ECA | QP ASSOCIATION
An ECA Foundation Interest Group

# QUALIFIED PERSON FORUM 2022

BERLIN, GERMANY & LIVE ONLINE | 01- 02 December 2022

PRE-CONFERENCE SESSIONS | 30 November 2022
Specific Requirements for IMPs (full day)
Quality Culture (1/2 day)

BENEFIT FROM UP TO 400 € DISCOUNT FOR REGISTRATIONS UNTIL 30 JUNE

**Speakers from Authorities, Inspectorates and Associations:**

**Dr Rainer Gnibl**
*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*
**Gillian Renouf**
*Royal Pharmaceutical Society QP Assessment Panel, U.K.*
**Dr Franz Schönfeld**
*GMP Inspector, Germany*

**Speakers from Industry:**

**Alexandra Bauloye**
*GlaxoSmithKline*
**Cheryl Chia**
*Lotus Phoenix Consulting*
**David Cockburn**
*EQPA*
**Dr Susanne Ding**
*Boehringer Ingelheim*
**Tor Gråberg**
*AstraZeneca*
**Arnoud Herremans**
*Y47 consultancy*
**Dr Afshin Hosseiny**
*ECA*
**Patryk Jegorow**
*Takeda*
**Dr Ulrich Kissel**
*EQPA*
**Aidan Madden**
*FivePharma*
**Sue Mann**
*Sue Mann Consultancy*
**Sandra Moricz**
*Sanofi*
**Dr Bernd Renger**
*former EQPA Chair*
**Dr Frank Seibel**
*Roche Diagnostics*
**Robert Schwarz**
*FH Campus Vienna*
**Maria Söderblom**
*AstraZeneca*
**Niina Taylor**
*Pfizer*
**Brenda Van Assche**
*Janssen*
*(other speakers invited)*

Dear Colleagues,

Times remain challenging. Life has been associated with many changes and restrictions, not only in the private sphere. The working world and focal points of the regulatory authorities have also changed, in some cases considerably.

But the normal working life of the QP also continued, with all the manifold tasks and responsibilities; these should not be left out.

**What are the real QP Responsibilities?**

As a QP, you have many interfaces with other functions in the company. Responsibilities can be shared or are located elsewhere. Unfortunately, too many activities and responsibilities are often taken over by QPs. In this forum we would like to work out exactly these tasks.

The EQPA Board has decided to offer this year's QP Forum also as a Live Online Conference. All lectures and sessions of the main Forum will be held consecutively and can be attended by all participants - either directly on-site in Berlin or live online at your screen.

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



## FULL DAY PRE-CONFERENCE SESSION

### Specific Requirements for IMPs

Facilitated by:
**Susanne Ding | Patryk Jegorow | Niina Taylor | Brenda Van Assche (other speakers invited)**

- New legislation impacting IMP QPs
- Practical implications for the IMP QP:
  - Clinical Trial Regulation
  - Remote Batch Certification
  - Annex 21 importation
  - Brexit
- Regulator's view on IMP topics
- Interactive Session – from the supply chain to the sponsor release
- IMP QPs working in a digital landscape
- Q&A sessions

## 1/2 DAY PRE-CONFERENCE SESSION

### Quality Culture - how to realise in daily QP business

Facilitated by:
**Arnoud Herremans | Aidan Madden**

- What is behind it
- How the QP can benefit from it
- How the QP could influence it

## Key Note: Performance beyond Compliance


**Bernd Renger**

- Is industry mainly causing new requirements on its own? Is there an end to be expected?

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

**Andreas Krassnigg**

- Developments in EU legislation
- PIC/S Annex 16 "Certification by the Authorised Person and Batch Release"

## Annex 1: Consequences for the QP

**Robert Schwarz**

- What's important for the QP
- What manufacturers of non-sterile medicinal products should know and take into account

## QPs in a Time of electronic Data

**Cheryl Chia and Tor Gråberg**

- Definitions of the different types of data
- Relationships between the different types of data
- Examples showing the linkages in practical situations
- How this translates to QP decisions and fulfilling QP responsibilities – not all data is equal

## Examples for inappropriate Risk Management – and how it could be done better

**Alexandra Bauloye and Franz Schönfeld**

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

## MAH, MIA, Senior Management: who's behind it?

**Sandra Moricz**

- Roles and responsibilities
- Interfaces with the QP

## The QP's Responsibilities in daily Practice

**Frank Seibel**

- QP, Head of Production, Head of Quality Control: how do these functions work together
- How can duplication of work be avoided
- How can responsibilities be delimited, e.g. also and especially at the interfaces: sample collection and storage, warehousing, batch record review, deviations, changes etc.

