ECA | QP ASSOCIATION
An ECA Foundation Interest Group

20 Years Anniversary Forum
50 Years Qualified Person

With six parallel sessions to foster interaction

QUALIFIED PERSON FORUM 2025

Barcelona, Spain, 27/28 November 2025 | Pre-Conference Sessions, 26 November 2025

Specific Requirements for IMPs | QP: Leadership with Impact | What the QP needs to know about AI Implementation

Key Note Speaker:

Patricia Kelly
Artist, Entrepreneur, Member of the Kelly Family

Speakers from Authorities and Inspectorates:

Dr Rainer Gnibl
GMP Inspector, Head of Inspectorate, Germany
Alexander Kammerlocher
Inspector, District Government, Germany
Mag.pharm. Andreas Kraßnigg
Austrian Agency for Health and Food Safety (AGES)
Richard O'Sullivan
HPRA Ireland
Martine Powell
UK MHRA

Speakers from Industry:

Cheryl Chia
BeOne Medicines
David Cockburn
EQPA
Dr Susanne Ding
Boehringer Ingelheim
Eike Feldmann
Sharp Services
Barbara Glantschnig
Takeda
Georg Göstl
Takeda
Rebecca Haywood
Pfizer
Cecilie Hejlskov
Ferring Pharmaceuticals
Dr Arnoud Herremans
Y47 Consultancy
Katrien Himpens
J&J Innovative Medicines
Dr Monika Hupfauf
Attorney-at Law
Marina Jarosch
Takeda
Patryk Jegorow
Takeda
Dr Ulrich Kissel
EQPA
Dr Nina Langoth-Fehringer
Langoth Pharma Consulting
Dr Aidan Madden
FivePharma
Sue Mann
Sue Mann Consultancy
Dr Umberto M. Musazzi
University of Milan
Paul Palmer
Pharma Quality Services
Martin Quigley
Quigley and Associates
Gillian Renouf
Royal Pharmaceutical Society QP Assessment Panel, U.K.
Mounir Rizovsky
Clinigen
Markus Roemer
comes compliance services
Ewa Rybak
JJP Biologics
Charis Schmidt
Ferring
Dr Andreas Schwinn
Roche

Dear Colleagues,

We must recognise and acknowledge the jubilees! 2025 is remarkable for QPs in that respect.

The Qualified Person (QP) was first introduced into EU legal texts in the year 1975. We therefore celebrate its 50th birthday! And it is the 20th QP Forum.

This 2025 QP forum will be remembered as a jubilee highlight. It intends though, to prepare QPs for the future.
Is there only joy and delight? A lot has changed in the past 50 years and it's worth to consider the developments in the world, trends and the outlook into the future. For 50 years the qualification profile for the QP has not changed. Is this still fit for purpose and the future?
The ongoing revision to the new EU Pharmaceutical legislation provides the unique opportunity to adequately modernise and strengthen the conceptual role of the QP. Will this chance be used? At the time of writing these lines, unknown. EQPA provided distinct comments, but we could not evaluate so far whether they are heard.
More important is our professionalism in the role. This includes that we QPs take direct responsibility to develop our role together in line and speed with major developments and trends which demand continuous reflection on the QP's role.

The 2025 QP Forum - like other offers by EQPA - will provide a fabulous platform to consider all these dimensions.

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 Barcelona.

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 will also appeal to upper management functions plus regulatory 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 | Barbara Glantschnig | Rebecca Haywood | Katrien Himpens | Marina Jarosch | Patryk Jegorow | Richard O'Sullivan | Martin Quigley | Mounir Rizovsky | Andreas Schwinn

- Legislation impacting IMP QPs
- IMP GMP inspection experiences
- How could AI & digital tools support an IMP QP? (Panel Discussion)
- Product Specification File
- Automated release file preparation using robotics process automation
- IMP QP release models – contractor's perspective
- The Enneagram Personality Model – why is it important for IMP QPs to understand yourself and understand others*
- Interactive case studies
- Time for questions and answers

** all delegates will get a free copy of the book "More than a Number" by Martin Quigley*

1/2 DAY PRE-CONFERENCE SESSION

QP: Leadership with Impact

Facilitated by:
Arnoud Herremans | Ewa Rybak

- Practicing leadership without being in a senior management position
- QP vision and strategy needed
- Examples and interaction

