QP ASSOCIATION

Speakers:

Dr Justin Barry
J&J Barry Consulting, Spain

Dr Susanne Ding
Boehringer Ingelheim, Germany

Martine Powell
Medicines & Healthcare products Regulatory Agency (MHRA), UK

Andreas Schwinn
Roche Pharma, Germany

Niina Taylor
Pfizer, UK

Brenda Van Assche
Janssen, Belgium

Gunter Van Hoof
Clinical Supplies Management, Belgium

IMP Working Group

The Qualified Person Forum Pre-Conference Session

The Qualified Person Forum Parallel Session

Specific Requirements for IMPs

Prague, Czech Republic, 28 November 2018

Transitioning to new IMP GMPs

moderated by Philippe Van der Hofstadt,
EU President, Clinical Supplies Management, Belgium

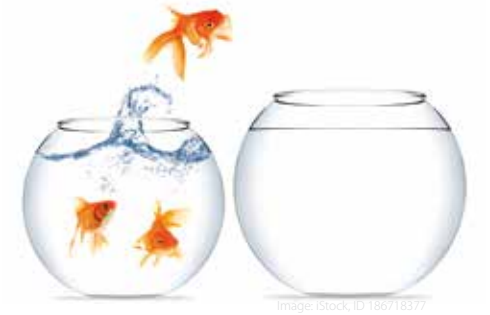

Image: iStock, ID 186718377

New legislation impacting IMP QPs
Clinical Trial Regulation
The IMP Order
To delegate or not to delegate
Delegated Act & Detailed Commission Guidelines
Inspection Findings on IMPs
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 strong IMP network within the EQPA
- Enhance knowledge of IMP QP members by sharing experiences, challenging ideas and providing insights
- Identify and promote opportunities for best practice
- Inform about 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 IMP GMP regulation consultation
- Discuss how to interpret regulatory guidance
- Represent the IMP QP role to others, 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, *J&J Barry Consulting, Spain*
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 – Niina Taylor
New legislation impacting IMP QPs: look forward and backwards

Lecture & Questions – Justin Barry
Clinical Trial Regulation – Outcome Efpia roundtable

Lecture & interactive discussion, Gunter Van Hoof
The IMP Order

Interactive Case Study
Decision making for IMP QPs

Lecture & Questions – Andreas Schwinn
"To delegate or not to delegate" Survey outcome

Lecture & Questions – Susanne Ding, Brenda Van Assche
Delegated Act & Detailed Commission Guidelines

Lecture & Questions, Martine Powell
Inspector's view on relevant topics for IMPs

Questions & Answer Sessions
(Please submit your questions in advance to impqp@qp-association.eu before 16 November 2018)

Welcome Reception QP Forum

Agenda Parallel Session QP Forum

Changes at the GMP-GCP Interface : continuing to shed light on grey zones and sharing experiences

- The Medical Order
- New draft guideline on the responsibility of the sponsor wrt handling and shipping of IMP according to GCP and GMP
- Current & future use of Interactive Response Technology

Speakers

Dr Justin Barry
Managing Director & Qualified Person, J&J Barry Consulting, Spain.

Dr Susanne Ding
Qualified Person IMPs, Boehringer Ingelheim, Germany.

Martine Powell
GMDP Inspector, Inspection, Enforcement and Standards Division Medicines & Healthcare products Regulatory Agency (MHRA), United Kingdom.

Andreas Schwinn
Head PQIP, Qualified Person, Roche Pharma AG, Germany

Niina Taylor
Qualified Person, Pharmaceutical Sciences QA, Pfizer, United Kingdom.

Brenda Van Assche
Director QA Clinical Supply Chain / Qualified Person IMP, Janssen, Belgium.

Gunter Van Hoof
VP EU Operations, Clinical Supplies Management, Belgium.

If the bill-to-address deviates from the specification to the right, please fill out here:

Reservation Form (Please complete in full)

☐ **Specific Requirements for IMPs**
Prague, Czech Republic, 28 Nov. 2018

☐ **QP Forum**
Prague, Czech Republic, 29-30 Nov. 2018

☐ 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)

CONCEPT HEIDELBERG
Postfach 10 17 64
Fax 06221/84 44 34

D-69007 Heidelberg

Date
Wednesday, 28 November 2018, 09.00 – 18.00
(Registration and coffee: 08.30 – 9.00)

Welcome Reception for all participants
Wednesday, 28 November 2018, 18.00 – 19.00

Date QP Forum
Thursday, 29 November 2018, 9.00 – 18.00
(Registration: Wednesday, 28 November 18.00 – 19.00 and
Thursday 29 November, 08.00 – 9.00)
Friday, 30 November 2018, 8.30 – 14.30

Venue
InterContinental Praha
Pařížská 30
110 00 Praha 1
Czech Republic
Tel: +420296631111 / Fax: +420224811216
Email: prague@icprague.com

Fee for Workshop
€ 890,- per delegate plus VAT.
The fee is payable in advance after receipt of invoice and includes conference documentation and all refreshments. VAT is reclaimable.

Fees for QP Forum
EU GMP Inspectorates: € 895,- plus VAT
QP Association Member: € 1.590,- plus VAT
Non-QP Association Member: € 1.790,- 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 form when you have registered for the event. Please use this form for your room reservation or be sure to mention QP Association to receive the specially negotiated rate (single room 155,- Euros per night incl. breakfast) for the duration of your stay. Reservation should be made directly with the hotel not later than 6 October 2018. 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
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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)!

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