

# Standard Operating Procedure

## Title: Quality Concerns Investigation Process

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- 3.2.4. An electronic copy of the completed Investigation report is circulated to key members of the Management team upon completion.
- 3.2.5. The Investigation Report with meeting minutes, supporting documentation and agreed corrective / preventive actions assigned is targeted for completion within 30 working days from the time DR was raised, or for more complex investigations, 10 days after the close-out meeting of an on-going investigation.
- 3.2.6. As the investigation report is finalised, QA management Rep. to circulate the DR, which was raised initially, to complete the management response tasks.
- 3.2.7. In the event an Investigation is on-going, and takes longer than 30 working days to complete, minutes of on-going meetings, which include justification for production and additional actions taken should be circulated to management and maintained with the final Investigation report.
  - The hard copy file number (see section 3.4.4) of the signed Investigation Report and supporting documentation is held in the QA office for the current year, and is assigned a investigation when archived.
- 3.2.8. Follow up tasks in the DR should be assigned to a QA member, for 3 months to check on completeness of implementation, if preventive actions are not completed at the time of closeout of Investigation. In the event that the preventive actions take longer than 3 months to complete additional follow-up task may need to be assigned to track the preventive action to completion.
- 3.2.9. Upon completion of all management response tasks and preventive action follow up tasks in the DR, hardcopy deviation report is printed and filed with the Investigation Report.

### 3.3. Investigation Steps

- 3.3.1. It is the responsibility of the department, where the problem originated, to involve in the investigation in consultation with the Quality Assurance Department to ensure adequacy of the investigation.
- 3.3.2. Define the problem in detail. Include who, what, when, where and how. Briefly describe why the event is a problem. This should be a statement of facts.
- 3.3.3. Identify the probable causes. These could be raw materials, processing/operations error or problem, equipment or instrument problems, adverse environmental conditions, supporting utilities, and/or testing, analytical errors.
- 3.3.4. Investigate each probable cause. Prepare a list of questions and records needed for review. Assign and delegate the gathering of information.
- 3.3.5. Analyse the information and identify the actual or suspect cause(s). Analysis of data must be objective and logical.
- 3.3.6. Determine the extent of the problem. Is this an isolated occurrence limited to one batch or is this a recurring or potentially system related problem. Evaluate the effects on other processes, products and batches.
- 3.3.7. Propose actions and recommendations for the affected batch(s). Evaluate the following aspects of the batch:
  - Quality Aspects such as product safety and integrity, product purity and efficacy, product stability, customer perception and potential complaints.
  - Regulatory Aspects such as deviations from product registration commitments.