EUROPE'S BIGGEST QUALIFIED PERSON CONFERFENCE

21st QP FORUM

Barcelona, Spain, 26/27 November 2026

Benefit from up to 600 € discount for registration until 30 June

Six parallel sessions to foster interaction

ECA | QP ASSOCIATION

An ECA Foundation Interest Group

Pre-Conference Sessions, 25 November 2026

- Specific Requirements for IMPs
- Data Quality and Data Management
- New QPs meet experienced QPs

Speakers from Authorities and Inspectorates:

Dr Björn Cohrs, *GMP Inspector, Germany*
Brendan Cuddy, *European Medicines Agency (EMA)*
Dr Rainer Gnibl, *GMP Inspector, Head of Inspectorate, Germany*
Mag.pharm. Andreas Kraßnigg,
Austrian Agency for Health and Food Safety (AGES)

Speakers from Industry:

Cheryl Chia, *BeOne Medicines*
Dr Susanne Ding, *Boehringer Ingelheim*
Rebecca Haywood, *Pfizer*
Katrien Himpens, *J&J Innovative Medicine*
Dr Monika Hupfauf, *Koch/Hupfauf Lawyers*
Patryk Jegorow, *Takeda*
Dr Ulrich Kissel, *EQPA*
Dr Nina Langoth-Fehringer, *Langoth Pharma Consulting*
Hanneke Later-Nijland, *Genome Lawyers*
Dr Elke A. Loris, *Merck Healthcare*
Dr Aidan Madden, *FivePharma*
Sue Mann, *Sue Mann Consultancy*
Heike Meichsner, *Dr. Falk Pharma*
Carme Espadamala Morató, *Boehringer Ingelheim España*
Susanne Müller, *Reddy Holding/ betapharm*
Gillian Renouf, *Royal Pharmaceutical Society QP Assessment Panel, U.K.*
Markus Roemer, *comes compliance services*
Ewa Rybak, *JJP Biologics*
Prof Dr Stefanie A. Schubert, *SRH University Heidelberg*

(other speakers invited)

WELCOME

Dear Colleagues,

The QP at a Crossroads – Responsibility, Reform and Readiness for the Future.

The jubilee celebrations are behind us, but the challenges remain. And they are becoming more concrete.

Following the remarkable 50th anniversary of the Qualified Person (QP) and the 20th QP Forum last year, this year's conference moves from reflection to action. The environment in which QPs operate is evolving rapidly. Legislative reform, digitalisation, AI-driven systems, and supply chain uncertainties are shaping our daily responsibilities.

Professionalism in the QP role has never been more important. It is no longer enough to rely on established practice. Continuous competence development, critical thinking, and proactive shaping of our professional standards are essential. The QP must remain an independent guardian of patient safety — but also a strategic quality leader in an increasingly digital and interconnected pharmaceutical world.

This year's QP Forum provides the platform to address these pressing questions openly and constructively.

I look forward to welcoming you again — and continuing this important dialogue together.

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

PRE-CONFERENCE SESSIONS

25 NOVEMBER 2026

IMP CONFERENCE DAY

Specific Requirements for IMPs

Facilitated by:
Susanne Ding | Rebecca Haywood | Katrien Himpens | Patryk Jegorow | Markus Roemer ***(other speakers invited)***

- Legislation impacting IMP QPs (incl. Annex 11)
- Data Quality and Data Management
- Inspector's view
- Product Specification File
- ATIMP release and valuable learnings
- Interactive case studies
- Early Access Treatments
- Medical Devices
- Q&A sessions

1/2 DAY PRE-CONFERENCE SESSION

What the QP needs to know about Data Quality and Data Management

Facilitated by:
Cheryl Chia | Rainer Gnibl | Markus Roemer

- Overview on current EU-requirements on Data Governance and Data Integrity
- Data Quality as a decision basis for batch confirmation and certification
- The wild mix on a QP's desk: Oversight of paper-based, hybrid and digital data
- Digital systems, MES, eBR, data warehouse – where the QP must be cautious

1/2 DAY PRE-CONFERENCE SESSION

New QPs meet experienced QPs

Facilitated by:
Björn Cohrs | Sue Mann | Ewa Rybak

A tailor-made session for new and aspiring QPs with round table discussions and lots of interaction. It is a safe space where issues, questions and any worries relating to the role of a QP can be discussed with experienced QPs and a GMP Inspector.

