

Adverse Event:

Any sign, symptom or illness which is associated with the use of a drug or device. Adverse events which may 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 hospitalization or prolongation of hospitalization; results in persistent or significant disability or incapacity; or results in congenital anomaly or birth defect

2. Complaint Handling System

All GMP manufacturing sites should establish a formalized program for the handling of customer complaints. A comprehensive complaint handling program should include the following elements:

- A written Standard Operating Procedure (SOP) for processing complaints;
- Individually numbered complaint files for each incident report received;
- When complaints are received orally, a system for documenting on the complaint form the information such that it is complete, factual and not editorial;
- Directions for handling the complaint samples in an appropriate and safe manner;
- Complete evaluation and documentation of results, including assessment of health risk, if any;
- Evaluation, documentation, and final disposition of the potential adverse event complaints.
- Review of relevant data and summary of findings to include a conclusion and/or corrective actions (with effective dates);
- Preparation of an appropriate response that includes results of the investigation;
- Review of the completed file, communication of the response to the complainant and maintaining a copy of the response in the file;
- Complaint files should be located in a designated area (accessible to the manufacturing area if kept offsite), and maintained according to the site's record retention policy.
- Complaint review and analysis for trends should be conducted and reported to senior management and affected departments (Sales, Marketing, Production, Product Development, Legal, Packaging, etc.) on a periodic basis.
- Computer systems used for report management and/or trend analysis should be validated.

In addition, the appropriate regulatory agencies and/or competent authorities should be informed, when necessary, if the site is considering action following possibly faulty manufacture, product deterioration, detection of counterfeiting or any other serious quality problems with a product.

3. Complaint Files

A complaint file should be established for any written or oral complaint received by the site. Each complaint file that is opened should be assigned a unique identifying number.