QP ASSOCIATION

ECA
EUROPEAN COMPLIANCE ACADEMY

Highlights

Understand European GMPs

- The European Pharmaceutical Legislation
- Import/ Export, CEPs and GMP Certificates
- EU Product Quality Review Requirements versus US Annual Report Requirements

Understand the Role of the QP

- The Legal and Professional Duties of the Qualified Person
- EU Inspections in the U.S. and the Involvement of the QP
- The EU Discretion Paper and the Release of Batches by the QP
- The Role of the QP in Contract Manufacturing
- The role of the QP in the Supply Chain and Supplier Qualification
- The US Quality Unit versus the EU QP

The view of FDA and EMA

With optional Post-Conference Sessions on June 9, 2011

- Session 1: Case studies: Certification by a QP and Batch Release
- Session 2: Clinical Trial Supplies: IMP Handling in Europe and the Role of the QP

Understand European GMPs and the Role of the QP

Bethesda, Washington D.C. Metro Area
June 7–8, 2011

With optional Post-Conference Sessions on June 9, 2011

Speakers

- **Richard M. Bonner,** *Qualified Person, Formerly with Eli Lilly and Company Ltd., UK*
- **Dr Christopher Burgess,** *Qualified Person, Burgess Analytical Consultancy, UK*
- **Dr Dimitrios Catsoulacos,** *European Medicines Agency, EMA*
- **Dr Bernd Renger,** *Qualified Person, Chairman, European QP Association*
- **Dr Janice Soreth,** *FDA, Office of International Programs at EMA*
- **Martine Tratsaert,** *Qualified Person, Johnson & Johnson, Belgium*
- **Mark Tucker, Ph.D.,** *Genentech Inc./ Roche Group, USA*

Welcome

Dear Colleagues,

The Pharmaceutical Industry is becoming more global due to international collaborations, mergers and acquisitions and more complex supply chains requiring companies to have a greater understanding of pharmaceutical legislation throughout the world. This is becoming increasingly evident by the number of non EU professionals contacting the European Compliance Academy and the Qualified Persons Association asking for more and more detailed information about the European GMPs and the unique role and responsibility of the EU QP.

The European Compliance Academy ECA and the European QP Association, recognising this need for further professional knowledge development, intend to support the pharmaceutical industry outside Europe in understanding the European approach and legal framework in this respect. Therefore the QP Association has set up the programme at hand on European GMP requirements and the role of the QP.

Representatives from the authorities as well as QPs and well-known experts will talk about the current issues and share their point of view. During the two post-conference workshops and, 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.

Best regards,

Dr Bernd Renger
Chairman of the Qualified Person Association

Background

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

This Conference is designed by QPs and international Experts as a forum with focus on sharing information and experience and on discussing the critical areas of European GMPs and the QP's daily work.

Target Group

The Conference has been designed for non-European QA and QCU personnel, upper management functions and authority representatives who want to be informed about the latest development regarding European GMPs and the duties and responsibilities of Qualified Persons.

Moderator

Dr Christopher Burgess, U.K.
QP and Advisory Board Member of the European QP Association

About the Organisers

The European Compliance Academy (ECA)

The European Compliance Academy (ECA) is an independent membership association and is today the leading European association with regard to pharmaceutical Quality Assurance and GMP compliance. Close to 4.000 members from all over Europe and abroad represent more than 60 countries. The Academy is a not for profit organisation and part of the ECA Foundation. You will find more at www.gmp-compliance.org.

The European QP Association

The European Qualified Person (QP) Association was founded in July2006 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.

Programme

Introduction
- ➲ Dr Bernd Renger

Part I: Understand European GMPs

The European Pharmaceutical Legislation
- EU Regulations, Directives, Decisions, Guidelines and their Deployment in the Member States
- The EU in MRA and PIC/S
- What is an MRA and ACAA and how does that impact the relationship between the EU and the USA
- EMA and FDA authority positions with respect to the differing GMPs and role of the QP
  - ➲ Dr Dimitrios Catsoulacos

Case Study: How we experienced EU GMPs and how we align our Quality Systems
- US GMPs versus EU GMPs
- Responsibilities of Head of the Production and the Head of Quality Control
- How to implement policies that will be compliant for EU and US GMPs.
- How to certify a batch for the EU market
  - ➲ Dr Mark Tucker

Import and Export: MIAs, GMP Certificates and EudraGMP
- What it is
- What is needed
- How to get it
  - ➲ Dr Dimitrios Catsoulacos

The View of the FDA
- What does FDA think about the EU QP
- Differences between ICH Q 10 and the US Quality Systems Guidance: why both guidances are out in parallel in the US
- EMA and FDA authority positions with respect to the differing GMPs and role of the QP
  - ➲ Dr Janice Soreth

