

Specific Requirements for IMPs

IMP QPs shaping for the future

Berlin, Germany, 24 November 2015



Key inspection issues for IMPs
New legislation

Revised Annex 16 – to delegate or not
Investigator Initiated Studies
eLabels, GDP – Distribution of IMPs
Risk Assessment Exercise
Interactive case study, Q & A sessions

Speakers:

Justin Barry
Midatech Biogune

Susanne Ding
Boehringer Ingelheim

Roger Lauwers
Janssen

Kati Mortier
Janssen

Andreas Schwinn
Roche Pharma

Jodi Smith-Gick
Eli Lilly and Company

Niina Taylor
Pfizer

Philippe Van der Hofstadt
B&C Group

Maria Wängelin
*Swedish Medical Products Agency
(MPA)*

Background IMP Working Group

The IMP Working Group is a well-established “sub-organisation” of the EQPA and its Pre-Conference Workshop a well-known part of this annual QP Association event. The workshop is also facilitated as an annual meeting of the IMP Working Group and provides a very good 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, challenges ideas, insights
- Identify and promote best practice opportunities
- 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 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*

Justin Barry, *Midatech Pharma España, Spain*

Kati Mortier, *Janssen, Belgium*

Niina Taylor, *Pfizer, United Kingdom*

Philippe Van der Hofstadt, *B&C Group, 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 Quality Assurance Managers for Investigational Medicinal Products

Agenda IMP Pre-Conference

Welcome and Introduction

Lecture

Key Inspection issues for IMPs vs regular manufacture – what do we have to concentrate on ?

Lecture

New legislation impacting IMP QPs

Roundtable Discussion

Revised Annex 16 « to delegate or not to delegate from an IMP QP’s perspective »

Lecture

Investigator Initiated Studies – report outcome of survey

Interactive Case Study

IMP QP decision making

Lecture

eLabels: technology, pilot project and next steps

Lecture

Good Distribution Practice – distribution of IMPs

Interactive Session

Risk Assessment Exercise

Questions & Answer Sessions

Welcome Reception QP Forum

Agenda Parallel Session QP Forum

Special requirements for IMP QPs / the role of the QP at the GMP/GCP interface

- Where does the IMP QP responsibility end ?
- Where and when should the IMP QP be involved in the clinical trial (e.g. site-to-site transfer, temperature excursions, shelf-life extension, complaint handling, joint GMP/GCP inspections, etc.)
- Managing incidents at the GMP/GCP interface

Speakers

Justin Barry

Qualified Person, Midatech Pharma España.

Susanne Ding

Qualified Person Investigational Medicinal Products, Boehringer Ingelheim.

Roger Lauwers

Director Clinical Supply Chain, Janssen, Belgium.

Kati Mortier

Manager QA Clinical Supply Chain / Qualified Person IMPs, Janssen, Belgium.

Andreas Schwinn

Head PQIP, Qualified Person, Roche Pharma AG, Germany.

Jodi Smith-Gick

Core Team Member TransCelerate Initiative e Labels, Eli Lilly and Company – (via video)

Niina Taylor

Qualified Person Pharmaceutical Sciences Quality Assurance, Pfizer.

Philippe Van der Hofstadt

CEO, B&C Group, Belgium.

Maria Wängelin

GDP/GMP Inspector at the Swedish Medical Products Agency.

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
Berlin, Germany, 24 November 2015

QP Forum
Berlin, Germany, 25-26 November 2015

Mr Ms

Title, first name, surname

Company

Department

Important: Please indicate your company's VAT ID Number

Street / P.O. Box

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

City Zip Code

Country

Phone / Fax

D-69007 Heidelberg

E-mail (Please fill in)

Date

Tuesday, 24 November 2015, 09.30 – 18.00
(Registration and coffee: 09.00 – 9.30)

Welcome Reception for all participants

Tuesday, 24 November 2015, 18.00 – 19.00

Date QP Forum

Wednesday, 25 November 2015, 9.00 – 18.00
(Registration: Tuesday, 24 November 18.00 – 19.00
and Wednesday 25 November, 08.00 – 9.00)
Thursday, 26 November 2015, 8.30 – 14.30

Venue

Steigenberger Hotel am Kanzleramt
Ella-Trebe-Str. 5
10557 Berlin
Germany
Tel.: +49 030 – 74 07 43 0
Fax.: +49 030 - 740743 999

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 139,- Euros per night incl. breakfast) for the duration of your stay. Reservation should be made directly with the hotel not later than 12 October 2015. 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

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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 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)!