After the MRA:

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

The Impact of the changing Guidance and the MRA

August 28 - 29, 2018
Chicago, Il., USA

Highlights

Understand European GMPs

- EU GMPs you should know
- Who will come and inspect/ audit?
- Import/ Export
- EU Validation versus US Validation

Understand the Role of the QP

- Batch Certification and Release for the EU
- Duties and Responsibilities
- Supply Chain and Supplier Qualification

Clinical Trial Supplies

- Revision of the EU Legislation
- IMP Handling in Europe and the Role of the QP

Speakers

David Cockburn
formerly European Medicines Agency (EMA)

Dr Susanne Ding
Boehringer Ingelheim

Dr Rainer Gnibl
EU-GMP Inspectorate

Dr Ulrich Kissel
European QP Association

Dr Bernd Renger
Past Chair of the European QP Association

A conference organized by the ECA Academy and the European QP Association

ECA Academy Your GMP/GDP Information Source

QP Association

Welcome

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 ECA Academy and the European QP Association, recognizing 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.

In light of the establishment of a Mutual Recognition Agreement between US and EU and the parallel move out of Great Britain from the EU, 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,

Ulrich Kissel
Chairman of the European Qualified Person Association

Objectives

This event 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 Audience

The Conference has been designed for non-EU 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

Wolfgang Schmitt,
on behalf of the European QP Association

About the Organizers

The ECA Academy

With close to 5,000 members the European Compliance Academy (ECA) has become the leading European association with regard to GMP and regulatory compliance. The ECA provides support to the Pharmaceutical Industry and Regulators to promote the move towards a harmonised set of GMP and regulatory guidelines by providing information and interpretation of new or updated guidance.
www.gmp-compliance.org

The European QP Association

The European Qualified Person (QP) Association was founded in 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. It currently counts more than 2,500 Qualified Persons as members.
www.qp-association.eu

Feedback from the last Conference

„The organization of the conference was great! The conference was one of the best I have been to."
- Dawn M. McCabe, Manager, Allergan

"Very interesting course and very useful for my particular duties. All presenters very knowledgeable and very friendly."
- Eva Maria Malnovicz, GMP Quality Program Manager, Takeda

"Speakers were all highly knowledgeable and engaging, with a lot of valuable and timely insights. Excellent conference".
- Bill Paulson, Editor-in-Chief, International Pharmaceutical Quality

Programme

Introduction: The ECA and the European QP Association

Part 1: Understand European GMPs

The EU Pharmaceutical GMP-/GDP Legislation & Facts on the Mutual Recognition Agreement EU-USA

- EU legal order and relevant guidelines (overview)
- EU Manufacturing Authorisation & EU-GMP Certificate
- Non-compliance with EU-GMP and authority actions
- MRA: Technical terms
- Exchange on GMP-information between US and EU
- MRA impact for industry
- Are inspections no longer required?
- Are audits no longer required?

EU-GMP/GDP Update - what's going on at the Moment

- The Current EU GMP Revisions and their consequences
- A brief look on the EU GDP requirements
- Challenges with differing FDA expectations

15 Years Development of EU GMPs and the Impact to the QP

- How things evolved
- The well-established European concept of the QP
- Future developments and the US-EU co-operation
- What EU expects from US companies

Import of Medicinal Products and APIs into the European Union

- Differences between originating countries
- Which types of materials do fall under EU import legislation?
- Regulatory requirements for import
- Which documents are needed for import activities of medicinal products and APIs
- Regulatory procedure to get an import licence to
- Procedure if a non-EU company imports to different EU Member States

The new EU Lifecycle Approach on Process Validation vs. the US-Approach

- Difference in US & EU Wording
- Comparison of validation stages – different, comparable or equal?
- Comparison US APR & EU PQR and how to synchronize
- What about Product Quality Reviews of APIs in US & EU?

