ECA ACADEMY

QP ASSOCIATION

The new GDP and Track & Trace Regulations in Europe

Jersey City, NJ (New York City Metro Area), USA – July 14-15, 2015

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

Speakers

Dr Susanne Ding
Boehringer Ingelheim, Germany

Tor Gråberg
Medical Products Agency, Sweden

Ian Holloway
Medicines & Healthcare Products Regulatory Agency (MHRA), U.K.

Afshin Hosseiny, Ph.D.
Tabriz Consulting Ltd., U.K.

Ann McGee,
Form. Irish Medicines Board, Ireland

Highlights:

The Distribution Chain to the EU and within the EU

The new EU Directive on Falsified Medicines (2001/83/EC)
- Content and Consequences
- The need for changing the Secondary Packaging
- Track & Trace

The new EU Guidelines on GDP
- Impact for the global Pharmaceutical Industry
- Qualified Person vs. Responsible Person
- How to deal with it

Plus:
- The Authority's Point of View
- Distribution of Clinical Trial Material

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Objective

The aim of this conference is to inform about the latest requirements when it comes to distribution of medicinal products to and within the European Union (EU). Challenges and possible solutions will be discussed and examples will demonstrate how the new European requirements can be put into practice.

Background

The globalisation of the pharmaceutical supply chain has created new challenges for manufacture and supply of medicinal products in various markets, resulting in reduced control and increased security risk to the products.

The **EU Directives and GDP Guidelines** have been extensively revised to take into account the changing nature of the globalised supply chain.

The new **EU GDP Guidelines have been effective since 2013 (2013/C343/01)**. These requirements highlight the need for an effective quality management system supported by risk assessment and appropriate controls in the distribution chain. Do you think you are compliant with the new requirements?

In 2014, **PIC/S** published their Guide to Good Distribution Practice for Medicinal Products (PE 011-1), adapting the EU GDP Guidelines for PIC/S purposes.

Already in 2011, the European Commission published Directive 2011/62/EC, the so called Falsified Medicines Directive (or FMD).The main goal is the fight against counterfeit medicines. In 2014 the technical characteristics of one key requirement were defined, the unique identifier delivering the possibility of verification of the authenticity of single folding boxes. This will be a 2D barcode (data matrix). As this **new requirement will become active in 2018**, it is time to start defining strategies for both technical implementation and change control strategy.

Target Group

Managers and Executives from companies involved in the distribution and supply of pharmaceutical products to the European Union.

Moderator

Wolfgang Schmitt
Concept Heidelberg

About the Organizers

The ECA 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 5.000 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

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. It currently counts more than 2.000 Qualified Persons as members. More information about the QP Association and a membership application form are available at www.qp-association.eu.

Please note: 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.

As a participant you will receive a Roadmap to Good Distribution Practice:
- Overview of the designated Responsibilities
- Checklist for the implementation of GDP principles

Programme

Introduction: The Distribution Chain to the EU and within the EU
- How distribution is changing: challenges and things to consider
- The Need for a GDP Working Group
- ECA's GDP Working Group
  - Goal
  - Achievements

The Authority's Point of View
- Who is responsible for maintaining product quality in the Supply Chain
- The existing international agreements and organisations linked to EU (MRAs, PIC/S, ICH, etc.)
- Marketing Authorisation Procedures
- What are Manufacturing Licence, GMP and GDP Certificate, Import Licence, CEP (what is what, how to get it)
- The GMP and GDP Inspection process (in and outside the EU)
- The PIC/S adaption of the EU GDP Guidelines

The new Directive on Falsified Medicines (2001/83/EC)
- The need to strengthen control and supervision
- What goes along with the Directive: Guidelines and Delegated Acts
- The delegated Act: Identification with the 2d matrix Code
- API requirements:
  - GMP compliance of the manufacturer
  - The written confirmation

Technical and regulatory Aspects for changing the Secondary Packaging (Barcode, Safety Features)
- Part 1: Artwork, packaging and quality control: what needs to be considered
- Part 2: Applicable EU Change Control requirements

Track & Trace
- The European Stakeholder Model (ESM) and the European Medicines Verification System (EMVS),
- Experiences made with the pilot programme in Sweden
- Anti-Counterfeiting provisions from company to patient and Identification with the 2d matrix Code – what the future will bring
- Other systems: EDQM Anti-counterfeiting Traceability Service for Medicines (eTACT), Aegate

Some Practical Concerns from the EU Inspectorates
- The EU inspection process
- Links and communications between US and EU partners
- Security in the supply-chain (examples of crime, tampering etc.) and ways to reduce risks
- What does an EU regulator/ inspector expect from both, the US based company and the EU branch when it comes to GDP and Track&Trace
- What could be an adequate Change Control Strategy?

