ECA | QP ASSOCIATION
An ECA Foundation Interest Group

QUALIFIED PERSON FORUM 2021

LIVE ONLINE | 02-03 December 2021

PRE-CONFERENCE SESSIONS | 01 December 2021

Specific Requirements for IMPs (full day)

Human Error (1/2 day)

How to certify Drug-Device Combinations (1/2 day)

Speakers from Authorities, Inspectorates and Associations:

Dr Rainer Gallitzendörfer
GMP Inspector, Germany
Dr Rainer Gnibl
GMP Inspector, Germany
Dr Thomas Hecker
EDQM, Council of Europe
Mag.pharm. Andreas Kraßnigg
Austrian Agency for Health and Food Safety (AGES)
Catherine Neary
Irish Health Products Regulatory Authority (HPRA)
Gillian Renouf
Royal Pharmaceutical Society QP Assessment Panel, U.K.

Speakers from Industry:

Alexandra Bauloye
GlaxoSmithKline
Cheryl Chia
Lotus Phoenix Consulting
David Cockburn
EQPA
Dr Darrin Cowley *(invited)*
AstraZeneca
Dr Susanne Ding
Boehringer Ingelheim
Dr Andreas Flückiger
Form. Roche
DI Georg Göstl
Takeda
Tor Gråberg
AstraZeneca
Energy Kristina Hansen
MilCor Consulting
Dr Afshin Hosseiny
ECA
Patryk Jegorow
Takeda
Dr Ulrich Kissel
EQPA
Aidan Madden
FivePharma
Sue Mann
Sue Mann Consultancy
Gábor Mihályi
MihaPharm
Dr Peer Schmidt
AbbVie
Niina Taylor
Pfizer
Brenda Van Assche
Janssen

(other speakers invited)

WELCOME

Dear Colleagues,

The year 2020 will remain in our memories for a long time; and 2021 probably will too. Life has been associated with many changes and restrictions, not only in the private sphere. The working world and focal points of the regulatory authorities have also changed, in some cases considerably. Many activities had to be carried out online; also audits, inspections and batch certifications. And hovering over everything was the Brexit.

But the normal working life of the QP also continued, with all the manifold tasks and responsibilities; these should not be left out. In this programme, we try to cover the classic tasks such as batch related decisions, increasingly important topics such as supply chain and quality risk management, and the challenges brought about by Brexit and the pandemic.

Therefore the EQPA Board has now decided to offer this year's QP Forum as a Live Online Conference. All lectures and sessions of the main Forum will be held consecutively and can be attended by all live online at your screen.

Best regards,

Dr Ulrich Kissel
Chairman of the Qualified Person Association

OBJECTIVE

This Conference is designed by QPs for QPs as an international Expert Forum with focus on sharing information and experience and on discussing the challenging parts of the QP's daily work.

TARGET GROUP

The Forum is designed for all Qualified Persons and aspiring Qualified Persons. It also addresses upper management functions and authority representatives who want to be informed about the latest development regarding the duties and responsibilities of Qualified Persons.

FORUM MODERATOR

Wolfgang Schmitt
(On behalf of the EQPA)

PRE-CONFERENCE SESSIONS – 01 DECEMBER 2021

FULL DAY PRE-CONFERENCE SESSION

Specific Requirements for IMPs

Facilitated by:
Susanne Ding | Rainer Gnibl | Patryk Jegorow | Sue Mann | Niina Taylor | Catherine Neary | Brenda Van Assche (other speakers invited)

- New legislation impacting IMP QPs
- Experiences with Brexit
- Are you ready for the new IMP GMP regulation?
- Inspector's view on IMP topics
- Investigational ATMPs
- Phase appropriate GMP
- Interactive sessions and case studies – decision making of IMP QPs
- Q&A sessions

1/2 DAY PRE-CONFERENCE SESSION

Human Error

Facilitated by:
Sue Mann | Energy Kristina Hansen

- What is behind "Human Error"?
- Considering human behaviours
- Is Human error avoidable?
- Tips for reducing human errors

1/2 DAY PRE-CONFERENCE SESSION

How to certify Drug-Device Combinations

Facilitated by:
Rainer Gallitzendörfer | Peer Schmidt

- What the QP needs to know about the new Medical Devices regulations
- Responsibilities of the QP when certifying DDCs (start and end)
- How to prove compliance with medical device regulations and other requirements
- Expectations of the Agencies
- Interface to and co-operation with Notified Body
- Examples and experience made

PROGRAMM QP FORUM – 02-03 DECEMBER 2021

Key Note: COVID-19 – the Challenge of making new Treatments available during Pandemic and dealing with missing Guidance

Darrin Cowley ***(invited)***

General GMP Update – News for the QP besides the big Topics

Andreas Krassnigg

Annex 21: Consequences for the QP

Rainer Gnibl and Ulrich Kissel

- Responsibility of the importing company and the QP
- Batch testing and certification
- Contractual regulations

