



**Speakers from Authorities:**

**David John Cockburn**

EMA, UK

**John Taylor**

MHRA, UK

**Speakers from the Industry:**

**Dr Richard M. Bonner**

Formerly with Eli Lilly and  
Company Ltd., UK

**Dr Tom Buggy**

DSM, The Netherlands

**Dr Christopher Burgess**

Burgess Consultancy, UK

**Dr Bernd Renger**

Vetter Pharma-Fertigung,  
Germany

**Dr Martin Wesch**

Lawyer, Germany

# Invitation

to the

# Qualified Person FORUM

## The Foundation of the European QP Association

Prague, Czech Republic, 30 November – 1 December 2006



Dr Bernd Renger

### **A European QP Association is urgently needed!**

Dear Colleagues,

the Qualified Person's function and responsibility is unique.

The European approach requires the QP not only to be highly qualified but also to always have the latest information on current developments in the area of GMP and regulatory compliance.

This is why the European Compliance Academy (ECA) initiated the idea to establish the

### **European QP Association.**

The Qualified Person Forum will be the initial meeting for the foundation of this new association.

I would like to invite you to this unique opportunity, and I look forward to meeting you.

Best regards,

Dr Bernd Renger  
Director Quality Control  
Vetter Pharma-Fertigung GmbH

## Objectives

Over the last 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 lots of issues to fulfil his responsibilities and to comply with the European legislation. The QP's main task among many others is to certify a drug product batch which is quite often not an easy decision – like when only minor deviations occur in the manufacturing process or when several QPs in different countries participate in the release process.

**This Conference is designed from QPs for QPs as an International Expert Forum** with focus on sharing experience and discussing the critical areas of the QP's daily work.

Representatives from the EU and the national authorities as well as QPs will present these issues from their point of view.

A special feature of this conference will be parallel sessions where case studies will be discussed to come up with possible solutions. The outcome of the sessions will be summarised and will be made available to the participants of the conference.

## Target Group

The Conference addresses all Qualified Persons and aspiring Qualified Persons.

## Moderator

Dr Christopher Burgess, Burgess Consultancy, UK

## **The Qualified Person within the European legislative framework**

- The EU's legislative framework and pharmaceutical legislation
- The EC GMP Guide
- The role of the QP in marketed products and clinical trials
- Recent developments and future developments affecting the QP
  - ⇒ David J. Cockburn, EMEA, UK

## **The various national ways to acquire the formal qualification of the QP**

- Minimum conditions of qualification according to Directive 2001/83/EC
- From 'A' like Austria to 'U' like United Kingdom – different requirements for the formal qualification of the QP across Europe
- Is there a need
  - ⇒ Dr Bernd Renger, Vetter Pharma-Fertigung, Germany

## **Relevant Guidances for the QP – an update on current EU GMP and ICH Guidelines and Initiatives**

- EU GMP Guidance
  - Chapter 1: Product Quality Review
  - Chapter 6: Ongoing Stability Testing
  - Annex 19: Reference samples and retention samples
- ICH Q8 – Pharmaceutical Development
- ICH Q9 – Quality Risk Management
- ICH Q10 – Quality – Management Systems
  - ⇒ Dr Christopher Burgess, Burgess Consultancy, UK

## **The challenge of ensuring GMP-compliant manufacturing of APIs by the QP**

- Directive 2001/83/EC; the requirement of Article 46(f)
- ICH Q7
- EU regulations on inspection and certification of API manufacturers
- Auditing of API suppliers
- Quality agreements
  - ⇒ Dr Richard M. Bonner, Formerly with Eli Lilly and Company Ltd., UK

## **Good Storage and Transportation Practice – the QP's responsibilities throughout the supply chain**

- Regulatory requirements for the supply chain
- What the QP has to take care about
- Risk areas and risk assessments
- The QP's involvement in stability testing scenarios and transport validation
  - ⇒ John Taylor, MHRA, UK

