ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified GDP Compliance Manager

Speakers

Prabjeet Dulai
form. U.K. Ministry of Defence

Heike Gottschalg
Boehringer Ingelheim, Germany

Isabelle Herre
GDP Inspectorate, Germany

Dr Afshin Hosseiny
Chairman of the European GDP Association.

Alfred Hunt
form. Irish Health Products Regulatory Authority (HPRA) and key member of the EMA drafting group for the revised EU-GDP Guidelines

Savvas Koulouridas
Fagron BV, Netherlands

Robert Müller
Boehringer Ingelheim, Germany

Supported by the
European GDP Association

ECA GDP ASSOCIATION
An ECA Foundation Interest Group

The GDP Compliance Manager

Recorded Online Training

Live Q&A session after each presentation

Highlights

- Expectations of the Inspectorates
- Gap Analysis and Risk Assessment
- Implementation Planning
- Key Areas of the new Regulations:
  - Quality Management and Organisation
  - Deviations and Complaints
  - Premises and Equipment
  - Personnel
  - Supplier Selection and Qualification
  - Transport
  - Contracting

All participants will receive a Roadmap to Good Distribution Practice:
- Overview of the designated responsibilities
- Checklist for the implementation of GDP principles

Programme

Objectives

This two-day Live Online Training on 6/7 October 2020 provides practical guidance to bring and keep your organisation in compliance with the GDP regulations.

Background

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

The **EU-GDP Guidelines** have been extensively revised to take into account the changing nature of the globalised supply chain. The new requirements have been effective since 2013. These requirements highlight the need for an effective quality management system supported by risk assessment and appropriate controls.

This two-day Live Online Training has been designed to bring you up-to-date with the current regulatory expectations and standards for Good Distribution Practice (GDP) and to provide you with **tools and guidance** to help you with identifying the gaps in your quality systems and **planning and implementing the actions required**.

Target Audience

GDP Compliance Managers and Responsible Persons from companies involved in the distribution and supply of medicinal products.

Moderator

Dr Markus Funk
CONCEPT HEIDELBERG (on behalf of ECA)

Programme

Welcome and Introduction

Introduction to the Course

The new GDP Guidelines: What is it all about?

- Background to development and revision of the new EU GDP Guidelines
- Well-known or new: A summary of the most important changes
- A look into the crystal ball: What is the impact on industry and other stakeholders?

Quality Management System (QMS)

- What is a QMS and why do we need it?
- What does an effective QMS look like?
- How to develop and implement an effective QMS

Operations

- Qualification of suppliers and customers
- Receipt, storage and return of medicinal products
- Deviation and Complaint Management in a wholesaler facility
- How to conduct a gap analysis, develop plans and implement the new requirements

GDP Inspection Findings and what to learn from them

- Findings and their ratings
- Examples from manufacturers, wholesalers, storage facilities and transport deviations

Case Study for a Successful Implementation Approach

- How we approached the new requirements
- Challenges and best practice

Premises & Equipment

- What is a must for medicinal products
- How to plan and implement facility improvement ensuring compliance with the current requirements

Transportation

- Key requirements for transportation of medicines
- How to develop and implement a GDP-compliant and cost effective transportation network.

Contracts in the Global Supply Chain

- International laws and systems – how they work and fit together
- Jurisdictions and conflict of law provisions
- Contract law, Technical/ Quality Agreement, Supply Agreement
- 3PL Providers: two bilateral agreements or one tripartite agreement?
- When things go wrong

Outsourced Activities

- What is an outsourced activity?
- How to set priorities to audit, approve and manage service providers
- How to develop and manage contracts and agreements

Personnel

- Competency requirements for GDP personnel
- Overview of the role and responsibilities of the Responsible Person
- Necessary documentation
- Training matrix and managing continuous training

Short Summary and Take Away Message

- Developing a take home action plan for the delegates

About the GDP Association:

The European GDP Association aims to support Pharmaceutical Industry, Authorities and Logistic Providers with regard to the implementation of Good Distribution Practice.