IMP QP at the Interface to commercial QP

IMP Working Group

- Hand-over from clinical to commercial

Creating or Improving QP Oversight into the Supply Chain

Cheryl Chia and Afshin Hosseiny

- How to understand Supply Chain Diagrams (SCD)
- What the QP really needs and why
- How to improve and implement SCDs

Brexit Implications for the QP

David Cockburn and Ulrich Kissel

- UK and EU Point of View
- Impact on the roles and responsibilities of the QP

Case Study: How to deal with severe Inspection Findings ("How not to lose your License")

Gábor Mihályi

- What had led to severe inspection findings
- What happened after receiving the inspection report
- What to do and who to involve with the inspection remediation?
- How was it affecting other sites?

Quality Risk Register/ Business Continuity Plan

Alexandra Bauloye and Aidan Madden

- What is it, how to develop it and which type of risks to include
- What to show to authorities?
- The way to business continuity – what can the QP learn from this overall process?
- Involvement of the QP (before things go wrong)

What to know about PDEs and Threshold Levels for Impurities

Andreas Flückiger

- What to know about impurities and other chemical contaminants
- How to deal with different contaminants from a toxicological point of view
- What do the limits mean? How are they set and how are they to be understood?
- Why to know your toxicologist (Why the relationship with the toxicologist is important)

QP Scenarios – How serious could each Issue be?

Sue Mann and Gillian Renouf

- Discuss real-life situations involving QPs
- Explore the potential risks and impact
- Make decisions on the product(s) involved

EDQM's approach on Real Time Remote Inspections

Thomas Hecker

- Results and impressions from EDQM's real time remote inspection pilot project
- Advantages/disadvantages of the approach and its future use within EDQM's GMP assessment system of API manufacturers

Discussion: Can Distant Assessments replace on-site Audits after the Pandemic?

Rainer Gnibl and Tor Gråberg

- GMP Inspectorate and Industry Point of View

Q&A SESSION

During the 2 days of the Forum, delegates can post their questions in writing. The answers will be given by the expert speakers after their presentation or in dedicated Q&A sessions. If not answered during the conference, open Q&As will be published in the members' area of the EQPA website.

SPEAKERS

Speakers from Authorities, Inspectorates and Associations:

Dr Rainer Gallitzendörfer, *Government of Upper Bavaria, Germany*
GMP Inspector for the District Government and the EMA and accredited as a technical assessor for testing laboratories (DIN EN ISO/IEC 17025). IEC 17025) in the sector committee "Consumer Health Protection"

Dr Rainer Gnibl, *Government of Upper Bavaria, Germany*
GMP Inspector for the District Government and the EMA, Advisory Board member of the Qualified Person Association

Dr Thomas Hecker, *EDQM, Council of Europe*
Scientific Officer

Mag.pharm. Andreas Kraßnigg, *Austrian Agency for Health and Food Safety (AGES), Austria*
Head Pharmaceutical Inspections and Member of Annex 16 Drafting Group

Catherine Neary, *Irish Health Products Regulatory Authority (HPRA)*
GMP Operations Manager

Gillian Renouf, *Royal Pharmaceutical Society QP Assessment Panel, U.K.*
Chair of the RPS QP Assessment Panel

Speakers from Industry:

Alexandra Bauloye, *GlaxoSmithKline, Belgium*
Risk Management and Governance Lead, GSK Corporate

Cheryl Chia, *Lotus Phoenix Consulting, Netherlands*
Consultant for GMP and GDP compliance in the pharmaceutical supply chain.

David Cockburn, *European Qualified Person Association (EQPA)*
Member of the EQPA Board of Directors. Former Chair of the EMA GMP/GDP IWG

Dr Darrin Cowley, *AstraZeneca, USA (invited)*
Head of Developmental Quality, Biologics
Quality Lead Covid Vaccine

Dr Susanne Ding, *Boehringer Ingelheim, Germany*
Qualified Person for Investigational Medicinal Products and member of the EQPA Board of Directors

Dr Andreas Flückiger, *form. Roche, Switzerland*
former Chief Occupational Health Officer for the Roche Group (retired)

DI Georg Göstl, *Takeda, Austria*
Qualified Person, Chair of the Austrian QP Association aqpa and member of the EQPA Board of Directors

Tor Gråberg, *AstraZeneca, Sweden*
Head of External Advocacy, Global Quality, Operations, and member of the EQPA Board of Directors. Former Head of the Drug Inspectorate at the Swedish Medical Products Agency and former PIC/S Chair

Energy Kristina Hansen, *MilCor Consulting, Denmark*
Certified quality auditor (GMP/GDP/ISO) and consultant

