- Explore the potential risks and impact
- Make decisions on the product(s) involved

Liability and Delimitation of Responsibilities within a Company

Fabienne Diekmann

- Delimitation of Responsibilities within
  - same site
  - different sites in the same country
  - different legal entities in different countries
- Delimitation of responsibilities without contract
- Allocation of responsibilities and liability to Head of QC, Head of Production and MAH
- Amending employment contracts to include delimitation of responsibility

The QP - QPPV Interface

Cristina De Simoni Klitgaard and Karsten Lollike

- Interfaces and delimitation of the responsibilities
- Why co-operation is important (with examples)
- How to foster co-operation
- Benefits and limits

The new Annex 1 – what QPs should expect

Aidan Madden and Andreas Krassnigg

- The most important changes
- Influence on the QP certification process
- Risk-based approach

Demystify Data Integrity: What's really important for QPs

Wolfgang Schumacher and Rainer Gnibl

- Data Governance and batch certification
- Batch Record and Audit Trail Review
- What are the critical data?

How to certify Drug-Device Combinations (DDCs, Combination Products)

Peer Schmidt

- What the QP needs to know about the new Medical Devices regulations
- Responsibilities of the QP when certifying DDCs
- How to ensure that the medical device part meets the general EU safety and performance requirements
- How to prove compliance with medical device regulations

Frequently asked Questions

David Cockburn

- Benefits of the EQPA discussion forum
- Answers to the most frequent questions
- Interesting issues and possible solutions

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.

SPEAKERS

Speakers from Authorities, Inspectorates and Associations:

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

Anne Hayes, *Health Products Regulatory Authority (HPRA), Ireland*
Inspection Manager at HPRA and PIC/S Chairperson

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

Catherine Neary, *Irish Health Products Regulatory Authority (HPRA)*
GMP Operations Manager

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

Speakers from Industry:

Richard M. Bonner, *U.K.*
Former Chairman of the EQPA Board of Directors and former Chair of the ECA Executive Board

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, U.K.*
Associate Director and Qualified Person

Cristina De Simoni Klitgaard, *Novo Nordisk, Denmark*
Vice President Customer Complaint Center, Global Safety

Dr Fabienne Diekmann, *Diekmann Lawyers, Germany*
Lawyer with main focus on pharmaceutical industry

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

DI Georg Göstl, *Takeda, 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

Patryk Jegorow, *Takeda, Ireland*
Qualified Person Biologics, Head of Quality Strategy and Business Operations

Dr Ulrich Kissel, *KisselPharma Consulting*
Qualified Person and Chairman of the EQPA Board of Directors

Karsten Lollike, *Novo Nordisk, Denmark*
Corporate Vice President and QPPV

Aidan Madden, *FivePharma, Ireland*
CEO and Qualified Person

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 Peer Schmidt, *AbbVie, Germany*
Senior Manager Global Quality Systems

Dr Wolfgang Schumacher, *formerly F. Hoffmann-La Roche Ltd., Switzerland*
Former Head of the Quality Computer Systems department

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

Kristina Smith Hansen, *Leman, Denmark*
Head of Group QSHE & Qualified Person; Founder of MilCor Consulting

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

Date Full Day Pre-Conference Session:
Specific Requirements for IMPs
Wednesday, 25 November 2020, 9.00 – 18.00 h
(Registration and coffee: 8.30 – 9.00 h)

Date ½ Day Pre-Conference Session:
Human Error
Wednesday, 25 November 2020, 13.30 – 18.00 h
(Registration, snacks and coffee: 13.00 – 13.30 h)

Date ½ Day Pre-Conference Session:
Serialisation re-revisited
Wednesday, 25 November 2020, 13.00 – 18.00 h
(Registration, snacks and coffee: 12.30 – 13.00 h)

Welcome Reception for all participants
Wednesday, 25 November 2020, 18.00 – 19.00

Date QP Forum
Thursday, 26 November 2020, 9.00 – 18.00 h
(Registration: Wednesday, 25 November 18.00 – 19.00 h and
Thursday 26 November, 08.00 – 9.00 h)
Friday, 27 November 2020, 8.30 – 14.30 h

Venue
Radisson Blu Hotel Berlin **NEW**
Karl-Liebknecht-Straße 3
10178 Berlin
Germany
Phone: +49 (0)30 238 28 0
E-Mail: info.berlin@radissonblu.com

Fees for QP Forum
QP Association Members € 1.690,- per delegate plus VAT.
EU GMP Inspectorates € 895,- per delegate plus VAT.
Non-QP Association Members € 1.890,- per delegate plus VAT.
The conference fee is payable in advance after receipt of invoice. VAT is reclaimable.

Fees for Full Day Pre-Conference Session:
Specific Requirements for IMPs
€ 990,- per delegate plus VAT.
The fee is payable in advance after receipt of invoice. VAT is reclaimable.

Fees for ½ Day Pre-Conference Session:
Human Error
€ 590,- per delegate plus VAT.
The fee is payable in advance after receipt of invoice. VAT is reclaimable.

Fees for ½ Day Pre-Conference Session:
Serialisation re-revisited
€ 590,- per delegate plus VAT.
The fee is payable in advance after receipt of invoice. VAT is reclaimable.

Accommodation
You will receive a room reservation link for the hotel when you have registered for the on-site conference.
Reservation should be made directly with the hotel of your choice (using one of the reservation links). Early reservation is recommended.

Saving opportunities – Save up to 400 €! Early Bird now until August!

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.

Early Bird Special for QP Forum: If you register for the Forum until 31 August 2020 you will get an additional **discount of 200 €**.
(Early Bird Special not valid for inspectorate fee)

PLEASE NOTE: You can benefit from the Early Bird offer and register for the QP Forum now and decide later how you will participate – face-to-face in Berlin or remotely at your screen.

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 2020, 26-27 November 2020, Berlin, Germany & Live Online

☐ OPTIONAL PRE-CONFERENCE SESSION, 25 November 2020, Berlin, Germany & Live Online

PLEASE NOTE: To benefit from the Early Bird discounts (until 31 August 2020) you can already register now and decide later how you will participate – face-to-face in Berlin or remotely.

Participation: ☐ in Berlin ☐ remotely ☐ I will decide later

Please choose **one of the following**:
☐ Full Day Session "Specific Requirements for IMPs"
☐ 1/2 Day Session "Human Error"
☐ 1/2 Day Session "Serialisation re-revisited"

☐ 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.