The new EU Guidelines on GDP an their Impact for the global Pharmaceutical Industry
- Background to development and revision of the new EU GDP Guidelines
- Well-known or new: a summary of the most important changes
- What is the impact on industry and other stakeholders?

The new EU Guidelines on GDP in Practice
- How to plan and implement a programme to meet compliance with the current requirements (from gap analysis to implementation)
- How to develop and implement a GDP-compliant and cost effective transportation network
- Qualification of suppliers and customers
- How to develop and manage contracts and agreements
- Training of personnel involved in the supply chain

Qualified Person vs. Responsible Person
- Who needs a Responsible Person (RP)?
- Who needs a Qualified Person (QP)?
- The Qualified Person: why to certify the batch again?
- The new role of the Responsible Person
- QP and RP: where does the responsibility start, where does it end?

Case Study: IMP distribution
- How the new regulations impact IMP distribution
- IMP shipments into the EU from other countries
- Global comparator sourcing
- Control of distribution centres

Speakers

Dr Susanne Ding
Boehringer Ingelheim, Germany
As Qualified Person for IMPs at Boehringer Ingelheim Pharma, Susanne Ding has been in charge of releasing clinic trial samples for the use in clinical studies worldwide since 2005. Prior to that she worked in Analytical Development and as Head of Quality Control. Susanne Ding is Chair of the IMP Working Group of the European QP Association.

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 - 2011 he was Chairman of PIC/S (Pharmaceutical Inspection Co-operation Scheme). Mr. Gråberg is the current chair of the Sub-committee of Communication within PIC/S as well as the Swedish representative within the PIC/S committee.

Ian Holloway
Medicines & Healthcare Products Regulatory Agency (MHRA), U.K.
Ian Holloway is a GMP and GDP Inspector at the Medicines & Healthcare Products Regulatory Agency. Before that he was Head of the Defective Medicines Report Centre at MHRA.

Afshin Hosseiny, Ph.D.
Tabriz Consulting Ltd., U.K.
Dr Afshin Hosseiny is Managing Director of Tabriz Consulting Ltd and Qualified Person. Before working as a consultant, he was Director of Quality Assurance for the Global Supply Network of GlaxoSmithKline. He is Chairman of the ECA GDP Working Group.

Ann McGee
McGee Pharma International, form. Senior Inspector of the Irish Medicines Board
Ann McGee has extensive experience both in the pharmaceutical industry and as a regulator. She is a former Senior Inspector of the Irish Medicines Board (now called Irish Health Products Regulatory Authority – HPRA), Chief Executive of the Pharmaceutical Society of Ireland and Deputy Chair of PIC/S. Ann McGee also has many years "hands-on" experience in industry.

Date Conference
Tuesday July 14, 2015, 9.00am – 5.30pm
(Registration and breakfast 8.30am – 9.00am)
Wednesday July 15, 2015, 9.00am – 3.30pm
(Breakfast 8.30am)

Venue
Hyatt Regency Jersey City
Two Exchange Place
Jersey City, NJ 07302-US
Tel.: +1 201 469 4750
Fax:+1 469 4560

The hotel is located on the Hudson River with a view to the Manhattan skyline. It is located near easy transportation and just minutes from New York by ferry or the PATH train.
From LaGuardia Airport: 14 miles
From Newark Airport: 12 miles

Fees Conference

	ECA Members	Non-ECA Members	Government/ Health Authority
Before 31 March 2015	US$ 1,690	US$ 1,890*	US$ 750
31 March - 15 May 2015	US$ 1,890	US$ 2,100*	US$ 1,990
After 15 May 2015	US$ 1,990	US$ 2,200*	US$ 1,990

* 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, breakfast and 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@gmp-compliance.org or by fax to +49 (0) 6221 / 84 44 34 . Or you register online at www.gmp-compliance.org.

Conference language
The official conference language will be English.

Organisation / Contact
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P.O. Box 10 17 64
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Mr Wolfgang Schmitt (Operations Director) at +49 (0)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.

Easy Registration

Reservation Form:
CONCEPT HEIDELBERG
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Germany

Reservation Form:
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e-mail:
info@gmp-compliance.org

Internet:
www.gmp-compliance.org

The new GDP and Track & Trace Regulations in Europe

July 14-15, 2015, Jersey City, NJ (New York City Metro Area)

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 and conditions

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 weeks 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 HEIDELBERGwill 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)!

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.