

Speakers

Lynne Byers

GSK, U.K., RX-360 Representative

Dr Brendan Cuddy

European Medicines Agency (EMA)

Anthony Gould

WHO

Dr Thomas Hecker

EDQM, France

Dr Bernd Renger

*Vetter Pharma-Fertigung GmbH,
Germany*

Benoît Rime

United States Pharmacopeia (USP)

Anthony Storey

Pfizer, U.K., APIC Representative

Beam Suffolk

IPEC Europe, Belgium

The GMP Auditing Conference

How to use external sources of compliance information
and to share information between QPs

London, U.K., 24 November 2010

A Pre-Conference Session of the QP Forum 2010 in London



Objective

Audits performed by industry and inspections performed by regulatory authorities are the key element to safeguard the global supply chain. A number of initiatives are currently under way. It is the focus of these initiatives to increase the efficiency of the GMP audit/inspection process and to identify non-compliance and counterfeit.

The GMP Auditing Conference aims

- to inform about the different initiatives that have been set up by for example APIC, IPEC, Rx-360, EDQM
- to discuss potential ideas to further develop the idea of information sharing (e.g. Shared Audit Reports, Audit Database)
- to support the dialogue between industry and authorities

In a global environment neither industry nor authorities alone are able to supervise the complete supply chain. This forum will create an information platform about available “compliance sources” and will develop ideas to share information between the parties involved. The QP Association has therefore decided to invite the major stakeholders to this unique event.

Programme

09:00 – 09:20 **Introduction and Welcome**

09:20 – 10:00 **The QP’s Responsibility in Supplier Qualification in a global Environment**

- How to use Third Party information (the major differences in EU and US FDA regulations)
- The QP Association point of view
- QPSHARE – the new database for EQPA Members
- How to exchange information between Authorities and Industries
 - ⇒ **Dr Bernd Renger,**
Vetter Pharma-Fertigung,
Chairman QP Association

10:00 – 10:40 **WHO Prequalification of Medicines Programme**

- The WHO Prequalification of Medicines programme
- Public Inspection Reports (WHOPIR)
 - ⇒ **Anthony Gould,**
WHO

10:40 – 11:10 **Coffe Break**

11:10 – 11:50 **EudraGMP and international collaboration on API inspections**

- ⇒ **Dr Brendan Cuddy,**
Scientific Administrator at EMA

11:50 – 12:30 **Integration of APIC Audit Programme in Supplier Qualification - what is the QP's Role?**

- How to avoid a conflict of interest according to EMA's Q and A Document
- How to share an Audit Report based on the APIC Programme
- How can QPs initiate a joint audit
 - ⇒ **Tony Storey**, Pfizer,
Vice President APIC/CEFIC

12:30 – 14:00 **Lunch Break**

14:00 – 14:40 **EDQM Database - How to obtain Information about withdrawn and suspended CEPs**

- What kind of information is available via the public database of EDQM
- How to receive update information about withdrawn CEPs
- What are the consequences for a marketing authorisation holder if a CEP has been withdrawn
 - ⇒ **Dr Thomas Hecker**,
GMP-Inspector at the EDQM

14:40 – 15:20 **Certified Excipients? Is the upcoming Certification based on IPEC/EFFC the Solution for the complex Excipient Market?**

- The problem with auditing excipient manufacturers when purchasing only a small quantity
- Certification of manufacturers: How to avoid a conflict of interest
- Certification Classification
- Auditable GMP and GDP Standard
 - ⇒ **Beam Suffolk**, IPEC Europe Chair

15:20 – 15:40 **Coffee Break**

15:40 – 16:15 **Integration of Rx-360 Initiative in Supplier Qualification – what is the QP's Role?**

- How does Rx360 consider the QP's role in the programme
- How to use information from Rx-360 for supplier qualification
 - ⇒ **Lynne Byers**, GlaxoSmithKline
Vice Chair of RX 360

16:15 – 16:50 **USP View: USP verified Programme for APIs and Excipients**

- How to obtain the USP verified mark
- USP verification requirements (e.g. GMP Audit, testing and sampling, documentation review)
- Acceptance by EU and US regulators
- Point of view of other Pharmacopeias
 - ⇒ **Benoit Rime**, United States Pharmacopeia (USP)

16.50 – 18:00 **Panel Discussion**

How to exchange and use Information provided by validated Resources from industry and Authority

It is the aim of the panel discussion to discuss the existing models from the point of view of the Qualified Person:

- How to use the initiatives which have been developed by different industry groups
- Are the initiatives meeting all criteria from the point of view of the QPs – What is needed?
- How to share information from different sources

Panel Discussion with representatives from IPEC, APIC/CEFIC, Rx360, USP, EDQM and the European QP Association

Speakers



Lynne Byers, GlaxoSmithKline, U.K.