More information at: www.good-distribution-practice-group.org

Speakers

Prabjeet Dulai
GDP & Quality Matters Ltd.

Prabjeet Dulai is a Consultant Responsible Person at GDP & Quality Matters Ltd. Before working as a consultant she was the RP and Senior Supply Chain Pharmacist for the UK Ministry of Defence, and prior to this worked as a Pharmacist within the NHS/private hospital sector, retail and pharmaceutical industry.

Heike Gottschalg
Boehringer Ingelheim Pharma GmbH & Co. KG

Heike Gottschalg is responsible for the Quality Oversight and Compliance for logistics from a global perspective in the Corporate Division Quality within Boehringer Ingelheim. Before that she has been responsible for the global implementation of the GDP requirements within Boehringer Ingelheim.

Isabelle Herre
GDP Inspectorate, Local Authorities
Schleswig-Holstein, Germany

Isabelle Herre is a Pharmacist and GDP Inspector at the Local Inspectorate in Schleswig-Holstein.

Afshin Hosseiny, Ph.D.
Chairman of the European GDP Association.

Dr Afshin Hosseiny is Chairman of the European GDP Association and Chair of the ECA Executive Board. Besides that, he is Managing Director of Tabriz Consulting Ltd and a Qualified Person. Before working as a consultant, he was Director of Quality Assurance for the Global Supply Network of GlaxoSmithKline.

Alfred Hunt
PharmaLex Ireland, form. Irish Health Products Regulatory Authority (HPRA)

Alfred Hunt is a consultant for PharmaLex. From 2008 until 2015 he was an Inspector with the Health Products Regulatory Authority (HPRA), formerly the Irish Medicines Board (IMB). He was also key member of the European Medicines Agency (EMA) drafting group which developed the revised EU GDP Guidelines (2013/C 343/01).

Savvas Koulouridas
Fagron BV, Netherlands

Savvas Koulouridas is Global Innovation Director of Fagron. He is leading the innovation and global marketing department of the company. He is a lawyer in profession and has also worked as a consultant on pharmaceutical law (GMP regulations and Pharmaceutical Contracts).

Robert Müller
Boehringer Ingelheim Pharma GmbH & Co. KG

Robert Müller is responsible for maintaining global standards for shipping and temperature monitoring in the Global Logistics group (Corporate Division Supply Network & Lifecycle Management). In collaboration with the colleagues of the Global Quality group he has been responsible for the global implementation of the GDP requirements within Boehringer Ingelheim.

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Reservation Form (Please complete in full)

The GDP Compliance Manager, Recoded Online Training

Title, first name, surname

Department | Company

Important: Please indicate your company's VAT ID Number | Purchase Order Number, if applicable

City | ZIP Code | Country

Phone / Fax

E-Mail (Please fill in)

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In case you do not appear at the event without having informed us, you will have to pay the full registration fee, even if you have not made the payment yet. Only after we have received your payment, you are entitled to participate in the conference (receipt of payment will not be confirmed)! (As of January 2012).
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 https://www.gmp-compliance.org/privacy-policy). 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.

Recorded Online Training from 06/07 OCtober 2020

The total length of this recording is approx. 9 h 20 min. With your registration confirmation for this re-corded version you will receive a link and the login. This login will be open for two days, in which you are free to watch the recorded version. Together with the link and login you will also receive the PDFs of all presentations. Please note that you will not need to install any additional software – the recording can be watched on any browser.

Fees (per delegate, plus VAT)

ECA Members € 1,790
European GDP Association Members € 1,790
APIC Members € 1,890
Non-ECA Members € 1,990
EU GMP Inspectorates € 995
The conference fee is payable in advance after receipt of invoice.

Registration

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

Certificate

Each participant will receive a certificate of participation at the end of the access period.

Conference language

The official conference language will be English.

Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this event.
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