ECA QP ASSOCIATION
An ECA Foundation Interest Group

Speakers:

Dr Susanne Ding
Boehringer Ingelheim, Germany

Dr Rainer Gnibl
GMP Inspector for the District Government and the EMA, Germany

Paulien Groll
Takeda, US

Katrien Himpens
Janssen, Belgium

Patryk Jegorow
Takeda, Ireland

Kelly Jenner
Pfizer, United Kingdom

Dr Nils Jost
Paul-Ehrlich-Institut Federal Institute for Vaccines and Biomedicines, Germany

Sue Mann
Sue Mann Consultancy, United Kingdom

Dr Andreas Schwinn
Roche Pharma, Germany

Niina Taylor
Pfizer, United Kingdom & Ireland

Brenda Van Assche
Janssen, Belgium

Bart Vannieuwenhuyse
Janssen, Belgium

IMP Working Group

The Qualified Person Forum Pre-Conference Session

Specific Requirements for IMPs

Berlin & Live Online
30 November 2022

Digitization – Challenges ahead for IMP QPs

Reducing operational uncertainty in clinical trials, the promise of Real-World Data
New legislation & practical implications
(Clinical Trial Regulation, Annex 21, Brexit, remote batch certification)
Extended Access Programs Taskforce
Panel discussion: From the supply chain to the sponsor release
Digitizing Quality Management Systems
Helpful tips from an inspector
Inspection readiness – strategy & tools
Regulatory Aspects of QbD, PAT and RTRT
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:
Dr Susanne Ding, *Boehringer Ingelheim, Germany*
Patryk Jegorow, *Takeda, Ireland*
Niina Taylor, *Pfizer, UK & Ireland*
Brenda Van Assche, *Janssen, Belgium*

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

Inspirational lecture
Reducing operational uncertainty in clinical trials, the promise of Real-World Data

Lecture & discussion
New legislation impacting IMP QPs

Interactive session
Practical implications of new legislations (Clinical Trial Regulation, Annex 21, Brexit, remote batch certification)

Taskforce update
Extended Access Programs

Panel discussion
From the supply chain to the sponsor release

Lecture & discussion
Digitizing QMS via new systems and dashboards

Lecture & discussion
Helpful tips to survive IMP GMP inspections

Lecture & discussion
Inspection Readiness – Strategy & Tools

Lecture & discussion
Regulatory Aspects of Quality by Design, Process Analytical Technology and Real Time Release Testing

Q&A sessions (submit your questions in advance to impqp@qp-association.eu before 11 Nov 2022)

Welcome Reception QP Forum

Speakers

Dr Susanne Ding
Qualified Person IMP, Boehringer Ingelheim, Germany, Member of the EQPA Board of Directors

Dr Rainer Gnibl
GMP Inspector for the District Government and the EMA, Germany. Advisory Board Member of the EQPA

Paulien Groll
Head of Compliance Excellence (VP), Global Quality Compliance & Enterprise Systems, Takeda US

Katrien Himpens
Head of QA Clinical Supply Chain / Qualified Person IMP, Janssen, Belgium

Patryk Jegorow
Head of Quality Compliance and Systems Biologics Operating Unit, Qualified Person, Takeda, Ireland, Member of the IMP Working Group within the EQPA

Kelly Jenner
Senior Manager QA Compliance, Pfizer United Kingdom

Dr Nils Jost
Quality and Non-clinical Assessor, Paul-Ehrlich-Institut Federal Institute for Vaccines and Biomedicines, Germany

Sue Mann
Sue Mann Consultancy, Qualified Person and QP Assessor working on behalf of the MHRA, representing the Royal Pharmaceutical Society, United Kingdom

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

Niina Taylor
Qualified Person, Pharmaceutical Sciences QA, Pfizer, United Kingdom & Ireland, Member of the IMP Working Group within the EQPA

Brenda Van Assche
Site Quality Head / Qualified Person IMP, Janssen, Belgium, Member of the IMP Working Group within the EQPA

Bart Vannieuwenhuyse
Data Science Lead, Janssen R&D, 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**
30 November 2022

☐ **QP Forum**
01-02 December 2022

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

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 %.

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.

Date Pre-Conference
Wednesday, 30 November 2022, 09.00 – 18.00* h
(Registration for taking part on-site in Berlin: 8.30 – 9.00 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 – 16.00 h*

* All times mentioned are CET.

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 event, it will be conducted live online. In this case, you will be informed in due time.

Technical Requirements for Live Online Participation
We use Webex Events for our live online training courses and webinars. At www.gmp-compliance.org/training/online-training-technical-information you will find all the information you need to participate in our events and you can check if your system meets the necessary requirements to participate. If the installation of browser extensions is not possible due to your rights in the IT system, please contact your IT department. Webex is a standard nowadays and the necessary installation is fast and easy.

Fee Pre-Conference
€ 990,- per delegate plus VAT.
The fee is payable in advance after receipt of invoice.

Fees QP Forum
EU GMP Inspectorates: € 895,- plus VAT
QP Association Member: € 1.690,- plus VAT
Non-QP Association Member: € 1.890,- plus VAT

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
P.O. Box 10 17 64
D-69007 Heidelberg, Germany
Phone +49 (0) 62 21/84 44-0, Fax +49 (0) 62 21/84 44 34
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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.

Important Information!

PLEASE NOTE: You can register 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.

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