ECA QP ASSOCIATION
An ECA Foundation Interest Group

- BENEFIT FROM UP TO 400 € DISCOUNT FOR REGISTRATION UNTIL 30 JUNE
- WITH SIX PARALLEL SESSIONS TO FOSTER INTERACTION

QUALIFIED PERSON FORUM 2024

AMSTERDAM, THE NETHERLANDS, 28/29 November 2024 | PRE-CONFERENCE SESSIONS, 27 November 2024
Specific Requirements for IMPs | QP Oversight for "Virtual Companies" | QP Liability and Indemnification

Speakers from Authorities, Inspectorates and Associations:

Emer Cooke
European Medicines Agency (EMA)
Brendan Cuddy
European Medicines Agency (EMA)
Rick Friedman
US Food and Drug Administration (FDA)
Dr Rainer Gnibl
GMP Inspector, Head of Inspectorate, Germany
Mag.pharm. Andreas Kraßnigg
Austrian Agency for Health and Food Safety (AGES), Chair of the PIC/S Sub-Committee on Expert Circles

(other GMP Inspectors invited)

Speakers from Industry:

Jyotsna Agnihotry
Flavine
Cheryl Chia
Lotus Phoenix Consulting
David Cockburn
EQPA
Dr Carsten Coors
Vetter Development Services
Dr Susanne Ding
Boehringer Ingelheim
Rebecca Haywood
Pfizer
Cecilie Hejlskov
Syntese
Dr Arnoud Herremans
Y47 Consultancy
Katrien Himpens
J&J Innovative Medicines
Dr Afshin Hosseiny
ECA **Dr Monika Hupfauf**
Nomos Attorneys-at Law
Patryk Jegorow
Takeda
Canice Kearney
Takeda
Dr Ulrich Kissel
EQPA
Dr Aidan Madden
FivePharma
Sue Mann
Sue Mann Consultancy
Madeleine Molster
Sagiure Legal
Dr Umberto M. Musazzi
University of Milan
Sonsee Neu
Stress Counseling
Gillian Renouf
Royal Pharmaceutical Society QP Assessment Panel, U.K.
Niina Taylor
Pfizer

(other speakers invited)

Dear Colleagues,

Times remain challenging for QPs. New and upcoming developments and increasing risks demand full attention and awareness from QPs. This requires continuous learning by exchange with regulators and colleagues to facilitate calibration with peers and adjustments to established concepts to prepare for the presence and future.

We are very delighted to offer with this Forum again the required highest level platform for QPs, representatives of competent authorities and other people interested in the topics presented. Networking is key in these days and we would like to invite all delegates to discuss exactly these challenges and tasks helping you to find solutions.

Make use of this event by exchanging experiences with your colleagues and by establishing informal contacts and networking. I look forward to meeting you in Amsterdam.

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.

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

FULL DAY PRE-CONFERENCE SESSION

Specific Requirements for IMPs

Facilitated by:
Susanne Ding | Rebecca Haywood | Katrien Himpens | Patryk Jegorow | Niina Taylor (other speakers invited)

- Legislation impacting IMP QPs
- Third country IMP GMP inspections
- Inspector's view
- Critical thinking as an IMP QP
- Survey outcome – Clinical Trial Regulation experience
- Quality Culture in the IMP context
- Interactive Case Study
- Q&A sessions

1/2 DAY PRE-CONFERENCE SESSION

QP Oversight for "Virtual Companies" and MAHs

Facilitated by:
Canice Kearney | Sue Mann

- QP responsibilities
- Batch certification – minimum requirements & best practices
- Control and format of Supply Chain Maps and setting the scope of responsibilities
- Post Product Release oversight responsibilities
- Examples and interaction

1/2 DAY PRE-CONFERENCE SESSION

QP Liability and Indemnification

Facilitated by:
Carsten Coors | Afshin Hosseiny | Monika Hupfauf | Madeleine Molster

- Civil and criminal law
- QP liability and indemnification in international comparison (EU)
- Risks in third countries
- Possible legal actions against the QP
- Internal and external liability
- How to deal with pressure from the employer
- Examples

PRESENTATIONS

Opening Address
Emer Cooke

EMA Presentation
Brendan Cuddy
- Topic to be announced soon

Harmonisation between the Agencies
Rick Friedman (remote)
- Acceptance of Annex 1
- FDA's role in PIC/S
- FDA inspections in the EU

Drug Shortages and a Relief from certain Requirements
Umberto M. Musazzi
- Papers published at EU level to mitigate drug shortages
- Aspects with impact on the manufacturing sector
- Shortage management plan
- Potential flexibility in certain GMP requirements

How a Mock Recall can be performed
Jyotsna Agnihotry
- How to plan, execute and document a Mock Recall
- Flow of information before
- Role (and involvement) of the QP

The Present and Future of Digitalisation for the QP
Cheryl Chia
- What is digitalization?
- Where are we now?
- What does this mean to the QP?
- Where do we go from here?

