ECA QP ASSOCIATION
An ECA Foundation Interest Group

Speakers:

Danielle Cullinan
Inspirational Speaker

Yogesh K Davé
Cypress Quality Consultancy Ltd., UK

Susanne Ding
Boehringer Ingelheim, Germany

Laura Fiammenghi
Propharma Group, Italy

Katrien Himpens
Janssen Pharmaceutica, Belgium

Joe Horvath
Takeda, United States

Patryk Jegorow
Takeda, Ireland

Anna Maria Kurzreiter, BSc, MSc, MSc
Austrian Medicines and Medical Devices Agency

Marianne Lunzer
Austrian Agency for Health and Food Safety (AGES)

Claudius Pop
Novartis, Germany

Niina Taylor
Pfizer, United Kingdom & Ireland

IMP Working Group

The Qualified Person Forum Pre-Conference Session

Specific Requirements for IMPs

Vienna & Live Online
11 October 2023

The Future is in our Hands

Inspirational talk
Legislation updates impacting IMP QPs
Clinical Trial Regulation – experience so far
What the IMP QP needs to know about CTIS
Application/s of Quality Risk Management
ATMP – Inspector's view – practical aspects
Practical examples
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:
Susanne Ding, *Boehringer Ingelheim, Germany*
Katrien Himpens, *Janssen Pharmaceutica, Belgium*
Patryk Jegorow, *Takeda, Ireland*
Niina Taylor, *Pfizer, United Kingdom and Ireland*

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 talk
Angelman syndrome - my story

Lecture & discussion
Legislation updates impacting IMP QPs

Taskforce report out
Clinical Trial Regulation – experience so far

Lecture & discussion
What the IMP QP needs to know about CTIS (Clinical Trial Information System)

Interactive case study

Lecture & discussion
Application/s of Quality Risk Management

Lecture & discussion
ATMP - Inspector's view

Lecture & discussion
ATMP – Practical aspects

Q&A sessions (submit your questions in advance to impqp@qp-association.eu before 20 September 2023)

Welcome Reception QP Forum

Moderator IMP Pre-Conference

Patryk Jegorow, Takeda, Ireland

Agenda Parallel Session "Challenges for IMP QPs"

- Product Specification File
- Legal Framework
  (contractual arrangements, technical agreements)
- Quarantine shipments

Speakers

Danielle Cullinan
Inspirational Speaker

Yogesh K Davé
EU/UK Qualified Person, Cypress Quality Consultancy Ltd., UK

Susanne Ding
Qualified Person IMP, Boehringer Ingelheim, Germany

Laura Fiammenghi
ATMP Qualified Person and Senior Consultant, Propharma Group, Italy

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

Joe Horvath
Head of Quality Risk Management, Takeda, United States

Patryk Jegorow
Head of Quality Compliance and Systems Biologics Operating Unit, Qualified Person, Takeda, Ireland

Anna Maria Kurzreiter, BSc, MSc, MSc
Inspector, Senior Expert, Dept. GMDP, Institute Surveillance, Austrian Medicines and Medical Devices Agency

Marianne Lunzer
Safety assessor in the clinical trials department at Austrian Agency for Health and Food Safety (AGES) and Clinical Trials Coordination Group (CTCG) chair

Claudius Pop
Head Clinical Supplies QA / Qualified Person, Novartis, Germany

Niina Taylor
Qualified Person, Pharmaceutical Sciences Operation Quality, Pfizer, United Kingdom & Ireland

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**
11 October 2023

☐ **QP Forum**
12-13 October 2023

PLEASE NOTE: You can already register now and decide later how you will participate – face-to-face in Vienna or remotely.

Participation: ☐ in Vienna ☐ 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 cancelation 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, 11 October 2023, 09.00 – 18.00* h
(Registration for taking part on-site in Vienna: 8.30 – 9.00 h*)

Date QP Forum
Thursday, 12 October 2023, 9.00 – 18.00 h*
(Registration for taking part on-site in Vienna:
Wednesday, 11 October 2023 18.00 – 19.00 h* and
Thursday, 12 October 2023, 8.00 – 9.00 h*)
Friday, 13 October 2023, 8.30 – 16.00 h*

* All times mentioned are CET.

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
€ 1.190,- per delegate plus VAT.
The fee is payable in advance after receipt of invoice.

Fees QP Forum
EU GMP Inspectorates: € 995,- plus VAT
QP Association Member: € 1.790,- plus VAT
Non-QP Association Member: € 1.990,- 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
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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.

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 Vienna 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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