ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified GDP Compliance Manager

Speakers

Prabjeet Dulai
GDP & Quality Matters, U.K.

Dr Markus Funk
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Mag.pharm. Andreas Kraßnigg
Austrian Agency for Health and Food Safety (AGES), Austria

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Anil Rattu
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Supported by the
European GDP Association

ECA GDP ASSOCIATION
An ECA Foundation Interest Group

The GDP Audit

How to conduct and pass GDP Audits and Inspections

Live Online Training on 13/14 December 2022

Highlights

- Regulatory Requirements and Expectations
- Audit Management (from Preparation to Follow-Up)
- Typical Audit Findings
- Industry Case Examples
- Quality Oversight
- Communication in an Audit

All participants will receive:
- an SOP on Self-Inspection
- a Checklist for GDP-Compliance

Objectives

The **EU GDP Guidelines** have been extensively revised to take into account the changing nature of the globalised supply chain. One important aspect is auditing partners in the supply chain. But who needs to audit which service provider - and how? And who will be inspected by the authorities? And how can I prepare myself?

In this live online training course you will learn

- How to plan and conduct audits efficiently
- How to prepare yourself when being audited
- How to face the various challenges
- What communication techniques are needed
- How you can avoid and solve conflicts

Background

The revised GDP-Guidelines highlight the need for an **effective quality management system and appropriate controls** for all partners and service providers in the distribution chain (like manufacturers, wholesalers, warehouses and transport and logistics providers).

Qualification of these partners, like for example with audits, is a core element to implement the GDP requirements.

Initial and continuous **professional training for auditors** is of utmost importance as the authorities expect highly qualified personal performing audits. Therefore the ECA has developed the programme at hand to give you a detailed overview about important matters to consider and to discuss important tasks and challenges of GDP audits.

On the other hand you will learn how to **prepare your company to pass an inspection or customer audit and how to assure the most positive outcome.**

Target Audience

This education course is designed for all managers, supervisors and other staff members who are involved in audits of pharmaceutical storage, transportation, cold chain and distribution activities.

Moderator

Dr Markus Funk

Programme

Regulatory Part

Overview: Regulatory Requirements and Guidance

- EU-GMP Guidelines
- EU-GDP Guidelines
- Other Guides
- Who needs to audit?
- Expectations of the Authorities

Regulatory Inspections and typical GDP Deviations

- GDP inspections
  - Who will be inspected
  - Different kinds of inspections
  - Approach
  - Classification of audit findings
- Examples of frequent observations and typical audit findings:
  - Storage
  - Transport
  - Wholesalers

Audit Management Part

Part 1: Planning the Audit

- Evaluation of the distribution chain/ Risk based planning
- Audit planning and resource planning
- Auditor training and qualification

Part 2: Audit Execution

- Aide Memoire vs. Checklist (benefits and risks)
- Audit strategy during the audit
- Audit report and classification of findings

Part 3: Audit Follow-Up

- Follow-up of corrective/ preventive actions (CAPA)
- Development of Key Quality Performance Indicators (KQPI)
- CAPA efficiency evaluation in the follow-up audit

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

Practical Part

The Psychology of Audits

- Understanding why people show certain behaviour
- The challenge of appropriate communication in an audit
- When things go wrong: conflict management

GDP Audits - the Devil is in the Detail

- Learning from industry experience
- How to find and handle the real problems
- Unexpected cases - different expectations

GDP Certification to Quality Oversight beyond the Audit

- Preparation for the GDP audit
- Auditing and qualifying service providers: a look behind the scenes - what can go wrong
- Deviation management
- Beyond GDP - Staying ahead of the game for IVD/MDs Product Quality specifics

About 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 free to all individuals involved in Good Distribution Practice (currently more than 2.000 members).

www.good-distribution-practice-group.org

GMP/GDP Certification Scheme

Building on your education the ECA GMP/GDP certification programmes provide you with the appropriate supplement to acquire this qualification. This training course is the first element for your additional certification. Simply choose any three courses within the programme according to your professional interest. Your certificate is then valid for two years. To renew it, you can pick any training from the ECA courses and conferences list within that two-years period – allowing you to broaden your knowledge in GMP and GDP compliance.
Please find more information at www.gmp-certification.org

Speakers

Prabjeet Dulai
GDP & Quality Matters Ltd., U.K

Prabjeet Dulai is a Consultant Responsible Person at GDP & Quality Matters Ltd. Before that 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.

Dr Markus Funk
Concept Heidelberg GmbH, Germany

Dr Markus Funk is Director Operations at Concept Heidelberg. Before that he was Deputy Head of Quality Assurance at Lipoid GmbH in Ludwigshafen and Head of Quality Management at HWI pharma services GmbH in Rülzheim.

Mag.pharm. Andreas Kraßnigg
Austrian Agency for Health and Food Safety (AGES)

Mag.pharm. Andreas Kraßnigg is Head of Inspections at the Austrian Agency for Health and Food Safety (AGES) and the Austrian Federal Office for Safety in Health Care (BASG).

Dr Martin Melzer
gempex GmbH

Dr Martin Melzer is Principal Consultant at gempex GmbH, Germany. Before that he was consultant for GMP/ GDP aspects, GMP-Inspector in a German Field Inspectorate in Germany, QA/ QC manager at a production site for AP/ and finished products, and head of laboratory for plant medicinal products.

Anil Rattu
Roche Diagnostics Ltd, U.K.

Anil Rattu is Quality Manager, Global Distribution Quality. He leads and ensures GPD compliance of Roche's Supply Chain network of hubs, local sales affiliate warehouses and 3PL partners.

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Reservation Form (Please complete in full)

The GDP Audit
Live Online Training on 13/14 December 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 %
- Cancellation 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 HEIDELBERGwill 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.
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, 13 December 2022, 9.00 h – 15.15 h
Wednesday, 14 December 2022, 9.00 h – 15.15 h
All times mentioned are CET.

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 € 1,490
European GDP Association Members € 1,490
APIC Members € 1,590
Non-ECA Members € 1,690
EU GMP Inspectorates € 845
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 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/recordings. 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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