Speakers from Authorities and Public Health Organisations:

Judit Fernandez Fernandez
European Medicines Agency (EMA)
Dr Rainer Gnibl
Government of Upper Franconia
Johanna Linnolahti
Finnish Medicines Agency (Fimea)
Mag. Dr Christina Meissner
Austrian Agency for Health and Food Safety (AGES)
Edit Szőcs
Hungarian Drug Inspectorate, National Institute of Pharmacy and Nutrition
Maria Wängelin
Swedish Medical Products Agency (MPA)

Speakers from the Industry:

Justin Barry
Midatech Biogune
Richard M. Bonner
Chairman of the EQPA, form. with Eli Lilly
Dr Christopher Burgess
EQPA, form. with Glaxo
Dr Susanne Ding
Boehringer Ingelheim
Dr Marcel Goverde
MGP Consulting
Tor Gråberg
AstraZeneca, form. Swedish Medical Products Agency (MPA)
Dr Afshin Hosseiny
Tabriz Consulting
RA Dr Monika Hupfauf
DLA Piper Weiss-Tessbach Lawyers
Dr Ulrich Kissel
Roche Pharma
Roger Lauwers
Janssen Pharmaceutica
Dr Wolfgang Loh
Immune Biotec
Dr Line Lundsberg-Nielsen
NNE Pharmaplan
Aidan Madden
FivePharma
Sue Mann
Sue Mann Consultancy
Dr R. D. McDowall
R D McDowall Limited
Katie Mortier
Janssen Pharmaceutica
Dr Bernd Renger
Immediate Past Chairman of the EQPA
Gillian Renouf
Chair of the Royal Pharmaceutical Society QP Assessor Panel
Dr Andreas Schwinn
Roche Pharma
Alexandra Staerk
Novartis
Niina Taylor
Pfizer
Liz Tolan
AbbVie
Philippe Van der Hofstadt
B&C Group
Mary-Anne Weatherhead
Pfizer
Allan Whiston
QA Resolutions

Invitation
to the

QP ASSOCIATION

Qualified Person Forum 2015

Berlin, Germany 25 – 26 November 2015

With three Pre-Conference Sessions
on 24 November 2015:

Investigational Medicinal Products (full day)

The Co-operation between Microbiologists and QPs (1/2 day)

Appropriate Quality of Excipients (1/2 day)

Welcome

Dear Colleagues,

In the last nine 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 10th 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

Dr Christopher Burgess

Important Information!
The presentations of the QP Forum and the Pre-Conference Workshop/ Session will be available for download and your print-out 1 week before the conference. You will also receive a USB memo stick when you register. **Note: there will be no print-outs available during the conference.**

Pre-Conference Sessions

24 November 2015

Full Day Pre-Conference Session

Specific Requirements for IMPs
Facilitated by:
IMP Working Group

- New legislation impacting IMP QPs
- Roundtable revised Annex 16: «to delegate or not to delegate»
- GDP: The distribution of IMPs
- Example: How to perform a risk assessment
- Investigator initiated trials: Survey results
- Interactive case studies: Decision making of IMP QPs
- Interactive Q & A sessions

1/2 Day Pre-Conference Session

Talking about Bacteria and QPs – The Co-operation between Microbiologists and QPs
Facilitated by:
Marcel Goverde / Alexandra Staerk / Mary-Anne Weatherhead

- What the QP should know about microbiology
- Deviation Management
- How a QP should interpret the data

1/2 Day Pre-Conference Session

Appropriate Quality of Excipients
Facilitated by:
Richard Bonner / Edit Szőcs / Allan Whiston

- QP survey on excipients: outcome and interpretation of the data
- What level of GMP and supplier qualification is needed (and what is too much)
- Challenges and solutions

Programme QP Forum

25 – 26 November 2015

Keynote: The QP Job - what about Ethics and Culture?
- Comply or die?
- Responsibility, confidence & dialogue: My triangle of orientation
  - ➲ Wolfgang Loh