- Head of Supplier Quality Shared Service
- Vice Chair of RX 360

Dr Brendan Cuddy, European Medicines Agency (EMA)

- Scientific Administrator at EMA Inspection Sector



Anthony Gould, WHO

- Manager of the Medicines Prequalification Program World Health Organisation (WHO)



Dr Thomas Hecker, EDQM, France

- GMP Inspector at the EDQM in Strasbourg



Dr Bernd Renger, Vetter Pharma-Fertigung GmbH, Germany

- Director of Quality Control
- Chairman of the QP Association Advisory Board



Benoît Rime, United States Pharmacopeia (USP)

- Senior International Account Manager USP Europe/ Middle East/Africa



Anthony Storey, Pfizer, U.K.

- Contract Operations Quality Assurance
- Vice President APIC/CEPIC



Beam Suffolk, Dow Europe, Belgium

- European Regulatory Affairs Manager
- IPEC Europe Chair

Information about the QP Forum

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

Speakers from EMA 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 2010 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 two pre-conference sessions and the six parallel sessions at the Forum

1. Risk Management Session: different approaches the QP should know and should know how to apply
2. QP Scenarios: Would you know what to do ? Make decisions based on real-life situations
3. Root cause analysis and troubleshooting techniques for QPs
4. The role of the QP in an R&D Environment
5. What is the role of the QP in cycle time reduction/ business process strategies without corrupting legal and GMP requirements
6. Define and secure your supply chain

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.

For more information: www.qp-association.eu.

Date Full Day Pre-Conference Session:

The GMP Auditing Conference
Wednesday, 24 November 2010, 9.00 – 18.00
(Registration and coffee: 8.30 – 9.00)

Welcome Reception for all participants

Wednesday, 24 November 2010, 18.00 – 19.00

Date QP Forum

Thursday, 25 November 2010, 9.00 – 17.30
(Registration: Wednesday, 24 November 2010, 18.00 – 19.00 and
Thursday, 25 November 2010, 08.00 – 9.00)
Friday, 26 November 2010, 8.30 – 15.00

Venue

Hilton London Metropole
Edgware Road
London W2 1JU, U.K.
Tel.: +44 (0)20 7402 4141, Fax: +44 (0)20 7724 8866

The Hilton London Metropole is just 20 minutes from Heathrow Airport via the Heathrow Express to Paddington Station (5min to hotel). Closest underground station is Edgware Road.

Accommodation

CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. Please make your reservation via the Personalised Online Group Page POG where you also can modify your reservation until 22 October 2010. Early reservation is recommended.

Fees for Full Day Pre-Conference Session

The GMP Auditing Conference

€ 890,- 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 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 electronic conference documentation, welcome reception, dinner on the first day, lunch on both days and all refreshments. VAT is reclaimable.

Saving Opportunity!

Book both the QP Forum and a Pre-Conference Workshop/ Session: Delegates who attend the QP Forum and a Pre-Conference Workshop/ Session will get a **discount of 200€** on the QP Forum.

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

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-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
Phone +49 (0) 62 21/84 44-0, Fax +49 (0) 62 21/84 44 34
E-mail: info@concept-heidelberg.de
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.

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.

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

Reservation Form (Please complete in full)

- 1 Full Day Session "The GMP Auditing Conference"**, London, U.K., 24 November 2010
- Qualified Person Forum 2010**, London, U.K., 25 – 26 November 2010
- Please choose **two of the six** parallel sessions:
- Session 1 Session 4
- Session 2 Session 5
- Session 3 Session 6

Mr Ms

Title, first name, surname

Company

Department

Important: Please indicate your company's VAT ID Number

PO Number (if applicable)

Street / PO Box

City

Zip Code

Country

Phone / Fax

E-mail (Please fill in)

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

D-69007 Heidelberg

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.