## **„To certify a batch or not; that's the question“ – The QP dealing with deviations and OOS results**

- Out of specification (OOS) results and their possible effect on batch certification
- Definition and classification of OOS results
- Minor deviations and the QP's release decision – possible solutions
- The EMEA reflection paper on minor deviations from the detail described in the MA
- Tools and ideas for handling OOS and deviations
  - ⇒ Dr Bernd Renger, Vetter Pharma-Fertigung, Germany

## **Legal actions against QPs – what can happen and when?**

- The relevant legal acts
  - Directives 2001/83/EC and 2003/94/EC
  - EU-GMP Guide Part I and II
- Responsibilities of the MA holder and the QP
- Cases of liability and sanctions against the QP
- Recommendations for QPs
  - ⇒ Dr Martin Wesch, Lawyer, Germany

## **Efficient auditing of API manufacturer by 3rd Party Audits**

- API GMP Audits – Legal Background
- Auditing API Manufacturers - Options
- Third Party Audit Principles
- The APIC Audit Programme
  - ⇒ Dr Tom Buggy, DSM, The Netherlands

### How would you decide as the responsible QP ?

Problems and Possible Solutions

#### Case Study 1

##### Deviations during the manufacture of an API – What actions should you take as the responsible QP?

You will be required to review a scenario associated with the manufacture of an API which has had a number of non-conformances associated with it during the course of its manufacture and to determine what actions, information, data will be necessary in order for you, as the responsible QP, to carry out batch disposition. Do you have enough information ? Do you require additional data ? Who should you talk to ? Does your decision impact any other batches ? Does market place availability, cost of product or the perceived risk associated with the non-conformances make any difference to your decision ? Participants will be able to discuss the alternative actions available and should arrive at an agreed disposition.

- ⇒ Dr Richard M. Bonner, Formerly with Eli Lilly and Company Ltd., UK

#### Case Study 2

##### Minor deviations during production of a finished product – What could your release decision look like?

The EMEA posted a reflection paper addressing the role of the Qualified Person (QP) when faced with a batch of product that does not fully comply with the details described in the dossier. The workshop will present two cases with batches that either do not fully comply or where it is not clear whether they comply with the requirements of the Marketing Authorization. Delegates may choose one of the examples and develop strategies and decision how to proceed.

- ⇒ Dr. Bernd Renger, Vetter Pharma-Fertigung, Germany

#### Case Study 3

##### Storage and shipping of sensitive products across the world - What do you have to consider as a QP?

Control of storage and transportation temperatures is essential in maintaining the quality of medicines in the supply chain. The workshop will examine the role of the Qualified Person in the global distribution network, using as an example the shipment of a consignment of vaccine from a manufacturer in the USA to a number of destinations in Europe.

- ⇒ John Taylor, MHRA, UK

### Presentation of the Case Study Solutions

#### Future issues and challenges for QPs – a survey

- Enlargement of the European Union
- Training, knowledge and skills of the QP
- The importance of non-technical skills
- The QP dealing with new technologies
  - ⇒ Speaker to be named

## Speakers

#### Dr Richard M. Bonner

Dr Bonner is currently located in the UK and works as a consultant to the Pharmaceutical Industry. Mr Bonner is a Qualified Person in Europe.

#### Dr Tom Buggy

Dr Buggy works as International GMP Compliance Adviser for DSM Anti-Infectives B.V. based in Delft, The Netherlands. Dr Buggy is the Leader of the APIC Third Party Audit Programme.

#### Dr Christopher Burgess

Dr Burgess is a Qualified Person and a qualified ISO Guide assessor, and he has recently been appointed to the PDA (USA) Scientific Advisory Board on 'OOS Task Force'.

#### David John Cockburn

David Cockburn is a Principal Scientific Administrator working in EMEA's Inspections Sector in London. David is also responsible for the EMEA PAT team.

#### Dr Bernd Renger

Dr Renger is Director of quality control at Vetter Pharma-Fertigung GmbH in Ravensburg, Germany.

#### John Taylor

John Taylor is Quality and Standards Manager Acting and Group Manager, Enforcement and Intelligence of the UK Medicines and Healthcare Products Regulatory Agency.

#### Dr Martin Wesch

Dr Wesch is a lawyer specialising in industrial law and working for the Stuttgart-based office of Wesch & Buchenroth. He is also managing director of the Gütegemeinschaft Pharma-Verpackung e.V.

