Complaint Handling and Recall Management

24-25 May 2016, Barcelona, Spain

SPEAKERS:

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

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

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

Aidan Madden
FivePharma, Ireland

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.

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

The Handling of Complaints (Part 1)

- Implementation into the 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

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.

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 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.

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

On 24 May 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

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

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Date

Tuesday, 24 May 2016, 9.00h – 18.00h
(Registration and coffee 8.30h – 9.00h)
Wednesday, 25 May 2016, 9.00 – 15.00h

Venue

Barceló Sants
Placa dels Paisos Catalans, s/n
Estació de Sants
08014 Barcelona, Spain
Phone +34 93 503 53 00
Fax +34 93 490 60 45

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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