ECA | QP ASSOCIATION
An ECA Foundation Interest Group

QUALIFIED PERSON FORUM 2023

VIENNA, AUSTRIA (WITH LIVE ONLINE OPTIONS)
12-13 October 2023

PRE-CONFERENCE SESSIONS | 11 October 2023
Specific Requirements for IMPs (full day)
Quality Culture (1/2 day)
New QPs meet experienced QPs (1/2 day)

BENEFIT FROM UP TO 400 € DISCOUNT FOR REGISTRATION UNTIL 15 JUNE

Speakers from Authorities, Inspectorates and Associations:

Daniel Fritz
PharmaLedger Association
Dr Rainer Gnibl
GMP Inspector, Head of Inspectorate, Germany
Alexander Kammerlocher
GMP Inspector, Germany
Mag.pharm. Andreas Kraßnigg
Austrian Agency for Health and Food Safety (AGES), Chair of the PIC/S Sub-Committee on Expert Circles
Anna Maria Kurzreiter
Austrian Agency for Health and Food Safety (AGES)
Dr Marianne Lunzer
Austrian Agency for Health and Food Safety (AGES)
Gillian Renouf
Royal Pharmaceutical Society QP Assessment Panel, U.K.

Speakers from Industry:

Alexandra Bauloye
GlaxoSmithKline
Cheryl Chia
Lotus Phoenix Consulting
David Cockburn
EQPA
Dr Carsten Coors
Vetter Development Services
Jan Dillingh
Fagron
Dr Susanne Ding
Boehringer Ingelheim
Walid El Azab
Steris
Georg Göstl
Takeda
Tor Graberg
AstraZeneca
Energy Kristina Hansen
Ferring
Katrien Himpens
Janssen
Dr Afshin Hosseiny
ECA
Dr Monika Hupfauf
Koch/Hupfauf Attorneys-at Law
Patryk Jegorow
Takeda
Dr Ulrich Kissel
EQPA
Aidan Madden
FivePharma
Sue Mann
Sue Mann Consultancy
Dr Frank Seibel
Roche Diagnostics
Dr Jörg Stüben
Boehringer Ingelheim
Prof Dr Ramzan Tabasum
Lonza
Niina Taylor
Pfizer

(other speakers invited)

- With six parallel sessions on-site to foster interaction
- Most sessions will be also available live online

WELCOME

Dear Colleagues,

Times remain challenging for QPs. New and upcoming developments will also have an influence on the work of the QP. These include developments in artificial intelligence (AI), blockchain technologies, personalised medicine and parametric release. In addition, the day-to-day business has to be taken care of - with all its challenges.

In this Forum we would like to discuss exactly these challenges and tasks helping you to find solutions.

The EQPA Board has decided to offer this year's QP Forum as a Live Online Conference as well. All lectures and selected sessions can be attended live online at your screen, if you can't come to Vienna:

Session only on-site in Vienna

Session available on-site and live online

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

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

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 15 June 2023 you will get an additional **discount of 200€**.
(Early Bird Special not valid for inspectorate fee)

You can benefit from the Early Bird offer and register for the QP Forum now and decide later how you participate (on-site or online).

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.

Live Online Participation: Only presentations/sessions marked with  are also available live online.

FULL DAY PRE-CONFERENCE SESSION

Specific Requirements for IMPs

Facilitated by:

Susanne Ding | Katrien Himpens | Patryk Jegorow | Anna Maria Kurzreiter | Marianne Lunzer | Niina Taylor (other speakers invited)

- Legislation impacting IMP QPs
- Clinical Trial Regulation – experience so far
- Clinical Trial Information System (CTIS) – what IMP QPs need to know
- ATMP GMP Part IV – challenges for IMP QPs
- Application of Quality Risk Management
- Interactive Case Study
- Q&A sessions

1/2 DAY PRE-CONFERENCE SESSION

Quality Culture

Facilitated by:

Energy Kristina Hansen

- Leadership roles on Q-Culture
- Steps to establishing an excellence led culture
- Q-Culture framework in the organisation

1/2 DAY PRE-CONFERENCE SESSION

New QPs meet experienced QPs

Facilitated by:

Georg Göstl | Andreas Kraßnigg | Sue Mann

A tailor-made session for new and aspiring QPs with round-table discussions and lots of interaction. Discuss your questions and worries with experienced QPs and a GMP Inspector.

PRESENTATIONS

Artificial Intelligence and Digitalisation in Pharma

Dr Jörg Stüben

- How will Artificial Intelligence (AI) influence GMP?
- Benefits and limits
- Possible consequences for the QP
- What else does the digital future bring?

General GMP Update – News for the QP besides the big Topics

Andreas Krassnigg

- Current legal developments
- EMA news
- Trusted Partners news

Parametric Release according Annex 17

Alexander Kammerlocher

- Current GMP requirements and developments
- Outlook

The Future of personalised Medicine and the Role of the QP

Jan Dillingh

- How personalised medicine is transforming healthcare
- Expectations, chances and limits
- The role of the QP

What the QP needs to know about Blockchain in Pharma

Daniel Fritz

- What exactly is blockchain
- Where is it used
- What it means for GMP-relevant activities
- Outlook

Reverse Risk Management and the Use for the QP

Alexandra Bauloye

- What it is
- How to use it
- Benefits for the QP

Contamination Control Strategy (CCS) Use for the QP

Walid El Azab

- The Importance of CCS for the QP to confirm reliance with the Quality System
- Implications of a robust CCS evaluation
- How to minimise the grey area in QP decision-making
- Shaping QP discretion

PARALLEL INTERACTIVE SESSIONS

1) Import/ Export Challenges for the QP

Rainer Gnibl and Ulrich Kissel

- What the QP needs to know
- Annex 21 in practice
- What are the QP responsibilities and where do they end?

