ECA QP ASSOCIATION
An ECA Foundation Interest Group

Speakers:

Susanne Ding
Boehringer Ingelheim, Germany

Alessandro Giuseppe Giunta
AbbVie, Germany

Rebecca Haywood
Pfizer, United Kingdom & Ireland

Katrien Himpens
J&J Innovative Medicines, Belgium

Patryk Jegorow
Takeda, Ireland

Shirly Murphy
Takeda, Ireland

Claudius Pop
Novartis, Germany

Andreas Schwinn
Roche Pharma AG, Germany

Niina Taylor
Pfizer, United Kingdom & Ireland

Brenda Van Assche
J&J Innovative Medicines, Belgium

IMP Working Group

The Qualified Person Forum Pre-Conference Session

Specific Requirements for IMPs

Amsterdam
27 November 2024

Strengthen the IMP QP's Foundation

Legislation updates impacting IMP QPs,
Clinical Trial Regulation survey,
third country IMP GMP inspections first practical experiences,
inspector's view,
critical thinking as an IMP QP,
Quality culture in the IMP context,
Use of GenAI in GxP regulated environment: application & considerations,
Practical examples,
Q&A sessions

Background IMP Working Group

The IMP Working Group is a well-established part of the EQPA and its Pre-Conference Workshop an established piece of the annual QP Association event. The workshop is also facilitated as an annual meeting of the IMP Working Group and provides an excellent opportunity for networking and cultivating personal contacts.

Objectives

- Represent QPs within the European Qualified Person Association
- Maintain and grow a strong IMP network
- Share and enhance knowledge of IMP QP members by exchanging experiences, challenges, ideas and insights
- Discuss and share interpretation of regulatory guidance
- Identify and promote best practices by benchmarking across industry
- Influence new legislation by providing expert review and feedback to Regulatory Authorities
- Represent the IMP QP role to other stakeholders, e.g., industry colleagues and non-EU regulatory bodies

Management and Administration

The IMP Working Group is led by:
Susanne Ding, *Boehringer Ingelheim, Germany*
Katrien Himpens, *Janssen Pharmaceutica, Belgium*
Patryk Jegorow, *Takeda, Ireland*
Niina Taylor, *Pfizer, United Kingdom and Ireland*

Administration work is provided by the EQPA Secretary. To become member of the IMP Working Group please contact us via eMail: info@qp-association.eu. Please note that membership in this group will be granted to Members of the QP Association only.

Target Audience

- Qualified Persons and aspiring QPs for IMPs,
- Authority representatives involved with IMPs,
- Regulatory Affairs,
- Senior Management & other IMP Industry stakeholders

Agenda IMP Pre-Conference

Welcome and Introduction

Lecture & discussion
Legislation updates impacting IMP QPs

Taskforce presentation survey
Clinical Trial Regulation – experience so far

Lecture & discussion
Third country IMP EU GMP inspections – first practical experiences

Lecture & discussion
Inspector's view

Interactive case studies – practical examples

Presentation & interactive discussion
Critical thinking as an IMP QP

Presentation & discussion
Quality culture in the IMP context

Presentation & discussion
Use of GenAI in GxP regulated environment - application and considerations

Q&A sessions (submit your questions in advance to impqp@qp-association.eu before 04 Nov 2024)

Welcome Reception QP Forum

Moderator IMP Pre-Conference

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

Agenda Parallel Session "Challenges for IMP QPs"

- ATIMP Release
- Phase appropriate Quality Management Systems (QMS)
- CTA / IMPD compliance check

Speakers

Susanne Ding
Qualified Person IMP, Boehringer Ingelheim, Germany

Alessandro Giuseppe Giunta
Qualified Person, Associate Director IMP Quality Management, AbbVie, Germany

Rebecca Haywood
Qualified Person, Pfizer, United Kingdom & Ireland

Katrien Himpens
Qualified Person / Site Quality head CAR-T, J&J Innovative Medicines, Belgium

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

Shirly Murphy
Head of Knowledge Management, Global Quality Compliance & Systems, Takeda, Ireland

Claudius Pop
Head Clinical Supplies QA / Qualified Person, Novartis, Germany

Andreas Schwinn
Senior Qualified Person, Roche Pharma AG, Germany

Niina Taylor
Qualified Person, Pharmaceutical Sciences Operation Quality, Pfizer, United Kingdom & Ireland

Brenda Van Assche
Site Quality Head / Qualified Person, J&J Innovative Medicines, Belgium

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)

☐ **Specific Requirements for IMPs**
27 November 2024

☐ **QP Forum**
28-29 November 2024

☐ Mr ☐ Ms ☐ Mx ☐ Dr

TTitle, first name, surname

Company Department

Important: Please indicate your company's VAT ID Number

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 %.

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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.

Date Pre-Conference
Wednesday, 27 November 2024, 09.00 – 18.00 h
(Registration: 08.30 – 9.00)

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

Fee Pre-Conference
€ 1.190,- per delegate plus VAT.
The fee is payable in advance after receipt of invoice.

Fees QP Forum
EU GMP Inspectorates: € 995,- plus VAT
QP Association Member: € 1.790,- plus VAT
Non-QP Association Member: € 1.990,- plus VAT

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

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
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.

Presentations/Certificate
The presentations will be made available to you prior to the Live Online Training as PDF files. After the event, you will automatically receive your certificate of participation.

Organisation / Contact
CONCEPT HEIDELBERG
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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.

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.

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