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

Prague, Czech Republic, 30 November – 1 December 2006

Mr

Ms

Title, first name, surname

Company

Department

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

Street / P.O. Box

CONCEPT HEIDELBERG

Postfach 10 17 64

Fax 06221/84 44 34

D-69007 Heidelberg

City

Zip Code

Country

Phone/Fax

E-mail ( Please fill in)

#### Date

Thursday, 30 November 2006, 9.00h – 18.30h

(Registration and coffee 8.30h – 9.00h)

Friday, 1 December 2006, 8.30h – 16.30h

#### Venue

Dorint Novotel Don Giovanni Prague

Vinohradská 157A

130 20 Prague 3

Phone +420 2 6703 1111

Fax +420 2 6703 6717

#### Conference fees

Non-QP Association Members € 1,790.- per delegate plus VAT.

QP Association Members € 1,611.- per delegate plus VAT.

EU GMP Inspectorates € 895.- per delegate plus VAT.

The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on both days and all refreshments. VAT is reclaimable.

#### Accommodation

CONCEPT has reserved a limited number of rooms in the Dorint Novotel. Reservation should be made directly with the hotel not later than 3 November 2006. 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 ECA/CONCEPT 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.

#### Organisation / Contact

CONCEPT HEIDELBERG

P.O. Box 10 17 64

D-69007 Heidelberg

Germany

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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:

Dr Gerhard Becker (project manager) at +49 (0) 62 21 / 84 44 65,  
or per e-mail at [becker@concept-heidelberg.de](mailto:becker@concept-heidelberg.de).

### For questions regarding reservation, hotel, organisation etc:

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).

### 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 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 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 QP's 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.

### Who can become a Member of the QP Association?

Only registered Qualified Persons in Europe can become regular members of the QP Association. Details about the registration of the QP will be required in the application form. Interested persons who want to become a Qualified Person can apply for an associated membership.

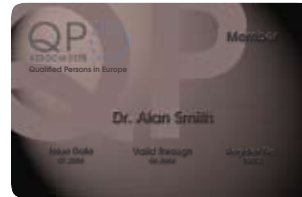
### How to become a Member of the QP Association?

The QP Association offers a free membership for the first 2 years after its foundation. In 2008 the Association's Board Members will decide if a regular membership fee is necessary to fulfil the tasks and objectives.

### What are the benefits of the membership?

As a member of the Qualified Person Association you can exchange your experience with other colleagues (e.g. by using the exclusive QP discussion forum), send comments on new Guidances and Directives to EU Authorities through the Association and join the annual QP Forum with a discount of 10%.

Members of the Qualified Person Association who will join the annual QP Forum receive the QP Association Card.



To become a Member please fill in the membership application form 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. ECA has entrusted CONCEPT HEIDELBERG with the organisation of its events.

### 1 I'm a Qualified Person

Yes

→ I'm registered at the following authority

Authority Name \_\_\_\_\_

Street / P. O. Box \_\_\_\_\_

City \_\_\_\_\_ Zip Code \_\_\_\_\_

Country \_\_\_\_\_

→ I've been registered since \_\_\_\_\_

### 2 My fields of interest are

EU Regulatory / GMP Requirements

Marketing Authorisation

Batch Release

Supplier Qualification

No

I'm currently preparing to become a Qualified Person and I'd thus like to become an associated member for the next two years.

*(this period can not be extended)*

Auditing of Suppliers / Contract Manufacturing

Preparation for Authority Inspection

Validation

Personal Training

### 3 I'm involved in the following kind of manufacturing

Sterile / Aseptic Production

Solid Dosage Production

Semi Solid Dosage Production

Others \_\_\_\_\_

Liquid Non Sterile Production

Biotech Production

Biologics (Blood, Vaccines, Herbals, etc)

### 4 Personal Information

\_\_\_\_\_  
First name, Last name

\_\_\_\_\_  
Company

\_\_\_\_\_  
Street / P. O. Box

\_\_\_\_\_  
City Zip Code

\_\_\_\_\_  
Country