Speakers from Authorities, Inspectorates and Societies:

Mark Birse
MHRA
David Cockburn
formerly EMA
Dr Rainer Gnibl
Government of Upper Bavaria
Mag.pharm. Andreas Kraßnigg
Austrian Agency for Health and Food Safety (AGES)
Mag. Dr Christina Meissner
Austrian Agency for Health and Food Safety (AGES)
Gillian Renouf
Royal Pharmaceutical Society QP Assessment Panel
Matthew Scherer
FDA
Dr Pieter Vankeerberghen
famhp

Speakers from the Industry:

Ørjan Apeland
Norsk Medisinsk Syklotronsenter
Justin Barry
Midatech
Richard M. Bonner
Chairman of the EQPA, form. with Eli Lilly
Sean Brennan
Shire Pharmaceuticals
Gabriella Cipra
Eurozyto
Dr Susanne Ding
Boehringer Ingelheim
Walid El Azab
Steris
Gerald Finken
Clinical Supplies Management
DI Georg Göstl
Shire
Dr Afshin Hosseiny
Tabriz Consulting
Dr Ulrich Kissel
EQPA
Cristina De Simoni Klitgaard
Novo Nordisk
Aidan Madden
FivePharma
Sue Mann
Sue Mann Consultancy
Dr Eric J.M. Meier
Novartis
Dr Rolf Ratke
AbbVie
Dr Bernd Renger
Immediate Past Chairman of the EQPA
Christiaan Rijksen
Lonza
Birgit Schultz
Novo Nordisk
Niina Taylor
Pfizer
Brenda Van Assche
Janssen
Philippe Van der Hofstadt
Clinical Supplies Management (CSM)

Invitation

to the

QP ASSOCIATION

Qualified Person Forum 2017

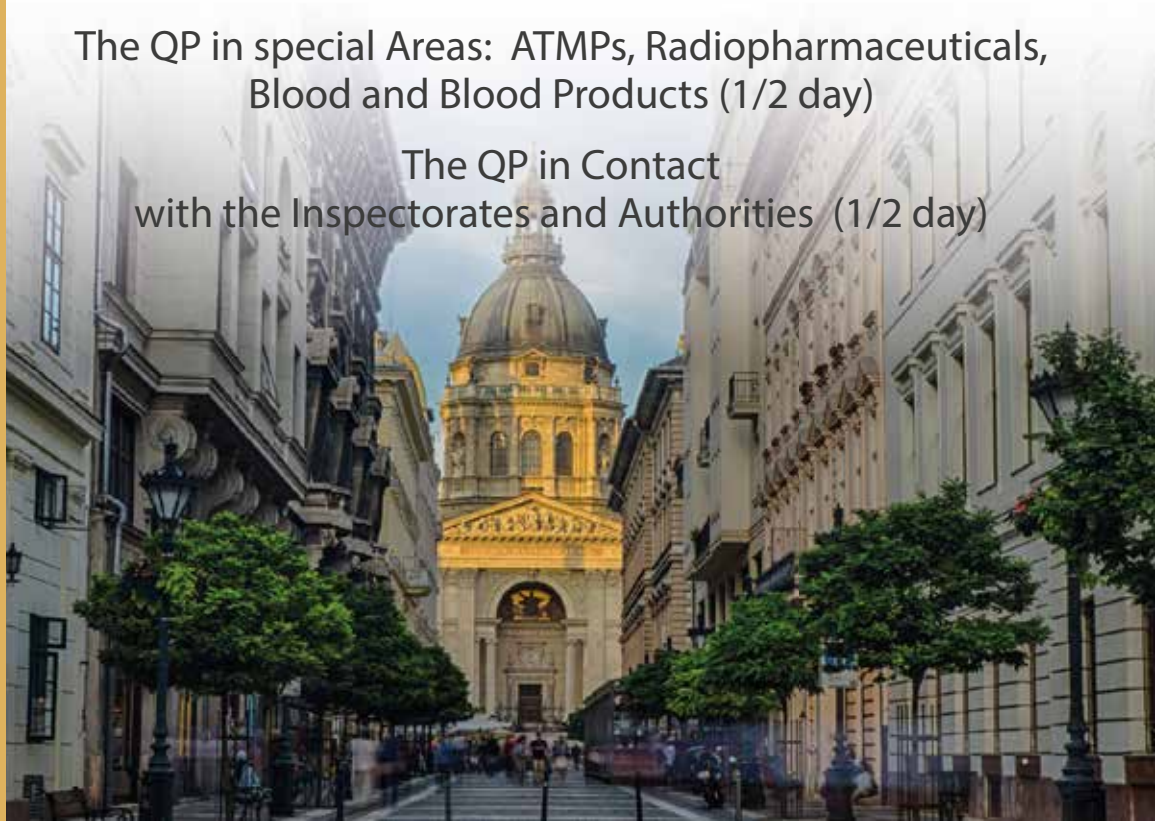
Budapest, Hungary, 30 November – 1 December 2017

