QP ASSOCIATION

ECA
EUROPEAN COMPLIANCE ACADEMY

The Bridge to European GMPs and the Role of the Qualified Person (QP)

The Impact of EU Directives and Guidelines on the Supply Chain

San Francisco, CA, USA – June 19-20, 2013

A conference organised by the European Compliance Academy (ECA) and the European QP Association

Speakers

Richard M. Bonner
Chairman of the European QP Association

Dr Rainer Gnibl
EU-GMP Inspectorate, Germany

Tor Gråberg
Medical Products Agency, Sweden

Dr Bernd Renger
Immediate Past Chair of the European QP Association, Germany

Martine Tratsaert
Johnson & Johnson, Belgium

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

Highlights:

Understand European GMPs
- The European Pharmaceutical Legislation
- EU GMP Update
- Import/ Export
- EU PQR versus US APR
- The US Quality Unit versus the EU QP

Understand the Role of the QP
- Duties and Responsibilities
- The EU Discretion Paper and the Release of Batches
- Supply Chain and Supplier Qualification

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

The Role of PIC/S in globalising World

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."

Welcome

Dear Colleagues,

The Pharmaceutical Industry is becoming more global due to international collaborations, mergers and acquisitions and more complex supply chains. Due to this development companies are required 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.

Recognizing this need for further professional knowledge development, the European Compliance Academy ECA and the European QP Association 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,

Richard M. Bonner
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 stick at the conference's registration desk.
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

Richard M. Bonner, U.K.
QP and Chairman of the Advisory Boards of the ECA Foundation and the European QP Association.

About the Organizers

The European Compliance Academy (ECA)

ECA
European Compliance Academy

The ECA Academy is a non-profit educational organization and part of the ECA Foundation. The ECA was founded in January 1999 as 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. You will find more at www.gmp-compliance.org.

The European QP Association

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 ECA Foundation and the European QP Association

➲ Richard M. Bonner

Part I: Understand European GMPs

The European Pharmaceutical Legislation

- Relevant European Pharma- and GMP-regulation
- Prerequisites for EU GMP-compliance
- Agreements between EU and third countries (MRA) and impact on USA
- Exchange of information between competent EU-authorities (EMA compilations of community procedures) and impact on USA

➲ Dr Rainer Gnibl

Plus: EU-GMP Update - what's going on at the Moment

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 into European Union: Preconditions and GMP-certificate/ MIA

- Requirements for different materials or products
- Who is allowed to import
- Which documents are needed for import
- How to obtain a GMP-certificate (GMP-compliance)
- How to prepare an EU GMP-inspection
- Inspection-procedure and follow-up
- Procedure from applicants import request till placing on the EU-market

➲ Dr Rainer Gnibl

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?
- The Role of the QP in Contract Manufacturing and Testing
- Comparison between the responsibilities of the Head of the US QCU and the EU QP
- Is there something like a US based QP?

➲ Richard Bonner

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 on "QP Discretion"
- The QP's true margin of discretion when releasing batches with deviations
- Selected examples

➲ Dr Bernd Renger

EU-PQR versus US-APR

- Goals and technical-terms of EU-PQR
- Critical points
- Practical implementation of EU-PQR
- Comparison between EU- and US-requirements
- PQR and contract manufacturing

➲ Dr Rainer Gnibl

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
- EU Inspections in the U.S. and the Involvement of the QP

➲ Richard Bonner

The US Quality Unit versus the EU QP (Panel Discussion)

➲ Richard Bonner

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 19, 2013, 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, *Chairman of ECA Foundation and the European QP Association, formerly with Eli Lilly*
Richard Bonner was a Senior Quality Adviser for Eli Lilly and Company. Mr Bonner is a Qualified Person in Europe, Chairman of the ECA and of the Qualified Person Association Advisory Board.

Dr Rainer Gnibl, *Government of Upper Bavaria, Germany*
Dr Rainer Gnibl is EU-GMP inspector in Germany and performs GMP inspections worldwide also on behalf of the European Medicines Agency (EMA).

Tor Gråberg, *Swedish Medical Products Agency*
Tor Gråberg is Chief Pharmaceutical Inspector and Head of the Drug Inspectorate of the Swedish Medical Products Agency. From 2010 - 2012 he was 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, *Immediate Past Chair European QP Association*
Bernd Renger is a member of the ECA Advisory Board and was Chairman of the QP Association until 2012. 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, *Johnson & Johnson, Belgium*
Martine Tratsaert is Senior Director Market Quality EMEA. Before that she was heading the center of excellence for QP certification of IMPs at J&J. She is a member of the Qualified Person Association Advisory Board and responsible for the IMP Working Group.

Mark Tucker, *Ph.D, form. FDA Investigator and Compliance Officer, USA*
Mark Tucker was Senior Director, GMP Compliance at Genentech Inc., South San Francisco, USA. 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 is now a consultant to the pharmaceutical industry.

Date Conference
Wednesday 19 June 2013, 9.30am – 5.20pm
(Registration and coffee 9.00am – 9.30am)
(Welcome Reception 5.30pm – 6.30pm)
Thursday 20 June 2013, 8.30am – 3.30pm

Venue
Hilton San Francisco Fisherman's Wharf
2620 Jones Street
San Francisco, CA 94133
USA
Phone: + 1 415 885 4700

Fees Conference

ECA Members	Non-ECA Members	Government/Health Authority
US$ 1,990	US$ 2,100*	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 organizers have reserved a limited number of rooms in the conference hotel. Please make your reservation via POG (Personalized Online Group Page). You will receive a reservation link together with your confirmation/invoice. Early reservation is recommended.

Registration
Via the reservation form on the back of this program, by e-mail to info@qp-association.eu or by fax to +49 (0) 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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Bridge to European GMPs and the Role of the Qualified Person (QP)

June 19-20, 2013, San Francisco, CA

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 $)

ECA Members	Non-ECA Members	Government / Health Authority
☐ $ 1,990	☐ $ 2,100*	☐ $ 750

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

2. Payment by Credit Card

(All cards will be charged in US $)

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

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)!