Complaint Handling and Recall Management

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Speakers

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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

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

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.

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 (QP) and the Qualified Person for Pharmacovigilance (QPPV) and decision makers who want to improve the existing process.

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 – apply root cause analysis

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.

Social Event

At the end 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.

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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