Please note: The presentations of this conference will be available for download and your print-out one week before the conference.
Note: there will be no print-outs available during the conference.

Part 2: 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 Q10 and the US Quality Systems Guidance
- What the QP is responsible for
- Batch certification and release for the EU Market
- 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?

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

Annex 16 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 QP's true margin of discretion when releasing batches with deviations
- Selected examples

The role of the QP in the Supply Chain and Supplier Qualification

- QP Declaration
- Supply Chain oversight and supply chain diagram
- EU Inspections and company audits in the U.S. and the Involvement of the QP

Part 3: Clinical Trial Supplies

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

- Current and future EU-GMP and QP requirements for the release of Investigational Medicinal Products (IMPs)
- Specific aspects of IMP supply chains
- GMP-GCP Interface
- QP oversight and being a QP in a global environment

Speakers

David Cockburn
formerly EMA, U.K.
David Cockburn was Principal Scientific Administrator at the European Medicines Agency and Chair of the EMA GMP/GDP Inspectors Working Group (IWG). In his role he was also EU technical lead for the EU-US Mutual Reliance Initiative.

Dr Susanne Ding
Boehringer Ingelheim, Germany
As Qualified Person for IMPs at Boehringer Ingelheim Pharma, Susanne Ding is in charge of certifying clinic trial samples for the use in clinical studies worldwide since 2005. Prior to that she worked in Analytical Development including the responsibility as Head of Quality Control. Susanne Ding is chair of the IMP Working Group and member of the European Qualified Person Association Board of Directors.

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). He is a member of the European Qualified Person Association Board of Directors.

Dr Ulrich Kissel
European QP Association
Ulrich Kissel is Qualified Person and Member of the Board of Directors of the European Qualified Person Association (EQPA). He works as a GMP consultant and contract QP to the Pharmaceutical Industry. Previous to his current role he held leadership positions in Quality and Supply Chain and served for many years as QP for Roche.

Dr Bernd Renger
Immediate Past Chair European QP Association
Dr Bernd Renger is a member of the European Compliance Academy (ECA) Advisory Board and Immediate Past Chair of the European QP Association. Since 2011 he is running his own consultancy business. Before that he was VP of Quality Control at Vetter Pharma-Fertigung. He started his career 1977 at Hoechst AG as a research and development chemist. Since then, he has held several quality management positions at Mundipharma, Byk Gulen (now Takeda) and Baxter BioScience.

Date Conference

Tuesday 28 August 2018, 9.00am – 5.45pm
(Registration and Breakfast 8.00– 9.00am)
Wednesday 29 August 2018, 9.00am – 4.00pm
(Breakfast 8.00– 9.00am)

Venue

Hyatt Regency Chicago
151 E Wacker Dr
Chicago, Il 60601
USA
Phone: +1 (312) 565-1234
Fax: +1 (312) 239-4541

Fees Conference

Registration Fee...	ECA/EQPA Members	Non-ECA/EQPA Members	Government/ Health Authority
After 15 July 2018	US$ 1,990	US$ 2,190*	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 and lunch on both days and all refreshments.**

Accommodation

CONCEPT has reserved a limited number of rooms in the conference hotel.
You will receive a POG when you have registered for the course. Reservation should be made directly with the hotel. Early reservation is recommended.

Registration

Via the attached reservation form, by e-mail or by fax message. Or you register online at www.gmp-compliance.org.

Conference language

The official conference language will be English.

Organisation / Contact

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For questions regarding reservation, hotel, organisation etc:
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After the MRA: Understand European GMPs and the Role of the Qualified Person (QP)

August 28 – 29, 2018, Chicago, Il, USA

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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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)!

German law shall apply. Court of jurisdiction is Heidelberg.

Privacy Policy: By registering for this event, I accept the processing of my Personal Data. CONCEPT HEIDELBERG will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. CONCEPT HEIDELBERG will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at http://www.gmp-compliance.org/eca_privacy.html). I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.