ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Quality Assurance Manager

Speakers

Dr Rainer Gnibl
GMP Inspector for EMA and Local Government, Germany

Dr Gerald Kindermann
formerly F. Hoffmann-La Roche, Switzerland

Dr Ágnes Kis
Compliance Consultant, formerly F. Hoffmann La-Roche, Switzerland

Dr Ulrich Kissel
European QP Association, KisselPharmaConsulting, Germany

Aidan Madden
FivePharma, Ireland

Complaint Handling and Recall Management

Live Online Training on 17/18 November 2020

How to implement EU-GMP Chapter 8 and FDA Requirements

Highlights

- Regulatory Requirements
- Complaint Handling
  - Management
  - Documentation
  - Failure Investigation
- Quality Risk Management
  - Background
  - Implementation
  - Case Study
- GMP-GVP Interface: the Role of the QP and QPPV
- Recall
  - Management
  - Mock-Recalls
  - Decision Making Process

Facing the GMP- GVP Interface: the Role of the QP and the QPPV

Programme

Objectives

During this Live Online Training, you will learn all relevant aspects to efficiently organise and improve your Complaint Handling and Recall System to **fulfil current GMP requirements and to get the best benefit for your daily business.**

Background

In principle, every complaint might cause a recall, and every complaint may provide an opportunity to improve.

According to the **EU-GMP Guide Chapter 8**, the pharmaceutical industry **must review all complaints** and other information concerning potentially defective products carefully according to written procedures. In order to provide for all contingencies, a system should be designed to investigate the need to **recall, if necessary, promptly and effectively products** known or suspected to be adulterated from the market-place.

According to the EU- GMP Guide, a person should be designated responsible for handling the complaints and deciding the measures to be taken. The **Qualified Person (QP)** together with the **Qualified Person for Pharmacovigilance (QPPV)** should be made aware of any complaint, and be actively involved in the investigation and any subsequent recall.

The handling of technical complaints (also called non-medical complaints) triggers high demands on the process organisation and quality system. However, these complaints are also a chance for **continuous improvement** and to prevent the reoccurrence of future failures.

Reviewing **FDA's Warning Letters** of the last fiscal years reveals that Complaint Handling processes are a hot topic. Recent media coverage of recalls due to non-GMP operations and counterfeit products entering the supply chain are also an indication of how important it is to treat all complaints with the highest priority. The main failures can be found in the overall process and in inadequate investigations, as the following excerpts show:

- "Your firm failed to follow procedures for the handling of all written and oral complaints"
- "The inadequacy of your firm's quality oversight is demonstrated by the failure to perform thorough investigations of product failures and complaints."
- "The QCU failed to ensure customer complaints were adequately investigated"
- "Your firm failed to review and approve complaints"

Target Audience

This Live Online Training is designed for all personnel involved in complaint handling and/ or recall activities at their company and all responsible persons like the Qualified Person / the Qualified Person for Pharmacovigilance (QPPV) and decision makers who want to improve the existing process.

Programme Day 1

09.00 - 09.15 h Welcome and Introduction

Complaint Handling Session

09.15 - 10.15 h
How to handle Complaints - Complaint Management Process

- Regulations (EU, US FDA)
- How to organize the process
- The complaint sample and sample chain custody
- Complaint investigation: Examples
- Pitfalls

10.15 - 10.30 h Break

10.30 - 11.30 h
Regulatory Requirements for Complaint Handling and Recalls - The Inspector's View

- EU Legislation on Complaints, Recalls & Falsification
- Real Intension of Complaint Handling
- Definition and Classification of Quality Defects
- Rapid Alert System - RAS
- What a Complaint Handling SOP should consider
- What a Recall SOP should consider

11.30 - 12.30 h
How to handle Complaints - Complaint Management Quality System

- Quality Metrics & KPIs
- Reporting and trend evaluation
- Technical complaints versus safety signals
- The role of the QP and QPPV
- Effectiveness of PQS

12.30 - 13.00 h Q & A Session 1

13.00 - 14.00 h Break

Quality Risk Management Session

14.00 - 15.00 h
The Basics of Quality Risk Management

- Definitions and abbreviations
- Fundamentals
- Regulatory requirements and expectations
- Areas of application
- Construction of a QRM matrix

15.00 - 16.00 h
Implementation of a Quality Risk Management System in Complaint Handling

How to use real data from global issues to determine process understanding and customer satisfaction and to set priorities.