With three Pre-Conference Sessions
on 29 November 2017:

Specific Requirements for
Investigational Medicinal Products (full day)

The QP in special Areas: ATMPs, Radiopharmaceuticals, Blood and Blood Products (1/2 day)

The QP in Contact
with the Inspectorates and Authorities (1/2 day)



Welcome

Dear Colleagues,

In the last eleven years, the European QP Association Forum has been becoming a major event for European Qualified Persons. Speakers from EMA, FDA and various national authorities as well as QPs have been sharing their view of roles and responsibilities of the Qualified Person.

Hoping to continue the success of this unique Forum, the Advisory Board of the QP Association has set up the programme at hand for the 12th QP Forum to give you an update about recent developments and important matters to consider. Representatives from the authorities as well as QPs and well-known experts will present latest issues and share their point of view. During the three pre-conference sessions and the six parallel sessions at the Forum, various case studies will be presented and discussed to come up with possible solutions.

Make use of this event by exchanging experiences with your colleagues and by establishing informal contact and networking.

I would like to invite you to this outstanding event, and I look forward to meeting you.

Best regards,

Richard M. Bonner
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 critical areas 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.
Note: there will be no print-outs available during the conference.

Pre-Conference Sessions

29 November 2017

Full Day Pre-Conference Session

Specific Requirements for IMPs
Facilitated by:
Justin Barry / Mark Birse / Susanne Ding / Gerald Finken / Niina Taylor / Brenda Van Assche / Philippe Van der Hofstadt / Pieter Vankeerberghen

- New legislation impacting IMP QPs
- GMP inspection findings on IMPs
- Just-in-time labelling/ on demand packaging and labelling
- Interactive sessions and case studies – decision making of IMP QPs
- Q&A sessions
- ATMP Task Force (IMP focus): introduction and current status

1/2 Day Pre-Conference Session

The QP in special Areas: ATMPs, Radiopharmaceuticals, Blood and Blood Products
Facilitated by:
Ørjan Apeland / Gabriella Cipra / Georg Göstl / Sue Mann / Christina Meissner

New classes of medicines such as ATMPs, Blood and Tissue Products or Radiopharmaceuticals are creating special challenges for the QPs certifying these products. This session aims to provide good insight and experienced views, address and discuss challenges and see what the participating delegates can learn from each other.

1/2 Day Pre-Conference Session

The QP in Contact with the Inspectorates and Authorities
Facilitated by:
Rainer Gnibl / Ulrich Kissel / Christiaan Rijksen

- GMP-Inspection: how much QP involvement is needed?
- Typical questions for QPs in inspections
- QP quality oversight: Focus on third country products
- Delegation of tasks and responsibilities: requirements, possibilities and boundaries
- How the QP can demonstrate the on-going reliance on the QM-System

Programme QP Forum

30 November – 1 December 2017

The X-Factor – Sue Mann
- Human behaviours and errors & what the QP needs to know about these

