ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified GDP Compliance Manager

Speakers

David Abraham
Quality Resource Solutions Associates, UK

Prabjeet Dulai
GDP & Quality Matters, UK

Heike Gottschalg
Boehringer Ingelheim, Germany

Isabelle Herre
GDP Inspectorate, Germany

Alfred Hunt
Hunt Pharma Solutions, Ireland

Savvas Koulouridas
Fagron BV, Netherlands

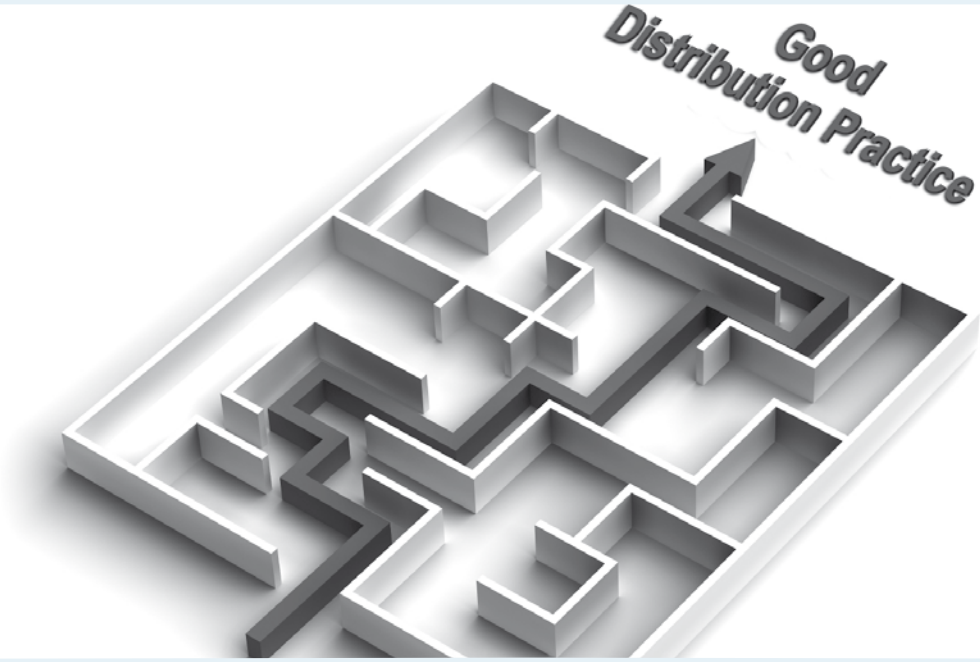
Robert Müller
Boehringer Ingelheim, Germany

Supported by the
European GDP Association

ECA GDP ASSOCIATION
An ECA Foundation Interest Group

The GDP Compliance Manager

Live Online Training on 11/12 October 2022



Highlights

- Expectations of the Inspectorates
- Gap Analysis and Risk Assessment
- Implementation Planning
- Key Areas of the EU-GDP Guidelines:
  - Quality Management and Organisation
  - Deviations and Complaints
  - Premises and Equipment
  - Personnel
  - Supplier Selection and Qualification
  - Transport
  - Contracting
- 4 Q&A sessions

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

Objectives

This Live Online Training 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)

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

Programme

Day 1 – Tuesday, 11 October 2022

Welcome and Introduction

The 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

Questions & Answers Session I

GDP Inspection Findings and what to learn from them

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

Personnel

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

Questions & Answers Session II

Day 2 – Wednesday, 12 October 2022

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

Questions & Answers Session III

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

Case Study for a successful Implementation Approach

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

Short Summary and Take Away Message

- Developing a take home action plan for the delegates

Questions & Answers Session IV

The four Q&A sessions ensure interaction and that your questions are answered.

Speakers

David Abraham, Quality Resource Solutions Associates, UK

David has extensive experience in both business and Quality Management. David's background has seen him working within Pharmaceutical and Healthcare arena from print and packaging, distribution as well as pharmaceutical manufacturing organizations. His work continues to see his engagement across the industry, supply chain and training organisations providing resource, awareness, training and consulting in quality management and the application of GXP as well as continue to provide input on a number of technical committees at a national, European and International level.

Prabjeet Dulai, GDP & Quality Matters Ltd., UK

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, Germany

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.

Alfred Hunt, Hunt Pharma Solutions, Ireland

Alfred Hunt is a consultant. 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, Germany

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 11/12 October 2022

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:
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 %,
- Cancellation until 1 weeks prior to the conference 50 %
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Terms of payment: Payable without deductions within 10 days after receipt of invoice.
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, 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.

Date of the Live Online Training

Tuesday, 11 October 2022, 09.00 – 17.00 h CEST
Wednesday, 12 October 2022, 09.00 – 17.00 h CEST

Technical Requirements

For our Live Online Training Courses and 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 € 1,590
European GDP Association Members € 1,590
APIC Members € 1,690
Non-ECA Members € 1,790
EU GMP Inspectorates € 895
The 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 Recordings

Independent from the Live Online Training Courses, you can also order recordings of selected Live Online Training Courses at the same conditions – at www.gmp-compliance.org/on-demand-online-training/recorded-online-training-webinars. These recordings will be provided on our media server. All you need to watch it is an Internet browser – no additional software.

Organisation and Contact

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

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