Moderated Panel Discussion on current Developments in GMP
EQPA Board and GMP Inspectors

1) Remote Certification: Are you ready?
Cheryl Chia and Ulrich Kissel
- Applicable guidance
- Things to consider
- Workflows needed

2) Annex 1 Implementation: Is your MIA at Risk?
Rainer Gnibl and Aidan Madden
- How to deal with gaps in the company and at CMOs
- How to mitigate risk
- How to differentiate between risk management and excuse management
- How the QP might influence risk management processes

3) QP Scenarios: How serious could they 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

4) Challenges for IMP QPs
IMP Working Group
- ATIMP Release
- Phase appropriate Quality Management System (QMS)
- CTA/IMPD compliance check

5) Critical KPIs for the QP
Cecilie Hejlskov and Arnoud Herremans
- KPIs that drive good quality behavior
- How KPIs can support or undermine your role as a QP
- Visualization of KPIs that benefit us all

6) Resilience for the QP
Sonsee Neu
- How resilience impacts decision-making
- Stress management
- Practical exercises to enhance resilience

Q&A SESSION

During the 2 days of the Forum, all delegates can post their questions verbally or in writing. The answers will be given by the expert speakers in dedicated sessions.

SPEAKERS

Speakers from Authorities, Inspectorates and Associations:

Emer Cooke, *European Medicines Agency (EMA)*
Executive Director of the European Medicines Agency

Brendan Cuddy, *European Medicines Agency (EMA)*
Lead Scientific Officer at European Medicines Agency

Rick Friedman, *US Food and Drug Administration (FDA)*
Deputy Director, Manufacturing Quality at FDA

Dr Rainer Gnibl, *Government of Upper Bavaria, Germany*
Head of Inspectorate and GMP Inspector, Advisory Board member of EQPA

Mag.pharm. Andreas Kraßnigg, *Austrian Agency for Health and Food Safety (AGES), Austria*
Head Pharmaceutical Inspections and member of Annex 16 Drafting Group, Chair of the PIC/S Sub-Committee on Expert Circles and Advisory Board member of EQPA

(other GMP Inspectors invited)

Speakers from Industry:

Jyotsna Agnihotry, *Flavine, Germany*
Head of Quality Operations

Cheryl Chia, *Lotus Phoenix Consulting, The Netherlands*
Consultant for GMP and GDP compliance in the pharmaceutical supply chain and member of the EQPA Board of Directors

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

Dr Carsten Coors, *Vetter Development Services, Austria*
Qualified Person

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

Rebecca Haywood, *Pfizer, UK*
Qualified Person

Cecilie Hejlskov, *Syntese, Denmark*
Operational Excellence Manager

Dr Arnoud Herremans, *Y47 Consultancy, The Netherlands*
Owner and Lean Kaizen Consultant

Katrien Himpens, *J&J Innovative Medicines, Belgium*
Qualified Person IMP, Senior Director QA Clinical Supply Chain

Dr Afshin Hosseiny, *ECA, France*
Qualified Person, former Director of Global Quality, GSK. Chair of the ECA Executive Board

Dr Monika Hupfauf, *Nomos Attorneys-at Law, Austria*
Lawyer with focus on the development of pharmaceuticals and medical products up to and including market entry

Patryk Jegorow, *Takeda, Ireland*
Qualified Person and Head of Quality Compliance and Systems Biologics Operating Unit

Canice Kearney, *Takeda, Ireland*
Qualified Person and Head of Quality, Biologics External Supply

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

Dr Aidan Madden, *FivePharma, Ireland*
CEO

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

Madeleine Molster, *Sagiure Legal, The Netherlands*
Attorney at Law for International Employment Law, Contract Law and Governance. Member of the People's Committee, American Chamber of Commerce in the Netherlands (AmCham)

