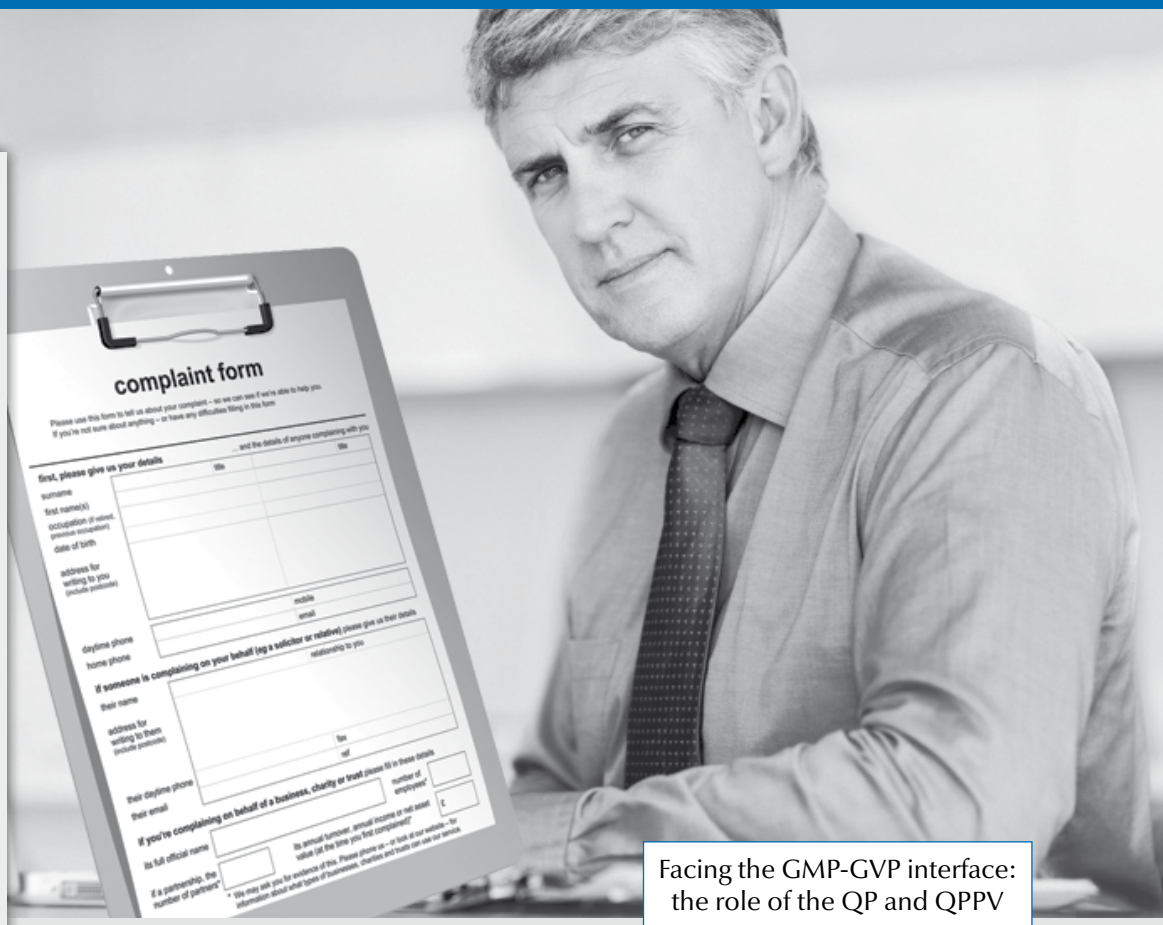
20 YEARS ECA Academy Your GMP/GDP Information Source

Complaint Handling and Recall Management

How to implement EU-GMP Chapter 8 and FDA-Requirements



Facing the GMP-GVP interface: the role of the QP and QPPV

12/13 November 2019, Vienna, Austria

SPEAKERS:

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

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

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

Dr Ulrich Kissel
European QP Association, KisselPharmaConsulting, Germany

Aidan Madden
FivePharma, Ireland

LEARNING OBJECTIVES:

- 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

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

Complaint Handling and Recall Management

12/13 November 2019, Vienna, Austria

Objectives

During this course, 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)** 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 course 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

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

Complaint Handling Session

How to handle complaints - complaint management process

- Regulations
- How to organize the process
- The complaint sample and sample chain custody
- Pitfalls

How to handle complaints - complaint management quality system

- KPIs
- Reporting and trend evaluation
- Technical complaints versus safety signals
- The role of the QP and QPPV
- Counterfeits

A practical view:
Share experience - access to the root cause

Quality Risk Management Session

The Basics of Quality Risk Management

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

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.

Workshop on Case Studies:
Quality Risk Management in Complaint Handling and Recall Procedures

Recall Session

The Handling of Recalls

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

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.

Workshop:
When to recall or not to recall – that's the question

The participants will work through a single hypothetical scenario. Working in small groups the participants will need to decide what action to take, what information is needed, who should be involved, and ultimately decide if a recall is required and if so to what level.

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.

Dr Gerald Kindermann
F. Hoffmann-La Roche Ltd., Switzerland
Dr Gerald Kindermann is 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.

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

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.

Social Event

In the evening of the first course day, you are cordially invited to a social event. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

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

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

Reservation Form (Please complete in full)

+ 49 6221 84 44 34

Complaint Handling and Recall Management
12/13 November 2019, Vienna, Austria

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Title, first name, surname

Company | Department

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

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D-69007 Heidelberg
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- until 2 weeks prior to the conference 10 %,
- until 1 weeks prior to the conference 50 %
- within 1 week prior to the conference 100 %.

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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)

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Date

Tuesday, 12 November 2019, 9.00h – 18.00h
(Registration and coffee 8.30h – 9.00h)
Wednesday, 13 November 2019, 9.00 – 15.00h

Venue

Radisson Blu
Park Royal Palace Hotel, Vienna
Schlossallee 8
1140 Vienna, Austria
Phone +43/1/89110 9 200
info.parkroyalpalace.vienna@radissonblu.com

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 and includes conference documentation, dinner on the first day, lunch on both 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

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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