Current and future Activities of the FDA – Matthew Scherer
- The role of the EU office
- The MRA with the EU and other international collaborations
- Current and future strategies

What the QP needs to know about Continuous Manufacturing and Real Time Release – Dr Eric J.M. Meier
- Batch definition in continuous manufacturing
- Important GMP and Quality aspects to consider
- Control Strategy using PAT and automation
- State-of-control operation
- Batch Release

Falsifications: Handling, Decision Making and Communication – Dr Rolf Ratke
- A case study on the amount of activities and involvement of the QP

International Developments and their possible Impact on GMP and Manufacturers – David Cockburn
- Brexit
- MRA with FDA and other MRAs
- The role of WHO in regulating GMP
- What is on the horizon in the GMP area

What the QP needs to know about the current Cleaning Validation Requirements – Walid El Azab
- What is new?
- Minimising the risk of cross contamination
- Change control and information flow
- Involvement of the QP

The Involvement of the QP in Auditing – Sean Brennan
- What is necessary
- How to instruct a 3rd party (or own company) auditor
- How to interpret 3rd party audit reports
- What to do with a negative audit outcome (QP Declaration and supplier approval)

Update: International Harmonisation and Working – Mark Birse

Parallel Sessions

Working on Case Studies

1) GMP-Update: new Regulations and Guidance – what is relevant for the QP? – Bernd Renger and Rainer Gnibl
- Discussion, questions, answers

2) Quality Oversight and Enforcement as Part of the Batch Certification Process – Birgit Schultz and Cristina Klitgaard
- Novo Nordisk Case Study
- Group work: What is needed for a QP with regard to Quality Oversight and enforcement in order to release a product?

3) QP Scenarios – How serious could they be? – Sue Mann and Gillian Renouf
- Make decisions based on real-life situations

4) IMP QPs implementing Annex 16: Continuing to shed Light on grey Zones and sharing Experiences – IMP Working Group
- How to handle one off deviations
- How to rely on the Pharmaceutical Quality System (PQS) in Development and IMP Manufacturing
- Delegation

5) Serialisation: What is important for the QP –
Afshin Hosseiny, Ulrich Kissel and Andreas Kraßnigg
- Delegated Act for the Safety Features: the impact for the QP
- Challenges and possible solutions

6) Quality Risk Management for the QP – Richard M. Bonner and Aidan Madden
The term "quality risk management" is used throughout the revised Annex 16. But how could the QP use this tool? In this session you will get some practical advice!

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 30 November, you are cordially invited to a social event in Budapest (city tour and Dinner). This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

Lufthansa Official Airline

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 Societies:

Mark Birse, *Medicines & Healthcare Products* Regulatory Agency (MHRA), U.K.
Group Manager for the MHRA Inspectorate.

David Cockburn, *formerly EMA, U.K.*
Former Chair of the EMA GMP/GDP IWG.

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.

Mag. Dr Christina Meissner, *Austrian Agency for Health and Food Safety (AGES), Austria*
GMP Inspector.

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

Matthew Scherer, *FDA*
Assistant Health Attache and International Program and Policy Analyst, FDA Office of International Programs - Europe Office

Dr Pieter Vankeerberghen, *Federal Agency for Medicines and Health Products (famhp), Belgium*
Head of R&D.

Speakers from the Industry:

Ørjan Apeland, *Norsk Medisinsk Syklotronsenter, Norway*
Qualified Person and Quality Assurance Officer.

Justin Barry, *Midatech Pharma España, Spain*
Managing Director

Richard M. Bonner, *Chairman of the European Qualified Person Association (EQPA)*
Chairman of the EQPA Board of Directors, Chair of the ECA Executive Board.

Sean Brennan, *Shire Pharmaceuticals Ltd, Ireland*
Vice President Quality, Biologics Operating Unit and Qualified Person.

Gabriella Cipra, *Eurozyto GmbH, Germany*
Head of Quality Assurance.

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.

