

Auditing a Complaint System

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Audit Training Manual: 07

Auditing a Complaint System

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New Drug Application (NDA): Application to the US regulatory agency (FDA) to allow the sponsor to market a drug product in the US.

National Drug Code (NDC): Product identifiers for human drugs, which include a unique NDC number (US term).

Product Quality Complaint (PQC) Notification: Any report involving 1. The possible failure of a drug product to meet any of its specifications. 2. Non typical product characteristics: color, odor, embossing, labeling etc. 3. Dissatisfaction with the design of the product or the package or labeling.

Recall: A Major Quality Incident that leads to the removal of the entire affected batch or batches of material from the market, or if clinical trials, from a study.

Explanation of Topic

Introduction

Every effort is made to ensure that drug products that reach the market are safe, pure, effective and of the highest quality. However, a company may receive complaints from a patient, pharmacist or physician about a drug product not meeting its specifications. The company or site must know how to manage these complaints.

The goal of this training module is to describe how to audit a complaint system using the appropriate GMP standards.

Some of the principles outlined in this module can apply to a quality management system based on ISO 9001 or other similar systems as well as GMPs.

Overview

Although regulatory agencies do not specify a standard complaint handling system, the GMP requirements specify certain actions that shall be included in any system.

Manufacturers shall:

- Document, review, evaluate and file all complaints.
- Formally designate a unit or individual to perform these activities.
- Determine if an investigation is necessary.
- Record the reason if no investigation is made.
- Assign responsibility for deciding when not to investigate.

The site should have an approved SOP for managing complaints. It should contain the roles and responsibilities of the quality unit regarding complaints, the method for recording and retaining complaint information and the criteria for determining if the complaint should be investigated. The Quality Unit should review the complaint and the subsequent investigation or document the decision not to perform an investigation.

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- Mislabeled or Product Mix-up. This may include a package that contains two different products or a package where the drug or strength on the label does not agree with the contents of the market pack.
- Overfilled blister packet.
- Empty capsules.
- Inhaled mouthpiece of an inhaler
- Extraneous material in a sterile product
- Possible microbial contamination
- Alleged tampering
- Questionable authenticity of product
- Issue of product quality causing a patient death

Investigation of Emergency complaints must be expedited.

Adverse Event

If the complaint is categorized as an adverse drug event, the NDA holder must report the event to the FDA. In the EU the Adverse Event will be managed by the local Drug Safety Unit. All information associated with adverse drug events must be kept for 10 years. Adverse events may be related to a product quality issue. The company needs to have a process in place that ensure that potential quality defects are considered, when handling adverse events.

Medication Errors

Medication errors are any preventable events that may cause or lead to inappropriate medication use.

Causes of these errors include:

- Similar labeling or packaging.
- Similar sounding drug names.
- Poor communication.
- Ambiguities in product names, directions for use, medical abbreviations or writing.
- Poor procedures or techniques.
- Patient misuse because of poor understanding of the directions for use of the product.

Investigation

Once the status of a product quality complaint has been established, it should be investigated using the site investigation procedures. If a product defect is discovered or suspected in a batch, consideration should be given to checking other batches in order to determine whether they are also affected. In particular, other batches which may contain reworks of the defective batch should be investigated.

If Quality determines that the complaint does not need a complete investigation, the reason must be documented. The QA unit should approve the investigation reports.

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Training of Complaint Personnel

All personnel who are involved in the complaint process should be appropriately trained. This training should include investigation techniques for those personnel involved in performing investigations and other training as needed. If the contractor is responsible for receiving all POCs, then their personnel should have telephone skills and scripted questions.

Complaint Analysis

There should be a procedure that defines the process for tracking trends, the criteria for a trend and the process for investigating a trend. Complaints should be tracked and trends detected. Trending should take product, batch and defect into account.

Recalls

A product shall be recalled from the market when it has become evident that the product may cause unacceptable risk to the health of the consumer or if further sales of the product may otherwise adversely impact the company.

A person should be designated with the responsibility of executing and co-coordinating recall activities. The recall procedures shall be capable of being implemented rapidly at any time. The procedure should be updated regularly and effectiveness of arrangements checked and evaluated on a regular basis.

There should be distribution records with sufficient information to identify the wholesalers and customers with batches and quantities supplied.

The competent authorities should be informed if a manufacturer is considering action following possibly faulty manufacture, product deterioration, detection of counterfeiting or any other serious quality problems with a product.

Summary

Complaints may be received from various sources. They should be categorized, tracked and analyzed for trends. Quality should be responsible for managing complaints and investigating complaints.

Key Parameters of Auditing a Complaint System

Prior to the Audit

- Determine the site's main functions, (manufacturing, packaging, etc.).
- Request an organizational chart.
- Review the chart for appropriate separation of Quality and Production units.
- If the contractor is a manufacturing site, review the site's record for meeting complaint investigations deadlines.
- For investigations, obtain both sponsor's reference number and the contractor's number.