Dr Afshin Hosseiny, *Tabriz Consulting, U.K.*
Managing Director and Qualified Person, Chair of the ECA Executive Board and Chair of the European GDP Association

Patryk Jegorow, *Takeda, Ireland*
Qualified Person Biologics, Head of Quality Strategy and Businees Operations

Dr Ulrich Kissel, *KisselPharma Consulting, Germany*
Qualified Person and Chairman of the EQPA Board of Directors

Aidan Madden, *FivePharma, Ireland*
CEO

Sue Mann, *Sue Mann Consultancy Ltd. U.K.*
Qualified Person and QP Assessor working on behalf of the MHRA, representing the Royal Pharmaceutical Society

Gábor Mihályi, *MihaPharm Consultancy B.V., Netherlands*
Qualified Person, Auditor and Consultant

Dr Peer Schmidt, *AbbVie, Germany*
Director Global Quality Systems

Niina Taylor, *Pfizer, U.K.*
Director Quality Assurance and Qualified Person

Brenda Van Assche, *Janssen Pharmaceutica NV, Belgium*
Senior Director Quality Assurance Clinical Supply Chain and Qualified Person

Other speakers invited

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)

☐ QUALIFIED PERSON FORUM 2021, 02-03 December 2021, Live Online
☐ OPTIONAL PRE-CONFERENCE SESSION, 01 December 2021, Live Online

Please choose **one of the following**:
☐ Full Day Session "Specific Requirements for IMPs"
☐ 1/2 Day Session "Human Error"
☐ 1/2 Day Session "How to certify Drug-Device Combinations"

☐ Mr ☐ Ms

Title, first name, surname

Company Department

Important: Please indicate your company's VAT ID Number

P.O Number (if applicable)

Street / P.O. Box

City Zip Code Country

Phone / Fax

E-mail (Please fill in)

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)!

About the European QP Association
The European Qualified Person (QP) Association was founded on 7 July 2006 by the European Compliance Academy's (ECA) Advisory Board Members. With this unique association the ECA wants to provide QPs in Europe with a platform allowing them to exchange their experience, discuss the latest regulatory requirements, to identify and address difficulties and challenges and to support a harmonised European approach.

More information about the QP Association and a membership application form are available at www.qp-association.eu.

About CONCEPT HEIDELBERG
Founded in 1978, CONCEPT HEIDELBERG is the leading organiser of seminars on pharmaceutical production, quality control, quality assurance and GMP in Europe. This year more than 300 events will be organised by CONCEPT HEIDELBERG. The European QP Association has entrusted CONCEPT HEIDELBERG with the organisation of its events.

Date Full Day Pre-Conference Session:
Specific Requirements for IMPs
Wednesday, 01 December 2021, 9.00 – 18.00 h*

Date ½ Day Pre-Conference Session:
Human Error
Wednesday, 01 December 2021, 13.30 – 18.00 h*

Date ½ Day Pre-Conference Session:
How to certify Drug-Device Combinations
Wednesday, 01 December 2021, 09.00 – 13.00 h*

Date QP Forum
Thursday, 02 December 2021, 9.00 – 18.00 h*
Friday, 03 December 2021, 8.30 – 16.00 h*

** All times are CET*

Technical Requirements
For the QP Forum and the pre-conference Sessions, we use Cisco WebEx, one of the leading suppliers of online meetings.
At https://www.webex.com/test-meeting.html you can check if your system meets the necessary requirements for the participation at a WebEx meeting and at the same time install the necessary plug-in. Please just enter your name and e-mail address for the test. If the installation is not possible because of your rights for the computer system, please contact your IT department. WebEx is a standard nowadays and the necessary installation is fast and easy.

Fees for QP Forum (per delegate plus VAT)
QP Association Members € 1.690,-
EU GMP Inspectorates € 895,-
Non-QP Association Members € 1.890,-
The conference fee is payable in advance after receipt of invoice. VAT is reclaimable.

Fees for Full Day Pre-Conference Session:
Specific Requirements for IMPs
€ 990,- per delegate plus VAT.
The fee is payable in advance after receipt of invoice. VAT is reclaimable.

Fees for ½ Day Pre-Conference Session:
Human Error
€ 590,- per delegate plus VAT.
The fee is payable in advance after receipt of invoice. VAT is reclaimable.

Fees for ½ Day Pre-Conference Session:
How to certify Drug-Device Combinations
€ 590,- per delegate plus VAT.
The fee is payable in advance after receipt of invoice. VAT is reclaimable.

Registration (please note the saving opportunities below)
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.

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.

Conference Language
The official conference language will be English.

Organisation / Contact
EQPA has entrusted Concept Heidelberg with the organisation of this event.

CONCEPT HEIDELBERG
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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 organisation:
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!

The presentations of the QP Forum and the Pre-Conference Sessions will be available for download and your print-out one week before and after the conference.
Note: there will be no print-outs available during the conference.