## Import and Export – what the QP needs to know

**David Cockburn, Rainer Gnibl and Ulrich Kissel**

- What the QP needs to know: basic requirements
- Consequences of Annex 21 and Brexit

## 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

## Current Challenges in the Supply Chain (and possible solutions)

**Maria Söderblom**

- The reasons for drug shortages / shortages of APIs, excipients, equipment and materials
- Possible solutions for industry and the QP

## Panel Discussion on the Downstream Part of the Supply Chain: Where do GMP and the QP responsibility really end?

**Cheryl Chia, David Cockburn, Afshin Hosseiny and Ulrich Kissel**

**More speakers for additional topics invited**

# Q&A SESSION

During the 2 days of the Forum, 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:

**Dr Rainer Gnibl,** *Government of Upper Bavaria, Germany*
GMP Inspector for the District Government and the EMA, 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

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

**Dr Franz Schönfeld,** *Government of Upper Franconia*
GMP Inspector for the District Government and the EMA

## Speakers from Industry:

**Alexandra Bauloye,** *GlaxoSmithKline, Belgium*
Risk Management and Governance Lead, GSK Corporate

**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 Susanne Ding,** *Boehringer Ingelheim, Germany*
Qualified Person for Investigational Medicinal Products 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

**Arnoud Herremans**, *Y47 Consultancy, Netherlands*
Lean Kaizen Coach

**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 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

**Sandra Moricz**, *Sanofi, Austria*
Deputy Country Quality Head Austria, Qualified Person for Sanofi in Austria

**Dr Bernd Renger,** *Bernd Renger Consulting, Germany*
Former Chairman of the European QP Association and member of the ECA Advisory Board

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

**Robert Schwarz,** *FH Campus Vienna, Austria*
University lecturer, freelancing trainer and consultant

**Maria Söderblom,** *AstraZeneca, Sweden*
Director Quality Assurance and Qualified Person

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

**Brenda Van Assche,** *Janssen Pharmaceutica NV, Belgium*
Senior Director Quality Assurance Clinical Supply Chain 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 2022, 01-02 December 2022, Berlin, Germany & Live Online

☐ OPTIONAL PRE-CONFERENCE SESSION, 30 November 2022, Berlin, Germany & Live Online

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

**PLEASE NOTE:** 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

☐ 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 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, 30,November 2022, 9.00 – 18.00 h*
(Registration for taking part on-site in Berlin: 8.30 – 9.00 h*)

Date ½ Day Pre-Conference Session:
Quality Culture
Wednesday, 30 November 2022, 13.30 – 18.00 h*
(Registration for taking part on-site in Berlin: 13.00 – 13.30 h*)

Welcome Reception for all participants on-site in Berlin
Wednesday, 30 November 2022, 18.00 – 19.00 h*

Date QP Forum
Thursday, 01 December 2022, 9.00 – 18.00 h*
(Registration for taking part on-site in Berlin:
Wednesday, 30 November 2022 18.00 – 19.00 h* and
Thursday, 01 December 2022, 8.00 – 9.00 h*)
Friday, 02 December 2022, 8.30 – 16.30 h*

** All times are CET*

Venue
Hotel Berlin, Berlin
Lützowplatz 17
10785 Berlin | Germany
Tel: +49 (0) 30/ 26050 | Email: info@hotel-berlin.de

*On-site, we will implement the necessary and required hygiene measures in close co-operation with the hotel. If infection rates and/or travel restrictions generally do not permit an on-site conference, we will switch to a complete Live Online Conference. In this case, you will be informed in due time.*

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

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.

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

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. Early reservation is recommended.

Registration (please note the saving opportunities below)
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
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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.

## 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 2022 you will get an additional **discount of 200€**.
(Early Bird Special not valid for inspectorate fee)

## Important Information!

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

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.