Gerald Finken, *Clinical Supplies Management, USA*
Chief Scientific Officer.

DI Georg Göstl, *Shire, Austria*
Qualified Person and Chair of the Austrian QP Association aqpa.

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

Dr Ulrich Kissel, *European Qualified Person Association (EQPA)*
Qualified Person and member of the EQPA Board of Directors.

Cristina De Simoni Klitgaard, *Novo Nordisk A/S, Denmark*
QA Director and Qualified Person.

Aidan Madden, *FivePharma, Ireland*
Managing Director and Senior Consultant.

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

Dr Eric J.M. Meier, *Novartis Pharma AG, Switzerland*
Head QA Continuous Manufacturing.

Dr Rolf Ratke, *AbbVie Biotechnology GmbH, Germany*
Director Biologics Quality Assurance and Qualified Person.

Dr Bernd Renger, *European Qualified Person Association (EQPA)*
Immediate Past Chairman of the EQPA.

Christiaan Rijksen, *Lonza AG, Switzerland*
Audit Manager.

Birgit Schultz, *Novo Nordisk A/S, Denmark*
Corporate Vice President and Qualified Person.

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

Brenda Van Assche, *Janssen Pharmaceutica NV, Belgium*
Director QA and Qualified Person.

Philippe Van der Hofstadt, *Clinical Supplies Management (CSM), Belgium*
EU President.

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 2017,** Budapest, Hungary, 30 November – 1 December 2017
Please choose **three of the six** parallel sessions:
☐ Session 1: GMP-Update: new Regulations and Guidance – what is relevant for the QP?
☐ Session 2: Quality Oversight and Enforcement as Part of the Batch Certification Process
☐ Session 3: QP Scenarios – How serious could they be?
☐ Session 4: IMP QPs implementing Annex 16
☐ Session 5: Serialisation: What is important for the QP
☐ Session 6: Quality Risk Management for the QP

☐ **Optional Pre-Conference Session**, Budapest, Hungary, 29 November 2017
Please choose **one of the following**:
☐ Full Day Session "Investigational Medicinal Products"
☐ 1/2 Day Session "The QP in special Areas"
☐ 1/2 Day Session "The QP in Contact with the Inspectorates and Authorities"

☐ 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, 29 November 2017, 9.00 – 18.00
(Registration and coffee: 8.30 – 9.00)

Date ½ Day Pre-Conference Session:
The QP in special Areas
Wednesday, 29 November 2017, 13.00 – 18.00
(Registration, snacks and coffee: 12.30 – 13.00)

Date ½ Day Pre-Conference Session:
The QP in Contact with the Inspectorates and Authorities
Wednesday, 29 November 2017, 13.30 – 18.00
(Registration, snacks and coffee: 13.00 – 13.30)

Welcome Reception for all participants
Wednesday, 29 November 2017, 18.00 – 19.00

Date QP Forum
Thursday, 30 November 2017, 9.00 – 18.00
(Registration: Wednesday, 29 November 18.00 – 19.00 and
Thursday 30 November, 08.00 – 9.00)
Friday, 01 December 2017, 8.30 – 14.30

Venue
Corinthia Hotel Budapest
Erzsébet körút 43-49
Budapest H-1073
Hungary
Tel.: +36 1 479 4000 / Fax: +36 1 479 4333
Email: budapest@corinthia.com

Fees for QP Forum
QP Association Members € 1.590,- per delegate plus VAT.
EU GMP Inspectorates € 895,- per delegate plus VAT.
Non-QP Association Members € 1.790,- 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
€ 890,- 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:
The QP in special Areas
€ 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:
The QP in Contact with the Inspectorates and Authorities
€ 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 when you have registered for the event. Please use this link for your room reservation or be sure to mention QP Association to receive the specially negotiated rate (single room 140,- Euros per night incl. breakfast, excl. 18% VAT and 4% city tax) for the duration of your stay. Reservation should be made directly with the hotel not later than 27 October 2017. 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,
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