QP ASSOCIATION

Speakers:

Dr Justin Barry
Emergex Vaccines, United Kingdom

Dr Susanne Ding
Boehringer Ingelheim, Germany

Dr Rainer Gnibl
District Government of Upper Bavaria, Germany

Silja Du Mont
GCP/GDP Inspectorate, Germany

Patryk Jegorow
Takeda, Ireland

Dr Andreas Schwinn
Roche Pharma, Germany

Niina Taylor
Pfizer, UK & Ireland

Brenda Van Assche
Janssen, Belgium

Philippe Van der Hofstadt
Clinical Supplies Management (CSM), Belgium

IMP Working Group

The Qualified Person Forum Pre-Conference Session

The Qualified Person Forum Parallel Session

Specific Requirements for IMPs

Munich, Germany, 27 November 2019

Looking to the Future

moderated by Philippe Van der Hofstadt,
Vice President Corporate Development, Clinical Supplies Management, Belgium

New legislation impacting IMP QPs
Continuous manufacture
Template manufacturer-sponsor agreement
Inspector's view on GMP/GCP/GDP interface
Virtual clinical trials – direct-to-patient shipment
Inspector's view on ATMP-IMPs incl. QP certification
Interactive case studies
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 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*
Dr Justin Barry, *Emergex Vaccines, United Kingdom*
Niina Taylor, *Pfizer, United Kingdom*
Brenda Van Assche, Janssen, Belgium
Philippe Van der Hofstadt, *Clinical Supplies Management (CSM), 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: look forward and backwards

Lecture & Questions
At the edge of innovation – Inspector's view "What to focus on ATMP-IMPs including QP certification"

Lecture & interactive discussion
Looking to the future – continuous manufacture
(inspection experience, how to certify?)

Interactive Case Studies
Decision making for IMP QPs

Lecture & Questions – outcome of task force
Template for a manufacturer – sponsor agreement

Lecture & Questions
Inspector's view on the GMP/GCP/GDP interface

Lecture & Questions
Looking to the future – virtual clinical trials: Direct-to-Patient shipment

Questions & Answer Sessions
(Please submit your questions in advance to impqp@qp-association.eu before 12 November 2019)

Welcome Reception QP Forum

Agenda Parallel Session QP Forum

Changes for IMP QPs : continuing to shed light on grey zones and sharing experiences

- Retention: samples and documentation
- Experience sharing, e.g. Brexit, new IMP GMP regulation, etc.
- Challenges for smaller companies

Speakers

Dr Justin Barry
Qualified Person, Emergex Vaccines, United Kingdom

Dr Susanne Ding
Qualified Person IMPs, Boehringer Ingelheim, Germany

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

Silja Du Mont
GCP/GDP Inspector and Head of Expert Group Clinical Trials (ZLG), Germany

Patryk Jegorow
Head of Quality Strategy and Business Operations, Qualified Person, Takeda, 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

Philippe Van der Hofstadt
VP Corporate Development, Clinical Supplies Management (CSM), 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**
Munich, Germany, 27 Nov. 2019

☐ **QP Forum**
Munich, Germany, 28-29 Nov. 2019

☐ Mr ☐ Ms

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, 27 November 2019, 09.00 – 18.00
(Registration and coffee: 08.30 – 9.00)

Welcome Reception for all participants
Wednesday, 27 November 2019, 18.00 – 19.00

Date QP Forum
Thursday, 28 November 2019, 9.00 – 18.00
(Registration: Wednesday, 27 November 18.00 – 19.00 and
Thursday 28 November, 08.00 – 9.00)
Friday, 29 November 2019, 8.30 – 14.30

Venue
Sofitel Munich Bayerpost
Bayerstrasse 12
80335 Munich
Germany
Tel.: +49 (0)89 599 48 0
E-mail: H5413@sofitel.com

Fee for Workshop
€ 990,- per delegate plus VAT.
The fee is payable in advance after receipt of invoice and includes electronic conference documentation and all refreshments. 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 Sofitel 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.

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