Summary - Product Quality Complaint Handling

This Complaint Handling guidance defines practices for establishing and maintaining a product quality complaint handling system, and for monitoring and reporting corrective actions based on the findings. The investigation of complaints related to product quality provides opportunities for improvement in customer satisfaction with products and services.

The complaint handling system should make provisions for analysis of trends and effectiveness of corrective actions.

Any possible failure of a drug product to meet any of its specifications. Quality complaints may be of a routine nature, or may be determined to be a potentially serious quality complaint allegation, and will be classified as an Expedited Complaint for the purpose of accelerating the complaint investigation and submission to the appropriate regulatory agencies and/or competent authorities, if necessary.

The sample should be properly identified with the complaint file number and stored in a designated secure area. If the samples are to be returned to the customer after evaluation, or if destructive testing is to be performed, consideration should be given to photographing the properly identified sample. Once the sample is evaluated it should be stored according to procedure.

A typical Investigation Report should include the following information, as appropriate:

- Documentation of the Batch Record review
- Review of analytical records as indicated for atypical data
- Results of examination or testing of retention samples, product from stock, and/or stability samples
- Any information provided by the complainant that could aid in the investigation
- Review of lots produced before or after the subject lot
- Examination or testing of the complaint sample
- Review of the complaint database for trends pertaining to similar events, similar products, and/or similar materials.
- Documentation of any medical, legal, expert, or literature review.
- Any planned or completed corrective actions.
- Any other supportive or pertinent follow-up information for the investigation.

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