QP FORUM

26/27 NOVEMBER 2026 / PRESENTATIONS

Keynote: How to lead and influence People without having direct disciplinary Power

Stefanie Schubert

This year's keynote focuses on two essential capabilities of QPs: the confidence to make the right decision even under organisational head-winds, and the ability to strategically influence stakeholders by shaping incentives so that others move with you, not against you.

GMP Update - Legislative Trends and News for the QP

Brendan Cuddy and Andreas Kraßnigg

- The topics will be based on current developments and will be defined in due time prior to the event.

Artificial Intelligence and the QP

Speakers invited

Case studies and discussion of current AI-related topics

What the QP needs to know about the Electronic Product Information ePI

Elke A. Loris

- What is the ePI?
- Current status
- What does it mean for our products?
- Digital material impact
- ePI and the release process

Case Study: The QP's Role in a Product Transfer to a New Manufacturing Facility

Carme Espadamala Morató

- Legal and personal responsibility: What does the QP really sign for?
- How to gain real process understanding
- Defining minimum expectations before release decisions

Further topics and speakers to be announced.

SOCIAL EVENT

On 26 November, you are cordially invited to a tapas dinner. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

PARALLEL INTERACTIVE SESSIONS

1) Everyday Concerns for QP - Legal Pitfalls and how avoid them

Monika Hupfauf and Hanneke Later-Nijland

- Responsibility, liability, and protection mechanisms for QPs
- How QPs can strengthen their legal position in the organisation
- Whistleblowing, compliance and integrity in GMP
- Case study: QP decision-making under uncertainty, i.e. after a suboptimal GMP inspection

2) The QP Role reflected in Quality Agreements, Contracts, etc.

Ulrich Kissel, Heike Meichsner and Nina Langoth-Fehringer

- The QP's legal and operational role
- Translating QP tasks and accountability into contractual clauses
- Identifying typical gaps between contracts and real GMP practice

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

- Sponsor responsibilities and sponsor release
- Early Access Treatments
- Comparators, Auxiliary Medicinal Products

5) Informed Choices when facing Risks: Risk-based Decision Making for QPs

Cheryl Chia and Aidan Madden

- What is your risk tolerance?
- How well do you know the processes?
- What risks are you choosing to accept or mitigate?
- How do the risk assessment processes at your company support you in your decision making as a QP?

6) Supply Chain, Quality and CMO Oversight for the QP

Rainer Gnibl and Susanne Müller

- Regulatory obligations on supply chain oversight and QP's role/ responsibility
- Oversight of CMOs beyond technical agreement: QP's instruments
- Oversight of subsidiaries vs. oversight of CMOs
- Practical pitfalls
- Discussion of participant's examples

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 FROM AUTHORITIES AND INSPECTORATES

Dr Björn Cohrs, *State Authority for Occupational Safety, Social Affairs and Health of Schleswig-Holstein, Germany*
GMP Inspector

Brendan Cuddy, *European Medicines Agency (EMA)*
Lead Scientific Officer at European Medicines Agency, Chair of the GMDP Inspectors Working Group

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

SPEAKERS FROM INDUSTRY

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

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

Rebecca Haywood, *Pfizer, UK*
Qualified Person, Board Member of the EQPA IMP QP Working Group

Katrien Himpens, *J&J Innovative Medicine, Belgium*
Qualified Person, Site Quality Head CAR-T, Board Member of the EQPA IMP QP Working Group

Dr Monika Hupfauf, *Koch/Hupfauf Lawyers, Austria*
Partner and Attorney-at-Law for Life Science Sector

Patryk Jegorow, *Takeda, Ireland*
Qualified Person and Head of Quality Compliance and Systems Biologics Operating Unit, member of the EQPA Board of Directors

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

Hanneke Later-Nijland, *Genome Lawyers, The Netherlands*
Lawyer and pharmacist. Former inspector at the Dutch Inspectorate for Healthcare (IGJ).