EU Product Quality Review Requirements versus US Annual Report Requirements
- ➲ Dr Christopher Burgess

Part II: Understand the Role of the QP

The Legal and Professional Duties of the Qualified Person
- The role of the QP within the pharmaceutical quality System
- The differences between ICH Q 10 and the US Quality Systems Guidance
- What the QP is responsible for
- Batch certification – how is it done?
- Comparison between the responsibilities of the Head of the US QCU and the EU QP
- Is there something like a US based QP?
  - ➲ Dr Christopher Burgess

QP Duties and Responsibilities – individual Member States' Regulations

The different Transformation of Directive 2001/ 83 into national Laws
- Article 49 (2) – "minimum conditions of qualification"
- Article 50 - "established rights and responsibilities"
- Continual professional development
- The role of professional bodies in the various member states
- Selected examples
  - ➲ Dr Bernd Renger

The EU Discretion Paper and the Release of Batches by the QP

European and national Guidance and Expectations on investigating Deviations and OOS Results
- Responsibilities of the QP
- The EMA Reflection paper "QP Discretion"
- The QP's true margin of discretion when releasing batches with deviations
- Selected examples
  - ➲ Dr Bernd Renger

EU Inspections in the U.S. and the Involvement of the QP
- Who can inspect in the U.S.
- Is an inspection from an EU country or the EMA different to an FDA inspection?
- What is the role of a QP with respect to U.S Inspections
- What are the key findings of EU inspections in the U.S.? Are these different to FDA observations?
  - ➲ Richard Bonner

The Role of the QP in Contract Manufacturing and Testing
- Supplier Qualification
- Quality Agreements
- Technical Agreements
- Co-operation and information exchange
  - ➲ Richard Bonner

The Role of the QP in the Supply Chain and Supplier Qualification
- Proposal to have the QP sign a declaration that the supply chain is secure
- Supply Chain oversight
  - ➲ Dr Christopher Burgess

The US Quality Unit versus the EU QP

1. Introduction

- Dr Christopher Burgess

2. Panel Discussion

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

Optional: Parallel Post-Conference Sessions (1/2 Day)

Session 1:
Case studies: Certification by a QP and Batch Release – what would you do if you were personally liable?
How would you have decided in the case you were personally liable for the decision whether to release or not.

- Richard Bonner and Dr Bernd Renger

Session 2:
Clinical Trial Supplies: IMP Handling in Europe and the Role of the QP

- EU GMP and QP requirements for the release of Investigational Medicinal Products
  - Roles and Responsibilities of the IMP QP
  - Regulatory basis for the IMP QP
  - IMP legislation
    - Commercial QP legislation versus IMP legislation
  - QP certification and sponsorship
    - EU-GMP compliance of non-EU sites
    - Comparator sourcing
    - Impurity/ Issue handling
- GMP-GCP Interface
  - GMP activities in a GCP environment
  - Drug transfer and returns
- QP oversight and being a QP in a global environment
  - QP oversight in a GMP and a GCP area
  - Strategies to prevent potential delays
  - Risk based approach
- Liability of the IMP QP
- Case studies
  - Martine Tratsaert

You may attend one of these parallel sessions. Please choose the one you would like to attend when you register for this Conference.

Important Information!
The presentations of this conference 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 Bethesda.
Note: there will be no print-outs available during the conference.

Social Event

On Tuesday, June 7 2011, you are cordially invited to a dinner. This is an excellent opportunity to share your experiences with speakers and colleagues from other companies in a relaxed atmosphere.

Speakers

Richard M. Bonner, *Qualified Person and Consultant, U.K.*
Mr Bonner is currently located in the U.K. and works as a consultant to the Pharmaceutical Industry. Previous to his current role he was a Senior Quality Adviser for Eli Lilly and Company. He had 31 years experience within the pharmaceutical industry working in production, technical services and both Quality Control and Quality Assurance functions. Mr Bonner is a Qualified Person in Europe and member of the Qualified Person Association Advisory Board.

Dr Christopher Burgess, *Qualified Person, Burgess Consultancy, U.K.*
Chartered Chemist with more than 30 years experience in the pharmaceutical industry primarily with Glaxo in Quality Assurance and Analytical R & D. He is a Qualified Person and a qualified ISO Guide assessor and a member of the PDA (USA) Scientific Advisory Board on 'OOS Task Force'. He is also member of the Qualified Person Association Advisory Board.

Dr Dimitrios Catsoulacos, *European Medicines Agency, EMA*
Dimitrios Catsoulacos is Scientific Administrator Manufacturing & Quality Compliance, Compliance & Inspection at the European Medicines Agency (EMA) in London, U.K.. Before that he was Senior Inspector at the National Organization for Medicines in Greece and Head of Process Development at FAMAR. He holds scientific degrees from Panepistimion Patron , Long Island University and Idaho State University.

