Regulatory Basis:
FDA Quality Systems Regulations

Reference: FDA CFR - Code of Federal Regulations Title 21

General Discussion
This Complaint Handling document defines practices for establishing and maintaining a product quality complaint handling system, and for monitoring and reporting corrective actions based on the findings. Regulatory agencies and cGMPs in most parts of the world require a mechanism to capture, investigate and take appropriate action with regard to customer complaints. Handling of a complaint requires evaluation, investigation, and communication of the outcome to the complainant. The investigation of complaints related to product quality provides opportunities for improvement in customer satisfaction with products and services.

In addition to handling complaints, a system for reporting adverse events should be established. Timely communication of adverse events is required by regulations and product registrations in most countries. The complaint handling system should make provisions for analysis of trends and effectiveness of corrective actions.

1. Definitions
Complaint:
Any report of dissatisfaction (written, oral or electronic) related to the identity, quality, safety or effectiveness of any product manufactured or distributed. A complaint may be classified as a product quality complaint, adverse event, or both, and must be identified as such in order to facilitate proper handling and follow up by the appropriate
group.

Product Quality Complaint:
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. Expedited Complaints include, but are not limited to: Allegations of tampering or mixed product sourced within the same manufacturing and/or packaging facility; alleged contamination; compromised integrity of a sterile product; or issues with product label causing product to be mislabeled or not properly identified. Any other issue that may represent a potential serious health risk to a patient/end-user may be deemed an Expedited Complaint.

Adverse Event:
Any sign, symptom or illness which is associated with the use of a drug or device. Adverse events which my be classified as ‘serious’ requiring expedited handling include, but are not limited to, an associated event which: results in death; is life-threatening; results in

However, each complaint is unique, and should be investigated in a manner consistent with the risk presented by the complaint, and the specifics of the situation. All the aspects listed above may not be required for a thorough investigation.

Special attention should be given to establishing whether a complaint was the result of counterfeiting. For products manufactured at a contractor facility, the responsibility for handling customer complaints needs to be defined in the contractual agreements between the parties concerned. Records and sample retention programs should also be considered in these agreements.

7. **Summary/Conclusion**
After the evaluation and investigation of the product complaint have been completed, a brief summary of the complaint should be added to the file determining, where feasible, the most probable explanation for the cause. Appropriate corrective actions and persons responsible for the execution should be documented in the file. If no corrective action is required, a statement to this effect should be included.

8. **Review and Response**
After the complaint has been summarized and the conclusions documented, the entire file should be reviewed and approved by appropriate site quality personnel. The review should be signed and dated.

Whenever possible, a response letter to the complainant with copies going to the required sales/marketing departments and any other interested parties should be prepared and sent in a timely manner. A copy of response letter should remain in complaint file.

9. **File Closure**
When all information and documentation is assembled in the file, the complaint file should be closed. Each site should have a mechanism for timely file closure included in its complaint handling procedure. Typically, routine complaints can be closed within 30 – 45 days. Those complaints which require product analysis may take up to 60 – 90 days, depending on the nature and seriousness of the complaint. Outside resources may be required to complete a thorough evaluation. If complaint analysis requires more than the specified time frame for closure, an explanation should be added to the file. Under no circumstance should a file remain open for more than the specified limit without a reasonable explanation for the delay documented in the file.

Internal audits of the complaint handling process should be conducted on a periodic basis.

10. **File Maintenance**
Complaint files (and any associated samples) should be maintained in accordance with local legal and regulatory requirements, and the site record retention policy, as appropriate.

11. **Training**
All individuals involved in the complaint handling process should be thoroughly trained in the site standard operating procedures for consistent handling of product complaints.

