



**Speakers from Authorities:**

**Andrew Charvill**, *MHRA, UK*

**Richard Funnell**, *MHRA, UK*

**Dr Siegfried Giess**,

*Paul-Ehrlich-Institut, Germany*

**Dr Jean-Denis Mallet**, *ICRC, formerly*

*Head of the French Pharmaceutical  
Inspection Department*

**Raquel San José Rodríguez**

*Spanish Agency for Medicines and Medical  
Devices*

**Dr Janice M. Soreth**, *Europe/US FDA*

**John Taylor**, *MHRA, UK*

**Rudolf Völler**, *Head of a German  
Inspectorate*

**Speakers from the Industry:**

**Dr Hendrikus Boersma**, *Groningen*

*University Medical Center, Netherlands*

**Richard M. Bonner**, *formerly with*

*Eli Lilly, UK*

**Dr Christopher Burgess**,

*Burgess Consultancy, UK*

**Dr Rango Dietrich**,

*PharmDev Innovations GmbH, Germany*

**Jenneke de Goeij**, *Pharma Services*

*International BV, Netherlands*

**Peter Gough**, *David Begg Associates,*

*UK*

**Dr Afshin Hosseiny**, *Tabriz*

*Consulting, UK*

**Heinz Lomen**, *asmit GmbH, Germany*

**Dr Michael Nölchen**,

*F. Hoffmann-La Roche Ltd, Switzerland*

**Dr Bernd Renger**,

*Vetter Pharma-Fertigung GmbH, Germany*

**Jolande Schoemaker**, *Schoemaker*

*Consultancy, Netherlands*

**May Smans**, *Johnson & Johnson,*

*Belgium*

**Dr Annemiek Stijnen**, *Kinesis*

*Pharma, Netherlands*

**Martine Tratsaert**,

*Johnson & Johnson, Belgium*

# Invitation

to the

# Qualified Person Forum 2009

Barcelona, Spain, 3 – 4 December 2009

with

## 3 Pre-Conference Workshops

- Specific Requirements for Investigational Medicinal Products –
- The Role of the QP in modern QM-Systems –
- The Role of the QP in Biotech Industry –

2 December 2009



# Welcome

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Dear Colleagues,



The European QP Association Forum has been becoming a major event for European Qualified Persons.

Speakers from EMEA 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 the QP Forum, the Advisory Board of the QP Association has set up the programme at hand for the 2009 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 workshops 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 unique opportunity, and I look forward to meeting you.

A handwritten signature in blue ink, appearing to be 'B. Renger'.

Dr Bernd Renger  
Chairman of the Qualified Person Association

## Background

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Over the past few years the role and duties of the Qualified Person keep increasing in significance and scope. Being the key person in the quality function of a pharmaceutical company, the QP has to consider many issues to fulfil the responsibilities and to comply with the European legislation.

## Objective

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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

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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

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Dr Christopher Burgess

Barcelona, Spain, 2 December 2009



### Specific Requirements for Investigational Medicinal Products

- GMP/GCP interface
- QP oversight upstream & downstream
- Manufacturing involving multiple QPs
  - ⇒ Hosted by the IMP Working Group

### The Role of the QP in modern QM-Systems

- The aim of this Pre-Conference Workshop is to elaborate on how to set up a QM System which reflects the need of the QP and how such a system can help the QP in its daily work.
  - ⇒ Hosted by Dr Christopher Burgess and Peter Gough

### The Role of the QP in Biotech Industry

- What are the specific attributes of biotech products?
- Manufacturing, in process controls and final testing
- Stability testing of biotech products
- Biotech products in clinical trials
  - ⇒ Hosted by Jolande Schoemaker and Dr Siegfried Giess

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### GMP & Regulatory Update: Developments that will impact Qualified Persons

- Supply chain concerns; counterfeits & adulteration
- Revised Reflection Paper on compliance with Marketing Authorisations
- Revised Variations process
- ICH Q8(R1), Q9, Q10 and Q11
  - ⇒ Peter Gough

### The special way of interpreting the role of the QP in Spain

- ⇒ Raquel San José Rodríguez

### Finding Trends in Analytical Release Data – How to detect (and how to react)

- What is a trend?
- Parametric and Non-Parametric Tests
- Statistical Tools
- Appropriate level of confidence and amount of data
- How to react upon an trend
  - ⇒ Dr Michael Nölchen

### Roles and Responsibilities of the QP in important Quality System Elements

- ⇒ Dr Christopher Burgess

### International Programs of the FDA

- Challenges in a globalised world
- FDA's international cooperation
- Collaboration with EMEA (GCP and GMP)
  - ⇒ Dr Janice M. Soreth

### The Risks and Threats Posed by Counterfeit APIs

- Points to cover
- What is a Counterfeit API
- What can go wrong
- Detection of Counterfeit APIs
- Whose problem is it
- The Role of the QP
- Understanding the Supply Chain
- The Audit Process
- Confirmation of Counterfeit Status by Analysis
  - ⇒ Andrew Charvill

