



The Qualified Person Forum Pre-Conference Session
The Qualified Person Forum Parallel Session

Specific Requirements for IMPs

Face-to-Face – Berlin, Germany

Remotely – Live Online

25 November 2020

IMP QPs exploring the Boundaries



New legislation impacting IMP QPs

Inspector's view on IMP GMP inspections –
Covid-19 – distant inspections

Compassionate Use/Managed Access Programs

Phase appropriate GMP

Interactive sessions – comparators, identification of
potential challenges for IMP QPs

Q&A sessions

Speakers:

Dr Susanne Ding

Boehringer Ingelheim, Germany

Patryk Jegorow

Takeda, Ireland

Catherine Neary

*Health Products Regulatory
Authority (HPRA), Ireland*

Dr Andreas Schwinn

Roche Pharma, Germany

Niina Taylor

Pfizer, UK & Ireland

Brenda Van Assche

Janssen, Belgium

IMP Working Group

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 as individuals acting on behalf of pharmaceutical companies
- Establish and maintain a strong IMP network within the EQPA
- Enhance the knowledge of IMP QP members by sharing experiences, challenges, ideas and insights
- Identify and promote best practice
- Inform on country specific items (import, export, views of global regulatory authorities)
- Influence new legislation by providing expert review and feedback to Regulatory Authorities
- Become the preferred body for consultation on IMP GMP regulations
- Discuss and assist in the interpretation of regulatory guidance
- 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, United Kingdom*

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

Lecture & Questions

New legislation impacting IMP QPs

Lecture & Questions

Inspector's view on IMP GMP inspections, how to cope with the Covid-19 situation, learnings from distant inspections

Lecture & Questions

Phase appropriate GMP

Lecture & Questions – Outcome of the Survey

IMP QP involvement in Compassionate Use / Managed Access Programs

Interactive Sessions

- **Use of comparators in clinical studies and IMP QP involvement**
- **Identification of potential challenges for IMP QPs and their mitigation strategies**

Questions & Answer Sessions

(Please submit your questions in advance to impqp@qp-association.eu before 10 November 2020)

Welcome Reception QP Forum

Agenda Parallel Session QP Forum

Challenges for IMP QPs

- Relationship between Sponsor and IMP QPs including Brexit considerations

Speakers

Dr Susanne Ding

Qualified Person IMP, Boehringer Ingelheim, Germany

Patryk Jegorow

Head of Quality Strategy and Business Operations, Qualified Person, Takeda, Ireland

Catherine Neary

GMP Operations Manager, Health Products Regulatory Authority (HPRA), Ireland

Dr Andreas Schwinn

Head PQIP, Qualified Person, Roche Pharma AG, Germany

Niina Taylor

Qualified Person, Pharmaceutical Sciences QA, Pfizer, United Kingdom & Ireland

Brenda Van Assche

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

- Face-to-Face – Berlin, Germany 25 November 2020
- Remotely – Live Online
- Mr Ms

QP Forum

- Face-to-Face – Berlin, Germany 26-27 November 2020
- Remotely – Live Online

Title, 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)

Date

Wednesday, 25 November 2020, 09.00 – 18.00
(Registration and coffee: 08.30 – 9.00)

Welcome Reception for all participants

Wednesday, 25 November 2020, 18.00 – 19.00

Date QP Forum

Thursday, 26 November 2020, 9.00 – 18.00 h
(Registration: Wednesday, 25 November 18.00 – 19.00 h and
Thursday 26 November, 08.00 – 9.00 h)
Friday, 27 November 2020, 8.30 – 14.30 h

Venue

Radisson Blu Hotel Berlin
Karl-Liebknecht-Straße 3
10178 Berlin
Germany
Phone: +49 (0)30 238 28 0
E-Mail: info.berlin@radissonblu.com

Fee for Workshop

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

Fees for QP Forum

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

Book both the Pre-Conference Session and the Forum and save money! Delegates who also attend the QP Forum will get a discount of 200€ on the QP Forum. More information about the European QP Association and the Forum: www.qp-association.eu

Accommodation

CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation link for the Radisson Blu Hotel and other hotels close by when you have registered for the conference. Reservation should be made directly with the hotel of your choice with one of the reservation links. 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.

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
E-mail: info@concept-heidelberg.de
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.

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)!