16.00 - 16.15 h Break

16.15 - 17.00 h
Case Study
Quality Risk Management in Complaint Handling and Recall Procedures

17.00 - 17.30 h Q & A Session 2

Programme Day 2

Recall Session

09.00 - 10.00 h
The Handling of Recalls

- Implementation in the system
- The recall process
- Flow of information
- Documentation

10.00 - 10.30 h
How to perform a Mock-Recall

Both FDA and EU GMPs call for regular evaluations of the effectiveness of the recall processes. This session will show you, how such an effectiveness check could be performed.

10.30 - 10.45 h Break

10.45 - 11.30 h
A practical View: Access to the Root Cause

11.30 - 12.30 h
When to Recall or not to Recall – Apply Root Cause Analysis
A hypothetical scenario will be shown: What action needs to be taken, what information is needed, who should be involved, and ultimately - Is a recall required and if so to what level?

12.30 - 13.00 h Q & A Session 3

Participants' comments

„Good mixture between lecture and workshops."
Margit Watervall, CSL Behring, Switzerland (May 2016)

"Excellent conference – I would like to see a „Level 2" on the same subject e.g. "Level 2 advanced".
Jill Fern, Théa PHARMA S.A., Switzerland (June 2017)

Speakers

Dr Rainer Gnibl
GMP Inspector for EMA and local Government, Germany

Dr Rainer Gnibl is pharmacist and GMP Inspector for the District Government of Upper Bavaria and the EMA and performs GMP-inspections worldwide. Before that, he was working for the Bavarian Ministry of Environment and Health. Rainer Gnibl also holds a lectureship at the University Erlangen-Nürnberg.

Aidan Madden
FivePharma, Ireland

Aidan Madden is Managing Directive and Senior Consultant with FivePharma. Before that he was Quality Manager at Wyeth, Senior Microbiologist at Baxter and QC Manager at Fort Dodge Laboratories. He was also working at Teagasc, a government research laboratory and at the National University of Ireland in Galway.

Dr Gerald Kindermann
Formerly F. Hoffmann-La Roche, Switzerland

Dr Gerald Kindermann was Product Quality Manager at the Global Quality Group at Roche working on quality systems. Before that he was Group Leader Quality Control and Quality Manager for the Supply Center. Since 2019 he is working as Senior Pharma Consultant at AGIDENS AG in Switzerland.

Dr Ágnes Kis
Compliance Consultant, formerly F. Hoffmann La-Roche, Switzerland

Before starting working as a consultant in July 2018, Ágnes Kis was Global Complaint Lead Investigator and Global GMP Compliance Auditor at Roche. In a similar role, she was with Novartis Vaccines and Diagnostics. Before her industrial career, Ágnes Kis was Senior GMP/GDP Inspector for the Hungarian National Institute of Pharmacy and Nutrition (OGYÉI) and expert member in various working groups at EMA, PIC/S and the European Commission.

Dr Ulrich Kissel
European QP Association, KisselPharmaConsulting, Germany

Ulrich Kissel is Qualified Person and Member of the Board of Directors of the European Qualified Person Association (EQPA). He works as a GMP consultant and contract QP to the Pharmaceutical Industry. Previous to his current role he held leadership positions in Quality and Supply Chain and served for many years as QP for Roche.

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Reservation Form (Please complete in full)

Complaint Handling and Recall Management
Live Online Training on 17/18 November 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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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 %.

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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 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.

Date of the Live Online Training

Tuesday, 17 November 2020, 9.00 – 17.30 h
Wednesday, 18 November 2020, 9.00 – approx. 13.00 h

All times mentioned are CET.

Technical Requirements

For our webinars, we use Cisco WebEx, one of the leading suppliers of online meetings. At https://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
APIC Members € 1,690
Non-ECA Members € 1,790
EU GMP Inspectorates € 895

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.

Organisation and Contact

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

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Your Benefits

Internationally Acknowledged Certificate from ECA Academy

The EU GMP Guide requires: „... All personnel should be aware of the principles of Good Manufacturing Practice that affect them and receive initial and continuing training...." This is why you receive an acknowledged participant certificate, which lists the contents of the Live Online Training in detail and with which you document your training.