Complaint Handling and Recall Management

25 - 26 March 2015, Heidelberg, Germany

SPEAKERS:

Richard M. Bonner
ECA, formerly with Eli Lilly, U.K

Dr Gerald Kindermann
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EU GMP Inspector, National Institute of Pharmacy, Hungary

LEARNING OBJECTIVES:

- Regulatory requirements
- Complaint Handling
  - Management
  - Documentation
  - Failure Investigation
- Quality Risk Management
  - Background
  - Implementation
  - Case Study
- Recall
  - Management
  - Mock-Recalls
  - Decision Making Process

ECA ACADEMY

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

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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 and decision makers who want to improve the existing process. Other parts of the organisation who may be on the receiving-end of complaints will also find the course very informative as to what to do when receiving complaints, who to involve and why it is so important to treat all complaints in a timely manner.

Programme

Regulatory requirements for Complaint Handling and Recall

- Guidelines, Regulations and Directives
- Medical and non-medical complaints
- Counterfeited medicinal products
- Recalls

Complaint Handling Session

The Handling of Complaints (Part 1)

- Implementation in GMP-System
- When do you need to involve the regulatory authorities?
- Interface to Pharmacovigilance, and the role of the QPs
- Incoming complaints, who receives them, who investigates and who approves communications and responses?
- Sample handling and storage
- What is a 3 day field alert (FDA requirement) and is this important in the EU?

The Handling of Complaints (Part 2)

- Initial documentation
- Software/ databases
- Sample evaluation
- Failure Investigation
- Why complaints can be good !!

Case Study:
Effective Root Cause Analysis and Failure Investigation

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

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

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

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.

Speakers

Richard M. Bonner

ECA, formerly with Eli Lilly, U.K.

Dick Bonner is Chairman of the ECA and the European QP Association. He also works as a consultant to the Pharmaceutical Industry. Previous to his current role he was a Senior Quality Adviser for Eli Lilly and Company. He had 31 years experience within the pharmaceutical industry working in production, technical services and both Quality Control and Quality Assurance functions.

Dr Gerald Kindermann

F. Hoffmann-La Roche Ltd., Switzerland

Dr Gerald Kindermann is Product Quality Manager at the 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.

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.

Edit Szöcs

National Institute of Pharmacy, Hungary

Edit Szöcs is GMP Inspector at the National Institute of Pharmacy, Hungary. She has over 10 years of QA experience in pharmaceutical industry. Additionally, Edit Szöcs gained expertise in manufacturing, testing and packaging of pharmaceuticals. During her time in industry, she was mainly working in Canada e.g. for Sanofi Pasteur and Abbott.

Social Event

On 25 March 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.

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

Reservation Form (Please complete in full)

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25-26 March 2015, Heidelberg, Germany

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Easy Registration

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Date

Wednesday, 25 March 2015, 9.00h – 18.00h
(Registration and coffee 8.30h – 9.00h)
Thursday, 26 March 2015, 9.00 – 15.00h

Venue

nH-Hotel Heidelberg
Bergheimer Strasse 91
69115 Heidelberg, Germany
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Heidelberg – Optimal Accessibility via Frankfurt:
Lufthansa Shuttle Bus: It leaves Frankfurt Airport approximately every 60 minutes to the Heidelberg Crowne Plaza Hotel, which is less than 1 km away from the nH-Hotel.
Info: www.lufthansa.com/de/en/Lufthansa-Airport-Bus
Airport Shuttle Service: Airport shuttle services bring you promptly and reliably from the airport to your hotel.
Info: https://www.tls-heidelberg.de/en/home/
Train: You can get on the train at the Airport Station. A train leaves up to three times per hour and it usually takes less than one hour to get to Heidelberg.

Fees (per delegate plus VAT)

ECA 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 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 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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