2) Oversight of the Tasks that QPs can delegate

Cheryl Chia and Frank Seibel

- What are the tasks, a QP is responsible for?
- How can QPs assure themselves that these tasks are completed as intended and expected?
- How can QPs rely on the processes?
- Exercise: examine your organisation's PQS if the processes provide sufficient assurance to QPs

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

- Product Specification File
- Legal framework (contractual arrangements, technical agreements)
- Quarantine shipments

5) What the QP needs to know about pharmaceutical Contracts

Carsten Coors and Monika Hupfauf

- What does a QP need to know?
- EU regulations vs. non-EU regulations – what counts?
- How to keep the overview
- How to integrate QP responsibilities and define the respective adequate remedies in the contract

6) QP's Leadership Role in strategic Management: Soft Skills for Quality Professionals

Afshin Hosseiny and Ramzan Tabasum

- How to say "no" when it is needed

Delegates participating on-site in Vienna will be able to attend three of these six parallel sessions. Please choose the ones you like to attend when you register for the Forum.
Delegates participating live online will be able to join the sessions marked with + .

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:

Daniel Fritz, *PharmaLedger Association, Switzerland*
Executive Director. More than 30 years of leadership and supply chain IT experience in the US Army, financial, and pharmaceutical industries

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

Alexander Kammerlocher, *Local Competent Authority Baden-Württemberg, Germany*
GMP Inspector

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

Anna Maria Kurzreiter, *Austrian Agency for Health and Food Safety (AGES), Austria*
Inspector and Senior Expert

Dr Marianne Lunzer, *Austrian Agency for Health and Food Safety (AGES), Austria*
Safety Assessor, Department Clinical Trials and Clinical Trials Coordination Group (CTCG) Chair

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

Speakers from Industry:

Alexandra Bauloye, *GlaxoSmithKline, Belgium*
Senior Director and Global Process Owner for Risk Management

Cheryl Chia, *Lotus Phoenix Consulting, Netherlands*
Consultant for GMP and GDP compliance in the pharmaceutical supply chain

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

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

Jan Dillingh, *Fagron, Netherlands*
Qualified Person and Managing Pharmacist at the Fagron Sterile Preparation Pharmacy

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

Walid El Azab, *Steris, Belgium*
Qualified Person and Technical Services Senior Manager, Life Sciences Division, leader of the ECA CCS Task Force

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

Energy Kristina Hansen, *Ferring, Denmark*
Certified quality auditor and consultant with her own company MilCor Consulting

Katrien Himpens, *Janssen, Belgium*
Qualified Person IMP, Senior Director QA Clinical Supply Chain

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

Dr Monika Hupfauf, *Koch/Hupfauf 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

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

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

Dr Frank Seibel, *Roche Diagnostics, Germany*
Quality Site Head

Dr Joerg Stüben, *Boehringer Ingelheim International, Germany*
Head of Regulatory Information Management and Senior Expert

Prof Dr Ramzan Tabasum, *Lonza, Switzerland*
Senior Director and Visiting Professor SBS Swiss Business School

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

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 2023, 12-13 October 2023, Vienna, Austria (with Live Online Options)
☐ OPTIONAL PRE-CONFERENCE SESSION, 11 October 2023, Vienna, Austria (with Live Online Options)

Please choose **one of the following**:
☐ Full Day Session "Specific Requirements for IMPs"
☐ 1/2 Day Session "Quality Culture"
☐ 1/2 Day Session "New QPs meet experienced QPs"

PLEASE NOTE: You can already register now and decide later how you will participate – face-to-face in Vienna or remotely.

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

For participants on-site: Please choose three out of the following six parallel sessions:
(if you participate remotely, you will be able to join the sessions marked with +)

☐ Import/ Export Challenges for the QP
☐ Oversight of the Tasks that QPs can delegate
☐ QP Scenarios – How serious could they be?
☐ Challenges for IMP QPs
☐ What the QP needs to know about pharmaceutical Contracts
☐ QP's Leadership Role in strategic Management: Soft Skills for Quality Professionals

☐ 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, 11 October 2023, 9.00 – 18.00 h*
(Registration for taking part on-site in Vienna: 8.30 – 9.00 h*)

Date ½ Day Pre-Conference Session:
Quality Culture
Wednesday, 11 October 2023, 13.30 – 18.00 h*
(Registration: 13.00 – 13.30 h*)

Date ½ Day Pre-Conference Session:
New QPs meet experienced QPs
Wednesday, 11 October 2023, 13.30 – 18.00 h*
(Registration: 13.00 – 13.30 h*)

Welcome Reception for all participants on-site in Vienna
Wednesday, 11 October 2023, 18.00 – 19.00 h*

Date QP Forum
Thursday, 12 October 2023, 9.00 – 18.00 h*
(Registration for taking part on-site in Vienna:
Wednesday, 11 October 2023, 18.00 – 19.00 h* and
Thursday, 12 October 2023, 8.30 – 9.00 h*)
Friday, 13 October 2023, 8.30 – 15.00 h*

* *All times are CEST*

Venue
Doubletree by Hilton Vienna Schönbrunn
(former Radisson Blu Park Royal Palace Hotel Vienna)
Schlossallee 8
1140 Vienna
Austria
Phone: +43 (1) 89 11 0

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:
Quality Culture
€ 690,- per delegate plus VAT.
The fee is payable in advance after receipt of invoice.

Fees for ½ Day Pre-Conference Session:
New QPs meet experienced QPs
€ 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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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.