Dr Elke A. Loris, *Merck Healthcare, Germany*
Qualified Person und Senior Quality Assurance Manager

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

Heike Meichsner, *Dr. Falk Pharma, Germany*
Qualified Person and QA Team Lead

Carme Espadamala Morató, *Boehringer Ingelheim España, Spain*
Qualified Person and QA Head

Susanne Müller, *Reddy Holding/ betapharm, Germany*
Qualified Person and Head Quality-Europe Generics

Gillian Renouf, *Royal Pharmaceutical Society QP Assessment Panel, UK*
Chair of the RPS QP Assessment Panel, Vice President Quality, Mereo Biopharma

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

Prof Dr Stefanie A. Schubert, *SRH University Heidelberg, Germany*
Professor of Economics, Negotiation Advisor and ICF-certified Executive Coach

Other speakers invited

DATES

IMP Conference Day
Specific Requirements for IMPs
Wednesday, 25 November 2026, 9:00–18:00 h
(Registration: 8:30–9:00 h)

Date ½ Day Pre-Conference Session:
What the QP needs to know about Data Quality and Data Management
Wednesday, 25 November 2026, 13:00–18:00 h
(Registration: 12:30–13:00 h)

Date ½ Day Pre-Conference Session:
New QPs meet experienced QPs
Wednesday, 25 November 2026, 13:30–18:00 h
(Registration: 13:00–13:30 h)

Welcome Reception for all participants
Wednesday, 25 November, 18:00–19:00 h

Date QP Forum
Thursday, 26 November 2026, 9:00–18:00 h
(Registration: Wednesday, 25 November, 18:00–19:00 h
and Thursday 26 November, 8:30–9:00 h)
Friday, 27 November 2026, 8:30–approx. 15:30 h

VENUE

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

ORGANISATION

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info@concept-heidelberg.de
www.concept-heidelberg.de

SAVING OPPORTUNITIES UP TO 600 €

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.

Early Bird Special for QP Forum: If you register for the Forum until 30 June 2026 you will get an additional **discount of 300€**.
(Early Bird Special not valid for inspectorate fee)

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.

FEES

Fees for QP Forum (per delegate plus VAT)
QP Association Members € 2.190,-
EU GMP Inspectorates € 1.195,-
Non-QP Association Members € 2.390,-

Fees for IMP Conference Day:
Specific Requirements for IMPs (per delegate plus VAT)
€ 1.390,- per delegate

Fees for ½ Day Pre-Conference Session:
What the QP needs to know about Data Quality and Data Management (per delegate plus VAT)
€ 890,- per delegate

Fees for ½ Day Pre-Conference Session:
New QPs meet experienced QPs (per delegate plus VAT)
€ 890,- per delegate

TABLE TOP EXHIBITION & SPONSORSHIP

At this event, we offer you the opportunity to participate as an exhibitor and/or sponsor.
More information: www.qp-forum.org/table-top.html

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.

CONTACT

For questions regarding content:
Mr Wolfgang Schmitt, +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 +49 62 21 84 44-18,
or per e-mail at marion.grimm@concept-heidelberg.de.

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 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.

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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D-69007 Heidelberg

☐ QUALIFIED PERSON FORUM 2026
26/27 November 2026, Barcelona, Spain
☐ OPTIONAL PRE-CONFERENCE SESSION
25 November 2026, Barcelona, Spain

Please choose one of the following:
☐ IMP Conference Day "Specific Requirements for IMPs"
☐ 1/2 Day Session "What the QP needs to know about Data Quality and Data Management"
☐ 1/2 Day Session "New QPs meet experienced QPs"

Please choose **three out of the following six parallel sessions**:
☐ Everyday Concerns for QP - Legal Pitfalls and how avoid them
☐ The QP Role reflected in Quality Agreements, Contracts, etc.
☐ QP Scenarios: How serious could they be?
☐ Challenges for IMP QPs
☐ Informed Choices when facing Risks: Risk-based Decision Making for QPs
☐ Supply Chain, Quality and CMO Oversight 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 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.