1/2 DAY PRE-CONFERENCE SESSION

What the QP needs to know about AI Implementation

Facilitated by:
Cheryl Chia | Monika Hupfauf | Markus Roemer

- What is AI – and what not?
- Possible implications of the new EU-GMP Annexes 11 and 22 and Chapter 4
- What questions to ask as a QP when implementing AI applications?
- How to use AI as supporting tool
- The role of AI and its acceptance in assessing documentation prior to batch certification
- How to rely on AI-generated output
- Legal challenges when relying on AI-generated output
- Liability of the QP when using AI

Opening Address
50 Years QP – 20 Years European QP Association
David Cockburn & Ulrich Kissel
- A short story about the evolvement of the role of the QP: where does it come from, where is it going?
- Different approaches in Europe and the world
- Achievements of the EQPA

Key Note: An Inspirational Talk on Resilience, Courage and Motivation
Patricia Kelly

General GMP Update – News for the QP besides the big Topics
Andreas Krassnigg
- Current legal developments
- EMA and IWP news
- Trusted Partners news

What the QP needs to know about Root Cause Analysis
Cecilie Hejlskov
- Handling of unexpected deviations according Annex 16 (3)
- How can a QP be sure that a deviation has been thoroughly investigated and the root cause corrected?
- How to assess the impact of deviation?

Decentralised Manufacturing – what is it and how will it develop?
Martine Powell
- How ATMPs lead the way
- Potential applications in Biotech and classical Pharma
- Key enablers for decentralised manufacturing
- Challenges and outlook

Drug Shortages: what the QP needs to know
Cheryl Chia and Umberto M. Musazzi
- Drug shortage policy in the EU: what's important for the QP
- How to deal with the requirements
- Potential flexibility in certain GMP requirements

SOCIAL EVENT

On 27 November, you are cordially invited to a tapas Dinner in a stately mansion that is considered part of Barcelona's cultural heritage. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

2026 and Beyond: Emerging Trends in the Pharmaceutical Industry
Paul Palmer
- Advancements in digital health
- Rise of personalised medicine
- Sustainability in manufacturing

1) Sharing and Delegating QP Responsibilities
Ulrich Kissel and Nina Langoth-Fehringer
- "The QP" according to EU GMP is not really uniform
- How to avoid that more than one QP in the organisation does not cause confusion?
- Supply chains involving many MIAHs
- How to split responsibilities and delegation of tasks?
- Exchange of best practices

2) How to deal with significant Non-Conformances?
Georg Göstl and Rainer Gnibl
- Open experience sharing between QPs: discussing everyday headaches

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
- IMP recall
- ATIMPs
- IMP reconstitution vs. manufacturing

5) Role of the QP in Supply Chain Oversight
Aidan Madden and Alexander Kammerlocher
- How should the traceability of the supply chain of the active substance and medicinal product be documented to support the QP?

6) Navigating Resource Challenges as a QP
Eike Feldmann and Charis Schmidt
- Science-based leadership strategies to manage high workloads with limited time and resources
- Key frameworks
- Solutions to improve efficiency, decision-making, and team collaboration under pressure

Q&A SESSION

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

SPEAKERS

KEYNOTE SPEAKER

Patricia Kelly
Singer, Songwriter, Keynote Speaker, Bestselling Author, Entrepreneur, Member of the Kelly Family

SPEAKERS FROM AUTHORITIES AND INSPECTORATES

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

Alexander Kammerlocher, *District Government, Germany*
Inspector for Medical and Pharmaceutical Affairs, Medical Devices

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

Richard O'Sullivan, *HPRA, Ireland*
GMP Inspector at Irish Health Products Regulatory Authority (HPRA)

Martine Powell, *MHRA, UK*
Expert GMP Inspector, Healthcare Quality and Access Group, Medicines and Healthcare Products Regulatory Agency

SPEAKERS FROM INDUSTRY

Cheryl Chia, *BeOne Medicines, The Netherlands*
Senior Director Distribution Quality, member of the EQPA Board of Directors

David Cockburn, *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 Susanne Ding, *Boehringer Ingelheim, Germany*
Qualified Person IMPs, Global Quality, Devices & IMP Delivery, member of the EQPA Board of Directors

Eike Feldmann, *Sharp Services, The Netherlands*
Qualified Person Market Release and independent consultant

Barbara Glantschnig, *Takeda, Austria*
Global Head of Quality, Plasma Derived Therapies

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

Rebecca Haywood, *Pfizer, UK*
Qualified Person

Cecilie Hejlskov, *Ferring Pharmaceuticals, Denmark*
Operational Excellence Manager

