

Auditing a Complaint System

Goals

When you have completed this unit, you should be able to:

- Perform an internal, supplier or contractor audit of a complaint system.
- Know and understand which of the worldwide requirements apply to managing complaints.
- Use a range of information tools, including the contents of this module and the Internet in support of a complaint audit.
- Recognize compliance or non-compliance to regulations pertaining to complaints.

Definitions

Adverse Event (AE): The development of an undesirable medical condition or the deterioration of a pre-existing medical condition following or during exposure to a pharmaceutical product, whether or not considered causally related to the product. An undesirable medical condition can be symptoms (e.g. nausea, chest pain), signs (e.g. tachycardia, enlarged liver) or the abnormal results of an investigation (e.g. laboratory findings, electrocardiogram). In clinical studies an AE can include an undesirable medical condition occurring at any time, including run-in or wash-out periods, even if no study treatment has been administered.

An adverse event can also be failure of expected pharmacological action.

Complainant: The person or organization who files or notifies the manufacturing company or FDA about a complaint involving a drug product.

Demographics: Information about the complainant which could include age, address, etc.

Product Quality Complaint: All manufacturing and/or packaging-related complaints involving samples and trade products. Customer may be a patient, pharmacist, doctor or other health professional, pharmacist, wholesaler or regulatory authority. A product quality complaint (PQC) may represent a physical defect in the formulated product or its packaging, but does not include customer complaints regarding accounts, billing, transportation or shipping.

Emergency Complaint : A complaint that could represent a serious defect or non-conformity with specifications, methods and current GMP, Good Manufacturing Practice, which may lead to injury or harm to a customer. The complaint has the potential to result in a recall if justified. Investigations of emergency complaints shall be expedited.

Major Quality Incident: An event that could adversely affect the safety, identity, strength, quality or purity of a product such that it could have an actual or potential adverse impact on the health of a patient, and if the product had reached the market, may have had the potential to result in a Product Recall.

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- 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.

When the investigation is completed, the complainant may receive a letter indicating the results of the investigation. Results of the investigation should be recorded and **Corrective Actions/Preventive Actions (CAPA)**, if determined, tracked.

Retention of Complaint Files

Complaint files should be retained for 10 years.