20 YEARS ECA Academy
Your GMP/GDP Information Source

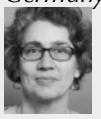
The GDP Compliance Manager

A 3-day Tutorial with practical Advice

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

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

24 – 26 September 2019, Barcelona, Spain

LEARNING OBJECTIVES:

- 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

Supported by:
European GDP Association

GDP ASSOCIATION

This education course is recognised for the ECA GMP Certification Programme „Certified GDP Compliance Manager".
Please find details at www.gmp-certification.eu

The GDP Compliance Manager

24 – 26 September 2019, Barcelona, Spain

Objectives

This education course provides practical guidance through workshops and interactive sessions 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 three day tutorial 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

Wolfgang Schmitt, Concept Heidelberg

The European GDP Association

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

It represents all stakeholders e.g. from Pharmaceutical Industry, Authorities and Logistic Providers and supports all members and stakeholders by providing them information and support in the implementation of GDP.

The Association is a not for profit organisation under the umbrella of the ECA Foundation. Membership is fee to all individuals involved in Good Distribution Practice (currently more than 2.000 members).
www.good-distribution-practice-group.org

Programme

The Inspector's Point of View

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?

GDP Inspection Findings and what to learn from them
- Findings and their ratings
- Examples from manufacturers, wholesalers, storage facilities and transport deviations

Workshops and interactive Sessions

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

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

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

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

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

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

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

Lessons learned and Action Planning

Case Study for a successful Implementation Approach

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

Summary and Take Away Message

- Developing a take home action plan for the delegates

Social Event

The ECA Academy and CONCEPT HEIDELBERG cordially invite you for a social event in the evening of the first course day. This will be an excellent opportunity to share your experiences and discuss the hot topics of the day with your colleagues and the speakers.

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.

If the bill-to-address deviates from the specifications on the right, please fill out here:

CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49 (0) 62 21/84 44 34

D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

+ 49 6221 84 44 34

The GDP Compliance Manager

24 – 26 September 2019, Barcelona, Spain

☐ Mr. ☐ Ms.

Title, first name, surname

Company Department

Important: Please indicate your company's VAT ID Number **Purchase Order No. (if applicable)**

Street/P.O. Box

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 %,
- until 1 week prior to the conference 50 %
- within 1 week prior to the conference 100 %.

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 without deductions within 10 days after receipt of invoice.
German law shall apply. Court of jurisdiction is Heidelberg.

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)

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.

Easy Registration

Reservation Form:
CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg
Germany

Reservation Form:
+ 49 6221 84 44 34

e-mail:
info@concept-heidelberg.de

Internet:
www.gmp-compliance.org

Date

Tuesday, 24 September 2019, 09.30 h – 17.30 h
(Registration and coffee 9.00 h – 09.30 h)
Wednesday, 25 September 2019, 9.00 h – 18.00 h
Thursday, 26 September 2019, 8.30 h – 15.00 h

Venue

Barcelo Sants Hotel
Pl. Països Catalans, s/n
08014 Barcelona, Spain
Phone +34 93 503 53 00
Email sants@barcelo.com

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 and includes conference documentation, dinner on the first day, lunch on all three days and all refreshments. VAT is reclaimable.

Accommodation

CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form/POG when you have registered for the event. 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 and Contact

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

CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg, Germany
Phone +49-(0)62 21/84 44-0
Fax +49-(0)62 21/84 44 34
info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content please contact:
Mr Wolfgang Schmitt (Operations Director) at
+49-(0)6221/84 44 39 or per e-mail at
w.schmitt@concept-heidelberg.de.
For questions regarding reservation, hotel, organisation etc. please contact:
Ms Nicole Bach (Organisation Manager) at
+49-(0)62 21 / 84 44 22, or per e-mail at
bach@concept-heidelberg.de.

WA/21122018