## **Avoiding individual financial Liability as QP – An Overview of the current Liability and Insurance Situation**

- The QP as individual of personal and private accountability
- Basis for claims against the individual QP
- The QP as insured person within the companies insurance coverage
- Discussion of real and potential insurance needs for the QP
- Insurance market alternatives for the QP
  - Heinz Lomen

## **Parallel Sessions – Case Studies**

### **1. So much Work, so little Time**

➤ Dr Afshin Hosseiny and John Taylor

This workshop will attempt to guide the practicing QPs on the art of delegation of activities, provide useful hints on how to supervise the work done by setting up secure and clear systems. It will cover:

- How to find suitable personnel to delegate to
- Defining the boundaries when delegating
- Training a support for staff
- How to supervise delegated tasks
- How to manage the regulator's expectations

### **2. Supplier Quality: What does the QP have to do?**

➤ Jenneke de Goeij and Dr Christopher Burgess

- Supplier Qualification; roles and responsibilities
- How much needs to be done; a risk assessment process
- Audits; evaluation of internal and external audit reports
- Team working on a Supplier Quality Scenario

### **3. Risk-based Decision Making when releasing Product with Deviations**

➤ Dr Bernd Renger and Dr Jean-Denis Mallet

- To certify or not, that's the Question
- What Actions should you take as the responsible QP?

### **4. The Role of the QP in an R&D Environment**

➤ Dr Hendrikus Boersma, May Smans, Dr Annemiek Stijnen and Martine Tratsaert

- IIT (presentation + workshop)
- Radio labelled IMPs (ADME/PET studies)

### **5. Rating and Classification of Deviations, Complaints and inspection Findings**

➤ Richard Bonner and Rudolf Völler

### **6. Contract QPs: What needs to be considered from both the Contract Giver and the QP?**

➤ Dr Rango Dietrich and Richard Funnell

- Selection process and pricing models-
- Risk mitigation for QP
- Liability, insurance and resignation
- Permanently and continuously available ?
- How to rely on the release decision of a contract QP ?
- Risks and opportunities with contract QPs

**You will be able to attend 2 of these parallel sessions. Please choose the ones you like to attend on when you register for the Forum.**

### **Q&A Session**

During the 2 days of the Forum a bulletin board will be set up where delegates can post their question cards. The answers will be given by the expert speakers in this dedicated session and published in the members' area of the EQPA website.

## **Social Event**



On 3 December, you are cordially invited to a social event. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

# Speakers

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## Speakers from Authorities

**Andrew Charvill, MHRA, UK**

Analytical Assessor Medicines Testing Scheme (MTS).

**Richard Funnell, MHRA, UK**

GMP Inspector

**Dr Siegfried Giess, Paul-Ehrlich-Institut, Germany**

Head of Immunochemistry Section.

**Dr Jean-Denis Mallet, International Committee Red Cross, Switzerland**

GMP auditor within the International Committee of the Red Cross (ICRC) in Geneva and former Head of the French Pharmaceutical Inspection Department

**Raquel San José Rodríguez, Spanish Agency for Medicines and Medical Devices**

Pharmaceutical Inspection Unit

**Dr Janice M. Soreth, Europe/US FDA**

Deputy Director, Liaison to EMEA

**John Taylor, MHRA, UK**

Quality and Standards Manager Acting and Group Manager, Enforcement and Intelligence.

**Rudolf Völler, Head of a German Inspectorate**

Director of the GMP Inspections Department of Hessen, Germany.

## Speakers from the Industry

**Dr Hendrikus Boersma, Groningen University Medical Center, Netherlands**

Hospital Pharmacist, Clinical Pharmacologist and Qualified Person for Clinical Trial Materials

**Richard M. Bonner, formerly with Eli Lilly, UK**

Qualified Person, Consultant to the Pharmaceutical Industry. Advisory Board member of the Qualified Person Association.

**Dr Christopher Burgess, Burgess Consultancy, UK**

Qualified Person, Consultant to the Pharmaceutical Industry and Advisory Board member of the Qualified Person Association.

**Dr Rango Dietrich, PharmDev Innovations GmbH, Germany**

Qualified Person, Managing Director of PharmDev Innovations GmbH.

**Jenneke de Goeij, Netherlands**

Qualified Person, Consultant to the Pharmaceutical Industry.

**Peter Gough, David Begg Associates, UK**

Qualified Person, Consultant to the Pharmaceutical Industry.

**Dr Afshin Hosseiny, Tabriz Consulting, UK**

Managing Director of Tabriz Consulting.

**Heinz Lomen, asmit GmbH, Germany**

Lawyer and Insurance Broker.

**Dr Michael Nölchen, F. Hoffmann-La Roche Ltd, Basel, Switzerland**

Research and TR&D Procurement; responsible for the outsourcing of preclinical services to Contract Research Organisations.

