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

Live Online Training on 06/07 October 2020

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

Day 1 – Tuesday, 06 October 2020

09.00 – 09.15 h
Welcome and Introduction

09.15 – 09.30 h
Introduction to the Course

09.30 – 10.15 h
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?

10.15 – 10.30 h
Break

10.30 – 11.45 h
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

11.45 – 12.00 h
Break

12.00 – 13.15 h
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

13.15 – 14.00 h
Lunch Break

14.00 – 14.45 h
GDP Inspection Findings and what to learn from them

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

14.45 – 15.00 h
Break

15.00 – 16.00 h
Case Study for a Successful Implementation Approach

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

16.00 – 16.30 h
Additional Time for Question & Answers

Day 2 – Wednesday, 07 October 2020

09.00 – 10.15 h
Premises & Equipment

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

10.15 – 10.30 h
Break

10.30 – 11.45 h
Transportation

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

11.45 – 12.00 h
Break

12.00 – 13.00 h
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

13.00 – 13.45 h
Lunch Break

13.45 - 15.00 h
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

15.00 – 15.15 h
Break

15.15 – 16.15 h
Personnel

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

16.15 – 16.30 h
Short Summary and Take Away Message

- Developing a take home action plan for the delegates

Q&A sessions after each presentation ensure interaction and that your questions are answered.

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, Live Online Training on 06/07 October 2020

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)

General terms and conditions
If you cannot attend the conference you have two options:
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Date of the Live Online Training

Tuesday, 06 October 2020, 09.00 h – 16.30 h CEST
Wednesday, 07 October 2020, 09.00 h – 16.30 h CEST

Technical Requirements

For our webinars, we use Cisco WebEx, one of the leading suppliers of online meetings.
At http://www.webex.com/test-meeting.html you can check if your system meets the necessary requirements for the participation at a WebEx meeting and at the same time install the necessary plug-in. Please just enter your name and email address for the test. If the installation is not possible because of your rights for the computer system, please contact your IT department. WebEx is a standard nowadays and the necessary installation is fast and easy.

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.

Presentations/Certificate

The presentations will be made available to you prior to the Live Online Training as PDF files. After the event, you will automatically receive your certificate of participation.

Conference language

The official conference language will be English.

Ordering a Recording

Independent from the Live Online Training, you can also order a recording of this training at the same conditions. This recording will be provided on our media server. All you need to watch it is an Internet browser – no additional software. YYou can order the recording of the Live Online Training at the earliest 10 days after the live performance at https://www.gmp-compliance.org/gmp-webinars/recorded-gmp-webinars.

Organisation and Contact

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