Qualified Person Forum 2019

Munich, Germany, 28-29 November 2019

NEW:
QP Forum App
to install scan the code

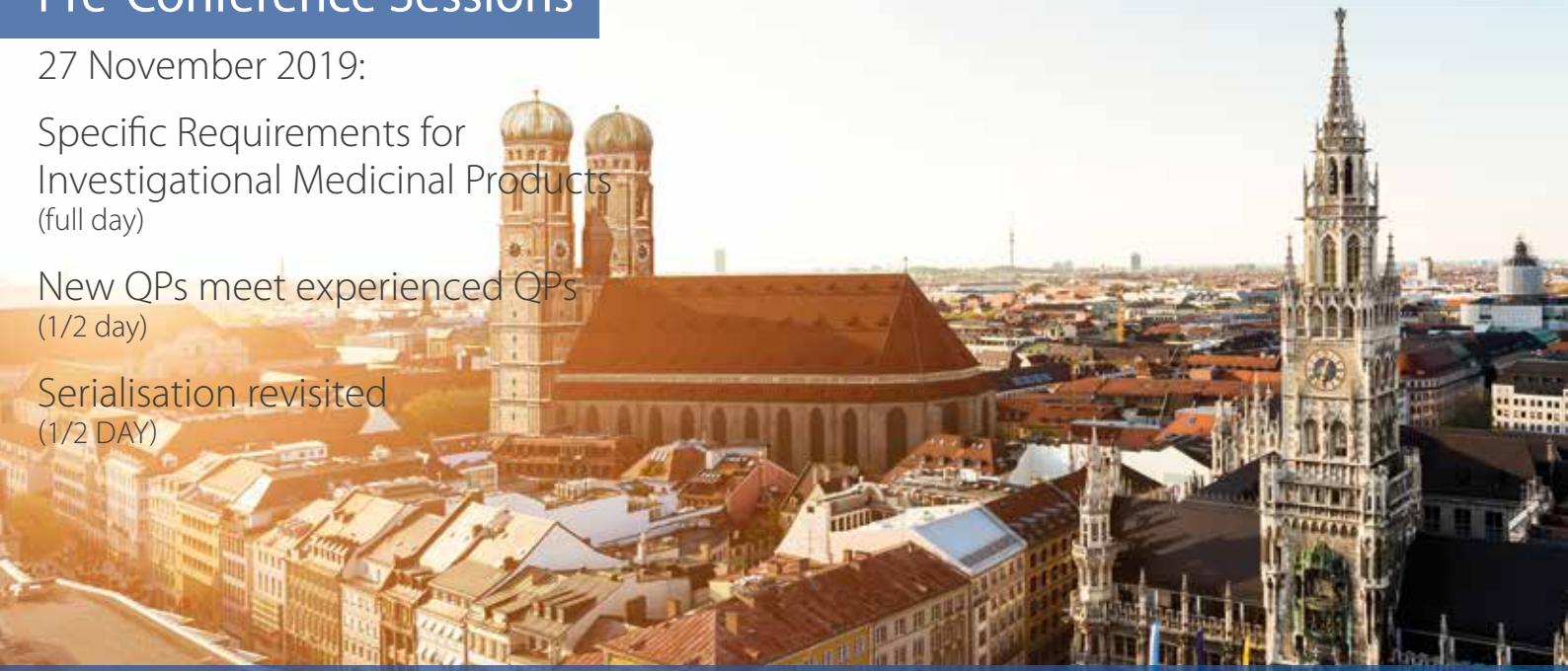
Pre-Conference Sessions

27 November 2019:

Specific Requirements for Investigational Medicinal Products
(full day)

New QPs meet experienced QPs
(1/2 day)

Serialisation revisited
(1/2 DAY)



Speakers from Authorities, Inspectorates and Associations:

Steven De Strycker
Federal Agency for Medicines and Health Products, fagg, Belgium
Silja Du Mont
GCP/GDP Inspector, Germany
Klaus Eichmüller
Wolnzach, c/o Regional Competent Authority, Germany
Dr Rainer Gnibl
Government of Upper Bavaria, Germany
Mag.pharm. Andreas Kraßnigg
Austrian Agency for Health and Food Safety (AGES)
Gillian Renouf
Royal Pharmaceutical Society QP Assessment Panel, U.K.

Speakers from Industry:

Justin Barry
Emergex Vaccines
Anthony Bennett
Anthony Inspires
Richard M. Bonner
former Chairman of the EQPA
David Cockburn
EQPA
Dr Susanne Ding
Boehringer Ingelheim
Walid El Azab
Steris
DI Georg Göstl
Takeda
Tor Gråberg
AstraZeneca
Dr Afshin Hosseiny
ECA
Patryk Jegorow
Takeda
Dr Ulrich Kissel
EQPA
Line Lundsberg-Nielsen
Lundsberg Consulting
Aidan Madden
FivePharma
Sue Mann
Sue Mann Consultancy
Edel Ryan
Mylan
Dr Andreas Schwinn
Roche Pharma
Kasper Buchwald Sønderskov
Novo Nordisk
Niina Taylor
Pfizer
Brenda Van Assche
Janssen
Philippe Van der Hofstadt
Clinical Supplies Management
Dr Anke von Harpe
QProgress
Peter C. Zimmermann
Iskom

QP ASSOCIATION

Welcome

Dear Colleagues,

The QP is responsible for ensuring that each individual batch has been manufactured and checked in accordance with the requirements of the marketing authorisation (MA) and in compliance with GMP. This is how it is described in Annex 16 of the EU-GMP Guidelines. The Annex also describes in detail other QP's responsibilities and activities in part 1.7.