**Dr Bernd Renger, Vetter Pharma-Fertigung GmbH, Germany**

Director of Quality Control and Chairman of The QP Association Advisory Board.

**Jolande Schoemaker, Schoemaker Consultancy, Netherlands**

Qualified Person and Consultant to the Pharmaceutical Industry.

**May Smans, Johnson & Johnson, Belgium**

Program Manager & Qualified Person, Global Qualified Person Group.

**Dr Annemiek Stijnen, Kinesis Pharma, Netherlands**

Director Chemistry, Manufacturing & Control and Senior Consultant Chemist at Kinesis Pharma.

**Martine Tratsaert, Johnson & Johnson, Belgium**

Department head of the Global Qualified Person Group (GQPG), center of excellence for QP certification of IMPs.

### **Date Pre-Conference Workshops/Sessions**

Specific Requirements for IMPs

Wednesday, 2 December 2009, 14.00 – 18.00

(Registration and coffee: 13.00 – 14.00)

The Role of the QP in modern QM-Systems

Wednesday, 2 December 2009, 14.00 – 18.00

(Registration and coffee: 13.00 – 14.00)

The Role of the QP in Biotech Industry

Wednesday, 2 December 2009, 14.00 – 18.00

(Registration and coffee: 13.00 – 14.00)

### **Welcome Reception for all participants**

Wednesday, 2 December 2009 18.00 – 19.00

### **Date QP Forum**

Thursday, 3 December 2009, 9.00 – 18.00

(Registration: Wednesday, 2 December 2009 18.00 – 19.00 and

Thursday, 3 December 2009 08.00 – 9.00)

Friday, 4 December 2009, 8.30 – 15.00

### **Venue**

Fira Palace Barcelona

Av. Rius Taulet, 1-3

08004 Barcelona

Spain

Tel: +34 93 426 22 23

Fax: +34 93 425 50 47

### **Fee for Pre-Conference Workshop**

€ 590,- per delegate plus VAT.

The fee is payable in advance after receipt of invoice and includes all refreshments. VAT is reclaimable.

### **Fees for QP Forum**

QP Association Members € 1.609,- 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 welcome reception, dinner on the first day, lunch on both days and all refreshments. VAT is reclaimable.

**Book both Forum and Pre-Conference Workshop and save money!  
Delegates who also attend the QP Forum will get a discount of  
200€ on the Workshop fee.**

### **Accommodation**

CONCEPT HEIDELBERG has reserved a limited number of rooms in the Fira Palace. Reservation should be made directly with the hotel not later than 20 October 2009. You will receive a room reservation form when you have registered for the course. Please use this form for your room reservation or be sure to mention "VA 6060 QP" to receive the specially negotiated rate for the duration of your stay. Early reservation is recommended.

### **Registration**

Via the attached reservation form, by e-mail to [info@qp-association.eu](mailto:info@qp-association.eu) or by fax to +49 6221 / 84 44 34 . Or you register online at [www.qp-association.eu](http://www.qp-association.eu).

### **Conference language**

The official conference language will be English.

### **Important Information!**

In recognition of the feedback we got from delegates, we want to replace the folders. The presentations 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 in Barcelona. **Note: there will be no print-outs available during the conference.**

### **Organisation / Contact**

CONCEPT HEIDELBERG

P.O. Box 10 17 64

D-69007 Heidelberg, Germany

Phone +49 (0) 62 21/84 44-0, Fax +49 (0) 62 21/84 44 34

E-mail: [info@concept-heidelberg.de](mailto:info@concept-heidelberg.de)

[www.concept-heidelberg.de](http://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](mailto: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](mailto:grimm@concept-heidelberg.de).

If the bill-to-address deviates from the specification to the right, please fill out here:

## Reservation Form (Please complete in full)

### **Qualified Person Forum 2009**, Barcelona, Spain, 3 – 4 December 2009

Please choose **two of the six** parallel sessions:

- Session 1 (Dr A. Hosseiny/J. Taylor)  Session 4 (M. Smans/A. Stijnen/M. Tratsaert)  
 Session 2 (J. de Goeyj/Dr C. Burgess)  Session 5 (R. Bonner/R. Völler)  
 Session 3 (Dr B. Renger)  Session 6 (Dr R. Dietrich)

### **Optional Pre-Conference Workshops/Sessions**, Barcelona, Spain, 2 December 2009

Please choose **one of the three** workshops:

- Specific Requirements for Investigational Medicinal Products  
 The role of the QP in modern QM Systems  
 The role of the QP in Biotech Industry

- Mr  Ms

Title, first name, surname

CONCEPT HEIDELBERG  
Postfach 10 17 64  
Fax 06221/84 44 34

Company Department

**Important: Please indicate your company's VAT ID Number**

Street / P.O. Box

D-69007 Heidelberg

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](http://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.