The Falsified Medicines Directive: Harmonisation needed?
- The Written Confirmation and the impact on global pharma
- Differences of the transposition of the FMD into national law
- Different countries – different approaches
- The FMD: a more secure supply chain now?
  - ➲ Liz Tolan

The Falsified Medicines Directive: What will be important?
- New packaging design and change control
- Batch Record Review and batch release
- How to handle returns (are all returns falsified medicines?)
- What to do in the case of suspected falsification
  - ➲ Tor Gråberg

Data Integrity: what the QP needs to know
- Why is it making everybody nervous?
- Data Integrity in the own company
- Data Integrity with suppliers and contractors
  - ➲ Dr Bob McDowall

PAT and Real Time Release: really a hot Topic for QPs?
- What is the current status? Is anyone doing that at all?
- Things to consider for QPs
- The link to process validation and master batch documentation
  - ➲ Dr Line Lundsberg-Nielsen

EU Perspective on Quality Metrics
- Current expectations and future developments
- What are the global challenges (different expectations / directions?)
- How Quality Metrics internally can enable QPs to better perform their tasks
  - ➲ Judit Fernandez Fernandez

Why QPs should love Statistics (a final Presentation)
- The power of statistical techniques and error theory
- Statistical interpretation of data
- What is necessary for QPs
  - ➲ Christopher Burgess

Parallel Sessions

Working on Case Studies

1) Update on GMP-relevant topics and what QPs are expected to do
- Discussion, questions, answers
  - ➲ Bernd Renger and Rainer Gnibl

2) Annex 16 – Status Quo and new tasks
- Delegation
- QP Discretion
  - ➲ Ulrich Kissel and Christina Meissner

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

4) 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
  - ➲ IMP Working Group

5) The QP/GDP Interface
- Where does responsibility end and when does it come back?
- QP and RP co-operation
- Deviations in the supply chain: reporting and handling
  - ➲ Johanna Linnolahti and Aidan Madden

6) The QP and Contracts
- What does a QP need to know?
- EU regulations vs. non-EU regulations – what counts?
- How to keep the overview
- Involvement of the QP: How to integrate QP responsibilities and define the respective adequate remedies in the contract
  - ➲ Afshin Hosseiny and Monika Hupfauf

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 you can post your questions on a bulletin board. Expert speakers will then provide answers in a dedicated session. This session will also be published in the members' area of the EQPA website.

Social Event

On 25 November, you are cordially invited to a social event in Berlin. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

Special Offer with Lufthansa – Discounted Travel

Lufthansa Official Airline

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 and Public Health Organisations:

Judit Fernandez Fernandez, *European Medicines Agency (EMA)*
Scientific Administrator, Manufacturing and Quality Compliance at the Compliance and Inspections Department

Dr Rainer Gnibl, *Government of Upper Franconia, Germany*
GMP Inspector for the District Government and the EMA.

Johanna Linnolahti, *Finnish Medicines Agency Fimea, Finland*
Senior Pharmaceutical Inspector.

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

Edit Szőcs, *Hungarian Drug Inspectorate, Hungary*
Inspector at the Hungarian Drug Inspectorate, National Institute of Pharmacy and Nutrition, Advisory Board member of the QP Association.

Maria Wängelin, *Medical Products Agency (MPA), Sweden*
GDP/GMP Inspector.

Speakers from the Industry:

Justin Barry, *Midatech Biogune, Spain*
Managing Director.

Richard M. Bonner, *Chairman of the EQPA*
QP, Chairman of the QP Association, formerly with Eli Lilly.

Dr Christopher Burgess, *formerly with Glaxo, U.K.*
QP, Advisory Board member of the QP Association. Visiting Professor at the Strathclyde Institute of Pharmacy and Biomedical Sciences (SIPBS).

Dr Susanne Ding, *Boehringer Ingelheim, Germany*
QP for Investigational Medicinal Products.