But the QP is not responsible for everything! Most activities may be delegated and the QP can rely on the respective Pharmaceutical Quality System. How this can be done will be a central topic of this year's QP Forum.

Don't forget: "The ultimate responsibility for the performance of a medicinal product over its lifetime, its safety, quality and efficacy, lies with the marketing authorisation holder (MAH)."

Make use of this event by exchanging experiences with your colleagues and by establishing informal contacts and networking. I look forward to meeting you in Munich.

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

Aidan Madden

Important Information!
The presentations of the QP Forum and the Pre-Conference Workshop/ Session will be available for download and your print-out one week before and after the conference.

NEW: QP Forum App

Just download the new QP Forum app to your smartphone or tablet and have everything at hand: agenda, presentations, speaker backgrounds, notifications and more... To install the app, please scan the QR code or search for "Pharma Events" in the Apple or the Google Play Store!

Note: there will be no print-outs available during the conference.

Pre-Conference Sessions

27 November 2019

Full Day Pre-Conference Session

Specific Requirements for IMPs

Facilitated by:

Justin Barry / Susanne Ding / Silja Du Mont / Rainer Gnibl / Patryk Jegorow / Andreas Schwinn / Niina Taylor / Brenda Van Assche / Philippe Van der Hofstadt

- New legislation impacting IMP QPs
- Looking to the future:
  - Continuous manufacturing
  - Virtual clinical trials
  - Direct to patient shipment
- Interactive sessions and case studies – decision making of IMP QPs
- An inspector's view on the GMP/GCP/GDP interface
- Template for a manufacturer – sponsor agreement
- Q&A sessions

1/2 Day Pre-Conference Session

New QPs meet experienced QPs

Facilitated by:

Richard M. Bonner / Georg Göstl / Andreas Kraßnigg / Sue Mann

A tailor-made session for new and aspiring QPs with round-table discussions and lots of interaction. Discuss your questions and worries with experienced QPs and a GMP Inspector.

1/2 Day Pre-Conference Session

Serialisation revisited

Facilitated by:

Steven De Strycker / Afshin Hosseiny / Ulrich Kissel

Nine months after implementation: Discuss challenges in the market and the impact on the QP's daily life and find answers and solutions.

Programme QP Forum

28-29 November 2019

Key Note: A Patient's View - What Dying taught me about Living

Anthony Bennett

After surviving multiple viral infections with a 10% survival rate, Anthony brings to light the importance of teamwork, from the perspective of his family and the medical professionals during his time in hospital. After listening to this session QPs should feel inspired, uplifted and proud of the work they do.

Experiences made with the MRA and post-Brexit

Tor Gråberg

- Difficulties and how to overcome (inspections, GMP certificates, importation)
- What we have experienced
- Problems occurred and solutions found

GMP Update Session

David Cockburn, Rainer Gnibl and Tor Gråberg

- New Regulations and Guidance and their relevance for the QP

What the QP needs to know about the current Contamination Control Strategy

Walid El Azab

- Development of a risk-based assessment for contamination control and sterility assurance maintenance
- What the QP should be aware of before certifying products
- Where the involvement of the QP is needed
- Information flow

Real Time Release Testing and Certification by the QP: a next Generation Process or still Phantasm?

Line Lundsberg-Nielsen

- What the QP needs to know about Annex 17, ICH Q12 and Real Time Release concepts
- What is already possible – and what not
- Pre-requisites, chances and challenges
- What do authorities expect?

The PQR and its benefit for the QP

Klaus Eichmüller

- How the PQR could be used in an efficient way and not end in a graveyard of data

Parallel Sessions

Working on Case Studies

1) Soft Skills for QPs

- How to analyse communication situations
- How to deescalate conflict situations
- How to show self-confidence in discussions with senior management?

Richard Bonner and Peter C. Zimmermann

2) Change Control and Certification for global Markets

- How to deal with change control challenges when regular approvals can take several months or years to cover all the relevant countries worldwide
- How to support decision making

Ulrich Kissel and Kasper Buchwald Sønderskov

3) QP Scenarios – How serious could each issue be?

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

Sue Mann and Gillian Renouf

4) Challenges for IMP QPs

- Sample and documentation retention, etc.
- Experience sharing, e.g. Brexit, new IMP GMP regulation
- Challenges for smaller companies

IMP Working Group

5) QP Oversight

- Practical aspects of keeping oversight on both external (third party) and internal (own site/ own company) QP-related processes
- QP responsibilities and delegation of tasks

Edel Ryan and Anke von Harpe

6) The QP in the Pharmaceutical Quality System

- Discuss how the QP can rely on a PQS and how such a system could be set up
- Assistance and support for the QP

Afshin Hosseiny and Aidan Madden

You will be able to attend three of these parallel sessions. Please choose the ones you like to attend when you register for the Forum.