Dr Bernd Renger, *Qualified Person, Chairman of the European QP Association*
Bernd Renger is a member of the ECA Advisory Board and Chairman of the QP Association. He held several quality positions in pharmaceutical industry, for example at Hoechst, Mundipharma, Altana, and Baxter. Until 2010 he was Vice President Quality Control and QP at Vetter Pharma-Fertigung. He is now running his own consultancy business (Bernd Renger Consulting).

Dr Janice M. Soreth, *Europe/US FDA*
Janice Soreth is Deputy Director Europe, Office of International Programs, U.S. FDA. She has been with the agency for more than 20 years at CDER's director of the division of Anti-Infectives and Ophthalmology as well as working in CBER and the Office of Combination Products/Office of the Commissioner.

Martine Tratsaert, *Qualified Person, Johnson & Johnson, Belgium*
Martine Tratsaert is the department head of the Global Qualified Person Group (GQPG), the center of excellence for QP certification of IMPs. She is a member of the Qualified Person Association Advisory Board and responsible for the IMP working group.

Mark Tucker, Ph.D., *Genentech Inc./ Roche Group, USA and former FDA Investigator and Compliance Officer*
Mark Tucker is Senior Director, GMP Compliance at Genentech Inc., South San Francisco, USA, where he has the full strategic responsibility for GMP Compliance. Before joining Genentech in 2002, Mark was Director, Investigations Branch at U. S. Food and Drug Administration (FDA). He also served as an Investigator and Compliance Officer with the FDA. He started his career as Assistant Professor at the University of Southern California and Adjunct Assistant Professor at the Research and Education Institute, Harbor/UCLA Medical Center.

Date Conference
Tuesday June 7, 2011, 9am – 5.30pm
(Registration and coffee 8.30am – 9.00am)
Wednesday June 8, 2011, 9.00am – 4.00pm

Date ½ Day Post-Conference Sessions
Thursday, June 9, 2011, 9.00am – 2.00pm

Venue
Double Tree
Hotel & Executive Meeting Centre
8120 Wisconsin Avenue
Bethesda, MD 20814
USA
Phone +1 301-652-2000
Fax +1 301-664-7317

Fees Conference
Standard: US$1,690
Government/Health Authority: US$ 600
The conference fee is payable in advance and includes conference documentation, dinner on the first day, lunch on all days and all refreshments.

Fees Conference plus Post-Conference Session
Standard: US$1,990
Government/Health Authority: US$ 700
The conference fee is payable in advance and includes conference documentation, dinner on the first day, lunch on all days and all refreshments.

Accommodation
The organisers have reserved a limited number of rooms in the conference hotel. Please make your reservation via POG (Personalized Online Group Page) until May 16, 2011. You will receive a reservation link together with your confirmation/invoice. 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-association.eu.

Conference language
The official conference language will be English.

Organisation / Contact
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Easy Registration

Reservation Form:
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Germany

Reservation Form:
+ 49 6221 84 44 34

e-mail:
info@qp-association.eu

Internet:
www.qp-association.eu

Understand European GMPs and the Role of the QP

June 7–8, 2011, Bethesda, Maryland

Optional Post-Conference Sessions
June 9, 2011, Bethesda, MD

Contact Information

Title, Last Name, First Name

Job Title

Company | Department

Mailing Address

City | State/Province | Zip+4/Postal Code

Country

Phone / Fax | EMail

1a. Registration for Conference – Understand European GMPs and the Role of the QP, June 7–8, 2011

(Please check appropriate fee in US $)

Standard	☐ $ 1,690
Government/Health Authority	☐ $ 600

1b. Registration for Conference **PLUS** Post-Conference Session, June 9, 2011

(Please check appropriate fee in US $)

Standard	☐ $ 1,990
Government/Health Authority	☐ $ 700

Please check the Session you would like to attend

☐ Session 1: Case studies: Certification by a QP and Batch Release – what would you do if you were personally liable?

☐ Session 2: Clinical Trial Supplies: IMP Handling in Europe and the Role of the QP

2. Payment by Credit Card

Please bill my: ☐ American Express ☐ Master Card ☐ VISA

(All cards will be charged in US $)

Total Amount

Account Number | Expiration Date | Card Validation Number (3/4 digits)

Name (exactly as it appears on the card) | Signature

Billing Address

City | State/Province | Zip+4/Postal Code

Country

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 in advance with credit card.

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 payable by registration. You are not entitled to participate in the conference until we have received your payment (receipt of payment will not be confirmed)!