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

Marina Jarosch, *Takeda, Austria*
Qualified Person, Head of IMP QPs

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

Dr Ulrich Kissel, *EQPA, Germany*
Qualified Person and Chair of the EQPA Board of Directors, Kissel Pharma Consulting GmbH

Dr Nina Langoth-Fehringer, *Langoth Pharma Consulting, Austria*
Consultant

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

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

Paul Palmer, *Pharma Quality Services Limited, UK*
Managing Director, QP, RP and RPi, Honorary Senior Lecturer University College London

Martin Quigley, *Quigley and Associates, Ireland*
Enneagram specialist, trainer, coach and author of the book "More than a Number"

Gillian Renouf, *Royal Pharmaceutical Society QP Assessment Panel, UK*
Chair of the RPS QP Assessment Panel

Mounir Rizovsky, *Clinigen, Belgium*
Lead Qualified Person, Clinical Supplies Management

Markus Roemer, *comes compliance services, Germany*
Managing Director

Ewa Rybak, *JJP Biologics, Poland*
Qualified Person and Head of Quality Compliance and Quality Systems, member of the EQPA Board of Directors

Charis Schmidt, *Ferring, Germany*
Head of Production/ Team Lead Sterile Production

Dr Andreas Schwinn, *Roche Pharma AG, Germany*
Senior Qualified Person

RESERVATION FORM – PLEASE COMPLETE IN FULL

If the bill-to-address deviates from the specification to the right, please fill out here:

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CONCEPT HEIDELBERG
Postfach 10 17 64
Fax 06221/84 44 34

D-69007 Heidelberg

☐ QUALIFIED PERSON FORUM 2025
27/28 November 2025, Barcelona, Spain
☐ OPTIONAL PRE-CONFERENCE SESSION
26 November 2025, Barcelona, Spain

Please choose one of the following:
☐ Full Day Session "Specific Requirements for IMPs"
☐ 1/2 Day Session "QP: Leadership with Impact"
☐ 1/2 Day Session "What the QP needs to know about AI Implementation"

Please choose **three out of the following six parallel sessions**:
☐ Sharing and Delegating QP Responsibilities
☐ How to deal with significant Non-Conformances?
☐ QP Scenarios: How serious could they be?
☐ Challenges for IMP QPs
☐ Role of the QP in Supply Chain Oversight
☐ Navigating Resource Challenges as a 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 http://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.

DATES

Date Full Day Pre-Conference Session:
Specific Requirements for IMPs
Wednesday, 26 November 2025, 9.00 – 18.00 h
(Registration: 8.30 – 9.00 h)

Date ½ Day Pre-Conference Session:
QP: Leadership with Impact
Wednesday, 26 November 2025, 13.30 – 18.00 h
(Registration: 13.00 – 13.30 h)

Date ½ Day Pre-Conference Session:
What the QP needs to know about AI Implementation
Wednesday, 26 November 2025, 13.00 – 18.00 h
(Registration: 12.30 – 13.00 h)

Welcome Reception for all participants
Wednesday, 26 November, 18.00 – 19.00 h

Date QP Forum
Thursday, 27 November 2025, 9.00 – 18.00 h
(Registration: Wednesday, 26 November, 18.00 – 19.00 h and
Thursday 27 November, 08.30 – 9.00 h)
Friday, 28 November 2025, 8.30 – 15.00 h

FEES

Fees for QP Forum (per delegate plus VAT)
QP Association Members € 1.990,-
EU GMP Inspectorates € 1.095,-
Non-QP Association Members € 2.190,-
The conference fee is payable in advance after receipt of invoice.

Fees for Full Day Pre-Conference Session:
Specific Requirements for IMPs
€ 1.290,- per delegate plus VAT.
The fee is payable in advance after receipt of invoice.

Fees for ½ Day Pre-Conference Session:
QP: Leadership with Impact
€ 790,- per delegate plus VAT.
The fee is payable in advance after receipt of invoice.

Fees for ½ Day Pre-Conference Session:
What the QP needs to know about AI Implementation
€ 790,- per delegate plus VAT.
The fee is payable in advance after receipt of invoice.

VENUE

Barceló Sants Hotel
Plaça dels Països Catalans, s/n
08014 Barcelona
Spain
Phone: +34 / 93 / 503 53 00
E-Mail: sants@barcelo.com

ACCOMMODATION & REGISTRATION

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.

ORGANISATION

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CONTACT

For questions regarding content:
Mr Wolfgang Schmitt (Operations Director) at +49 (0) 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 300 €** on the QP Forum.

LANGUAGE & DOWNLOAD INFORMATION

The official conference language will be English.

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.

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.