Q&A Session

During the 2 days of the Forum, delegates can post their questions. The answers will be given by the expert speakers in a dedicated session and/ or published in the members' area of the EQPA website.

Social Event

On 28 November, you are cordially invited to a Bavarian Evening. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

Special Offer with Lufthansa –

Discounted Travel

As an ECA course or conference attendee, you will receive up to 20% discounted travel fares (according to availability). And as Lufthansa German Airlines offers a comprehensive global route network linking major cities around the world you will most likely be able to benefit from these special prices and conditions.

And this is how it works: Once you registered for a course or conference you will receive a link together with your registration confirmation. Opening that link will take you to the Mobility Partner Program website where you can enter a code in the "Access to Event Booking" area you will also receive. This will take you into an online booking platform that will automatically calculate the discount offered or provide you with an even better offer if another promotional fare is available.

Speakers

Speakers from Authorities, Inspectorates and Associations:

Steven De Strycker, *Federal Agency for Medicines and Health Products, fagg, Belgium*
GMP Inspector

Silja Du Mont, *GCP/GDP Inspector, District Authority of Freiburg, Germany*
GCP/GDP Inspector, Head of the German GCP Inspectors Expert Group and European Expert GCP IWG EMA

Klaus Eichmüller, *Wolnzach, c/o Regional Competent Authority, Germany*
Head of the Inspectorate for Drug Products, APIs, Blood Products and Tissues in Hesse

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

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

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

Speakers from Industry:

Justin Barry, *Emergex Vaccines, U.K.*
Head of Global Manufacturing and member of the EQPA IMP Working Group Board

Anthony Bennett, *Anthony Inspires Ltd., U.K.*
Inspirational Speaker

Richard M. Bonner, *U.K.*
Former Chairman of the EQPA Board of Directors and former Chair of the ECA Executive Board

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

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

Walid El Azab, *Steris N.V./S.A., Belgium*
Technical Services Manager and former QP

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

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, *European Qualified Person Association (EQPA)*
Qualified Person and Chairman of the EQPA Board of Directors

Line Lundsberg-Nielsen, *Lundsberg Consulting Ltd, U.K.*
Founder and Owner

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

Edel Ryan, *Mylan, Ireland*
Director Complex Products Quality Operations

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

Kasper Buchwald Sønderskov, *Novo Nordisk A/S, Denmark*
Director Quality Assurance and Qualified Person

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

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

Philippe Van der Hofstadt, *Clinical Supplies Management, Belgium*
VP Corporate Development

Dr Anke von Harpe, *QProgress, Germany*
Qualified Person and Pharmaceutical Consultant

Peter C. Zimmermann, *Iskom, Germany*
CEO

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 2019,** Munich, Germany, 28-29 November 2019
Please choose **three of the six** parallel sessions:
☐ Session 1: Soft skills for QPs
☐ Session 2: Change Control and Certification for global Markets
☐ Session 3: QP Scenarios – How serious could each issue be?
☐ Session 4: Challenges for IMP QPs
☐ Session 5: QP Oversight
☐ Session 6: The QP in the Pharmaceutical Quality System

☐ **Optional Pre-Conference Session**, Munich, Germany, 27 November 2019
Please choose **one of the following**:
☐ Full Day Session "Specific Requirements for IMPs"
☐ 1/2 Day Session "New QPs meet experienced QPs"
☐ 1/2 Day Session "Serialisation revisited"

☐ 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, 27 November 2019, 9.00 – 18.00
(Registration and coffee: 8.30 – 9.00)

Date ½ Day Pre-Conference Session:
New QPs meet experienced QPs
Wednesday, 27 November 2019, 13.30 – 18.00
(Registration, snacks and coffee: 13.00 – 13.30)

Date ½ Day Pre-Conference Session:
Serialisation revisited
Wednesday, 27 November 2019, 13.00 – 18.00
(Registration, snacks and coffee: 12.30 – 13.00)

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

Fees for QP Forum
QP Association Members € 1.690,- per delegate plus VAT.
EU GMP Inspectorates € 895,- per delegate plus VAT.
Non-QP Association Members € 1.890,- per delegate plus VAT.
The conference fee is payable in advance after receipt of invoice and includes electronic conference documentation, welcome reception, dinner on the first day, lunch on both days and all refreshments. 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 and includes electronic conference documentation, welcome reception, lunch and all refreshments. VAT is reclaimable.

Fees for ½ Day Pre-Conference Session:
New QPs meet experienced QPs
€ 590,- per delegate plus VAT.
The fee is payable in advance after receipt of invoice and includes electronic conference documentation, welcome reception and all refreshments. VAT is reclaimable.

Fees for ½ Day Pre-Conference Session:
Serialisation revisited
€ 590,- per delegate plus VAT.
The fee is payable in advance after receipt of invoice and includes electronic conference documentation, welcome reception and all refreshments. VAT is reclaimable.

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.

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.

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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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.