

# Standard Operating Procedure

## Title: Cross functional investigation

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4.2.1.1 The Interim report is approved by the Quality Assurance Manager or delegate.

4.2.1.2 To track progress of the CFI report actions and recommendations and request interim reports where required.

4.2.1.3 To compile Progress reports of outstanding CFI reports, outstanding Action items and Recommendations in a Monthly Report which is sent to management and responsible persons.

### 4.2.2 Responsibility of CFI Team Leader and CFI Team

4.2.2.1 To carry out the CFI process using appropriate investigation tool and follow the DMAIC process.

4.2.2.2 To attend all CFI meetings and carry out all actions assigned to each member.

### 4.2.3 Responsibility of quality review team

4.2.3.1 To review and approve the final CFI report.

4.2.3.2 To review and assess CFI's that are greater than 90 days.

4.2.3.3 To review and assess CFI's where an assignable cause cannot be determined after investigation is complete.

4.2.3.4 To review the progress of the closure of CFI reports, actions and recommendations.

## 5.0 PROCEDURE

5.1 Quality Assurance and Compliance Manager or Delegate is responsible for recommending the initiation of a CFI when the root cause of a deviation cannot be determined, or when there is repeated trends in deviations, Customer Complaints, Annual Product Review Systems or any other Quality System.

5.2 The Quality Assurance Manager or Delegate assigns a CFI Team Leader to progress the investigation.

5.3 Use the Cause - Effect and DMAIC Process Chart to investigate. The DMAIC process gathers facts from interviewing colleagues, batch record review, complaint files, retain samples, procedures, stability data, trends in deviations or CFI's, Product Change Control, Annual Product reviews, etc. as appropriate. The investigation is extended to other batches of the same product or other products that may be associated with the specific failure or incident as required. Facts are gathered from other sites, and or outside vendors, if required.

5.4 Use the Cause - Effect Investigation Report to document the CFI process.

5.5 When potential root causes have been identified, ensure the following are addressed:

5.5.1 Impact on Product Quality, Qualifications or Validations of equipment, Systems, Processes, Analytical Methods

5.5.2 Ask questions such as: How does the problem item compare to items without the particular deviation? Does the difference in the problem item suggest a change may have occurred? How many units have the problem?

5.5.3 Other lots or products that might have been affected, are the raw materials from the same lot affected, the use of common pieces of equipment needs to be identified and considered for a similar situation.