Dr Marcel Goverde, *MGP Consulting, Switzerland*
Managing Director of MGP and Member of the EDQM Working Party for Modern Microbiological Methods (MMM).

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

Dr Afshin Hosseiny, *Tabriz Consulting, U.K.*
QP and Managing Director.

RA Dr Monika Hupfauf, *DLA Piper Weiss-Tessbach Lawyers, Austria*
Attorney at Law for contract law, intellectual property rights, life sciences.

Dr Ulrich Kissel, *Roche Pharma AG, Germany*
QP and Advisory Board member of the QP Association.

Roger Lauwers, *Janssen Pharmaceutica (part of Johnson & Johnson), Belgium*
Director Clinical Supply Chain.

Dr Wolfgang Loh, *Immune Biotec Pharma Consulting, Germany*
Qualified Person.

Dr Line Lundsberg-Nielsen, *NNE Pharmaplan, U.K.*
Senior QbD & PAT Consultant; Chair of the ISPE PQLI Control Strategy Team.

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

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

Dr R.D. McDowall, *R D McDowall Limited, U.K.*
Principal; Author of a book on validation and numerous articles on the validation of computerised systems.

Kati Mortier, *Janssen Pharmaceutica (part of Johnson & Johnson), Belgium*
IMP QP & Manager QA Clinical Supply Chain.

Dr Bernd Renger, *EQPA*
Immediate Past Chairman of the QP Association.

Gillian Renouf, *Chair of the Royal Pharmaceutical Society QP Assessor Panel, U.K.*
Qualified Person.

Dr Andreas Schwinn, *Roche Pharma AG, Germany*
QP for IMP Release and Head of the Release Preparation Group.

Alexandra Staerk, *Novartis Pharma AG, Switzerland*
Head QA/QC Biological & Microbiological Services.

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

Liz Tolan, *AbbVie, Ireland*
Senior Compliance Auditor.

Philippe Van de Hofstadt, *B&C Group, Belgium*
CEO of B&C, a Clinical Research Packaging & Logistics Organisation.

Mary-Anne Weatherhead, *Pfizer, U.K.*
QP for biological and vaccine products.

Allan Whiston, *QA Resolutions Ltd., U.K.*
EXCiPACT asbl Board Member.

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 2015,** Berlin, Germany, 25-26 November 2015
Please choose **three of the six** parallel sessions:
☐ Session 1: Update on GMP-relevant topics and what QPs are expected to do
☐ Session 2: Annex 16 – Status Quo and new Tasks
☐ Session 3: QP Scenarios – How serious could they be?
☐ Session 4: The Role of the QP at the GMP/GCP interface
☐ Session 5: The QP/GDP Interface
☐ Session 6: The QP and Contracts

☐ **Optional Pre-Conference Session**, Berlin, Germany, 24 November 2015
Please choose **one of the following**:
☐ Full Day Session "Investigational Medicinal Products"
☐ 1/2 Day Session "Talking about Bacteria and QPs – The Co-operation between Microbiologists and QPs"
☐ 1/2 Day Session "Appropriate Quality of Excipients "

☐ 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 240 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
Tuesday, 24 November 2015, 9.30 – 18.00
(Registration and coffee: 9.00 – 9.30)

Date ½ Day Pre-Conference Session:
Talking about Bacteria and QPs:
The Co-operation between Microbiologists and QPs
Tuesday, 24 November 2015, 13.00 – 17.45
(Registration, snacks and coffee: 12.30 – 13.00)

Date ½ Day Pre-Conference Session:
Appropriate Quality of Excipients
Tuesday, 24 November 2015, 13.30 – 18.00
(Registration, snacks and coffee: 13.00 – 13.30)

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, 8.00 – 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

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:
Talking about Bacteria and QPs:
The Co-operation between Microbiologists and 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:
Appropriate Quality of Excipients
€ 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.

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.

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
CONCEPT HEIDELBERG
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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.