QP ASSOCIATION

ECA
EUROPEAN COMPLIANCE ACADEMY

European GMPs and the Role of the Qualified Person (QP)

The Impact of EU Directives and Guidelines on the Supply Chain

Bethesda, Washington D.C. Metro Area
June 27–28, 2012

Speakers

Richard M. Bonner
Qualified Person and Consultant, U.K., formerly with Eli Lilly

Dr Christopher Burgess
Qualified Person, Burgess Consultancy, U.K., formerly with GSK

Dimitrios Catsoulacos
European Medicines Agency (EMA), UK

Tor Gråberg
PIC/S Chairman, Medical Products Agency, Sweden

Dr Bernd Renger
Qualified Person, Chairman of the European QP Association, Germany

Martine Tratsaert
Qualified Person, Johnson & Johnson, Belgium

Mark Tucker, Ph.D.
former FDA Investigator and Compliance Officer, USA

2011 Delegates' Voices:

"The conference was very informative and provided significant information regarding QP role and associated regulations."

"The openness and access to the speakers was great."

"I will definitely recommend this course to colleagues."

"This was a great event! Great information with great discussions."

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 Role of PIC/S in a globalising World

The European Directorate for the Quality of Medicines and Healthcare (EDQM)

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

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. 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

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.

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 Organizers

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: The European QP Association

➲ Dr Bernd Renger and Dr Christopher Burgess

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

➲ 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

➲ Dimitrios Catsoulacos

The Role of PIC/S in a globalising World

- PIC and the PIC Scheme
- Current and future activities
- USA as PIC/S member: benefits and challenges

➲ Tor Gråberg

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 Product Quality Review Requirements versus US Annual Report Requirements

➲ Dr Christopher Burgess

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 – Panel Discussion

➲ Dr Christopher Burgess

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
- GMP-GCP Interface
- QP oversight and being a QP in a global environment
- Liability of the IMP QP
- Case studies

➲ Martine Tratsaert

Welcome Reception

On Wednesday, June 27, 2012, you are cordially invited to a welcome reception after the programme. 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., formerly with Eli Lilly*
Mr Bonner works as a consultant to the Pharmaceutical Industry. Previous to his current role he was a Senior Quality Adviser for Eli Lilly and Company. 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., formerlyy with GSK*
Dr Burgess is Qualified Person and a member of the European QP Association Advisory Board. He has been appointed to the United States Pharmacopoeia's Council of Experts 2010 to 2015 and is a visiting professor of the University of Strathclyde's School of Pharmacy and Biomedical Sciences (SIPBS). In addition, he is the chairman of the ECA Analytical Quality Control Group and a member of the Executive committee of European Compliance Academy.

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.

Tor Gråberg, *PIC/S and Swedish Medical Products Agency*
Tor Gråberg is Chief Pharmaceutical Inspector and Head of the Drug Inspectorate of the Swedish Medical Products Agency. Since January 2010 he has been the Chairman of PIC/S (Pharmaceutical Inspection Co-operation Scheme). Mr Gråberg is also the Swedish representative within the EMA GMDP Inspection Working Group.

Dr Bernd Renger, *Qualified Person, Chairman of the European QP Association, Germany*
Bernd Renger is a member of the ECA Advisory Board and Chairman of the QP Association. He has held several quality positions at Hoechst, Mundipharma, Altana Pharma, and Baxter. Until 2010 he was Director of Quality Control at Vetter Pharma-Fertigung.

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., *former FDA Investigator and Compliance Officer, USA*
Mark Tucker was Senior Director, GMP Compliance at Genentech Inc., South San Francisco, USA, where he had the full strategic responsibility for GMP Compliance. Before joining Genentech in 2002, Mark was Director, Investigations Branch at the 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
Wednesday 27 June 2012, 9.30am – 6.00pm
(Registration and coffee 9.00am – 9.30am)
Thursday 28 June 2012, 8.30am – 4.00pm

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

	ECA Member	Non-ECA Members	Government/ Health Authority
Before May 15, 2012	US$ 1,790	US$ 1,890*	US$ 750
After May 15, 2012	US$ 1,890	US$ 1,990*	US$ 750

* Registration entails free ECA membership for the following two years after the event

The conference fee is payable in advance after receipt of invoice and includes conference documentation, a welcome reception on the first day, lunch on both 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 June 4, 2012. 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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Ms Marion Grimm (Organisation Manager) at +49 (0) 62 21 / 84 44 18,
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Easy Registration

Reservation Form:
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69007 Heidelberg
Germany

Reservation Form:
+ 49 6221 84 44 34

e-mail:
info@qp-association.eu

Internet:
www.qp-association.eu

European GMPs and the Role of the Qualified Person (QP)

June 27–28, 2012, Bethesda, Maryland

Contact Information

Title, Last Name, First Name

Job Title

Company | Department

Mailing Address

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

Country

Phone / Fax | EMail

1. Registration for Conference

(Please check appropriate fee in US $)

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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)!