

Conducting Investigations

deemed unnecessary to proceed or if additional or alternate action is taken, this must be documented and agreed by those responsible for approving the original investigation conclusions and actions.

All action taken must be documented separately, or as an addendum to the original investigation report and filed with the original investigation documentation or traceable to it.

5.11 Trending/Preventive Action Monitoring

Trending of incidents, problems and deviations must take place in order to monitor that corrective and preventive actions have been effective.

Where trends identify that actions have not been effective, systems must be in place to investigate the trends, including further root cause analysis and implementation of further corrective and preventive actions. Trending and resulting investigations must be documented.

5.12 Timing

Regulatory authorities view the prioritization and conduct of investigations as well as the timely implementation of corrective and preventive actions as critical elements in a Quality System.

The timeliness of an investigation is critical. Procedures should require that investigations take place in as timely a fashion as possible. Important information and evidence related to events can be lost if investigations are delayed. This delay can have a negative impact on identification of the cause and implementation of the appropriate corrective and preventive actions. Procedures should establish priorities for investigations. For example, an out-of-specification test failure on a stability sample should take priority over other activities. Immediate action should be required for those incidents, problems or deviations of the highest priority. Those of lesser priority should be documented on discovery with an investigation commenced as soon as reasonably possible.

Investigations must be closed and a report finalized within 30 working days of discovery of the incident. If an investigation is not closed within 30 working days, an interim report must be written detailing the justification for this, including additional actions taken to ensure that ongoing studies or production is not impacted or continuing at risk. A new closing date must also be indicated.

5.13 Documentation

All elements of an investigation must be documented in a report. Appendix 2 entitled "The Investigation Report" provides recommendations for content and preparation of an investigation report.

The investigation report should include the reason for the investigation, the areas investigated, key decisions made, actions taken/to be taken, by whom and when.

Documentation should be thorough and be prepared throughout the course of an