Dr Umberto M. Musazzi, *University of Milan, Italy*
Fixed-term Research Fellow B, Department of Pharmaceutical Sciences

Sonsee Neu, *Stress Counseling, Germany*
Certified Mindful Life and NLP Coach Practitioner. Former actress

Gillian Renouf, *Royal Pharmaceutical Society QP Assessment Panel, UK*
Chair of the RPS QP Assessment Panel, Country Quality Head UK, Ireland and Nordics at Novartis

Niina Taylor, *Pfizer, UK and Ireland*
Qualified Person and Director Quality Assurance

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 2024, 28/29 November 2024, Amsterdam, The Netherlands
☐ OPTIONAL PRE-CONFERENCE SESSION, 27 November 2024, Amsterdam, The Netherlands

Please choose one of the following:

☐ Full Day Session "Specific Requirements for IMPs"
☐ 1/2 Day Session "QP Oversight for "Virtual Companies" and MAHs"
☐ 1/2 Day Session "QP Liability and Indemnification"

Please choose **three out of the following six parallel sessions**:

☐ Remote Certification: Are you ready?
☐ QP Scenarios: How serious could they be?
☐ Critical KPIs for the QP
☐ Annex 1 Implementation: Is your MIA at Risk?
☐ Challenges for IMP QPs
☐ Resilience for the QP

☐ Mr ☐ Ms ☐ Mx ☐ Dr

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 and conditions

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 4 weeks prior to the conference 10 %,
- Cancellation until 3 weeks prior to the conference 25 %,
- Cancellation until 2 weeks prior to the conference 50 %
- Cancellation within 2 weeks prior to the conference 100 %.

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. Only after we have received your payment, you are entitled to participate in the conference (receipt of payment will not be confirmed)! (As of July 2022).

German law shall apply. Court of jurisdiction is Heidelberg.

Privacy Policy: By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at www.gmp-compliance.org/eca_privacy.html). I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.

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, 27 November 2024, 9.00 – 18.00
(Registration: 8.30 – 9.00)

Date ½ Day Pre-Conference Session:
QP Oversight for "Virtual Companies" and MAHs
Wednesday, 27 November 2024, 13.30 – 18.00
(Registration: 13.00 – 13.30)

Date ½ Day Pre-Conference Session:
QP Liability and Indemnification
Wednesday, 27 November 2024, 13.00 – 18.00
(Registration: 12.30 – 13.00)

Welcome Reception for all participants
Wednesday, 27 November, 18.00 – 19.00

Date QP Forum
Thursday, 28 November 2024, 9.00 – 18.00
(Registration: Wednesday, 27 November, 18.00 – 19.00 and
Thursday 28 November, 08.30 – 9.00)
Friday, 29 November 2024, 8.30 – 14.45

Venue
Leonardo Royal Hotel
Paul van Vlissingenstraat 24
1096 BK, Amsterdam
The Netherlands
Phone: (+31) 20 250 0000
E-Mail: info.royalamsterdam@leonardo-hotels.nl

Fees for QP Forum (per delegate plus VAT)
QP Association Members € 1.790,-
EU GMP Inspectorates € 995,-
Non-QP Association Members € 1.990,-
The conference fee is payable in advance after receipt of invoice.

Fees for Full Day Pre-Conference Session:
Specific Requirements for IMPs
€ 1.190,- per delegate plus VAT.
The fee is payable in advance after receipt of invoice.

Fees for ½ Day Pre-Conference Session:
QP Oversight for "Virtual Companies" and MAHs
€ 690,- per delegate plus VAT.
The fee is payable in advance after receipt of invoice.

Fees for ½ Day Pre-Conference Session:
QP Liability and Indemnification
€ 690,- per delegate plus VAT.
The fee is payable in advance after receipt of invoice.

Accommodation
You will receive a room reservation link when you have registered for the conference.
Reservation should be made directly with the hotel. Early reservation is recommended.

Registration (please note the saving opportunities)
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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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 marion.grimm@concept-heidelberg.de.

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.

Early Bird Special for QP Forum: If you register for the Forum until 30 June 2024 you will get an additional **discount of 200€**.
(Early Bird Special not valid for inspectorate fee)

Important Information!

Download: The presentations of the QP Forum and the Pre-Conference Sessions will be available for download and your print-out before and after the conference.
Note: there will be no print-outs available during the conference.