

# Standard Operating Procedure

## Title: Deviation Report System

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- 2.1.4. In parallel with the issue of a DR, deviations in a manufacturing process must be documented directly on the batch documents at the time of occurrence through a batch comment.
- 2.1.5. DRs are required to document deviations regardless of final batch disposition. If a batch is rejected a DR is still required.
- 2.1.6. All electronic and hard copy reports, tables and other documents generated in the course of DR investigation should be linked with the report.

### 2.2. Management Responsibilities

- 2.2.1. The department manager or delegate should initiate the DR, perform an initial investigation, write a short description of the fact with a title in the table on the form and notify the Quality Assurance department within one business day to identify the investigation.
- 2.2.2. QA has to evaluate the deviation and assess the potential impact to the product quality, validation and regulatory requirement. All DRs to be approved by QA Manager or delegate. QA manager to justify wither the deviation is a Critical, Serious or Standard. For a deviation of either critical or serious nature QA delegate has to arrange a Cross Functional Investigation as described in SOP **QMS-120**.
- 2.2.3. For a standard type deviation a Cross functional Investigation (CFI) is not necessary. Management Response tasks are to be completed before the final disposition of a batch. Final batch disposition is the responsibility of Quality Assurance Department.
- 2.2.4. A Standard type deviation which does not lead to a CFI should be completed within 5 working days of initiation.
- 2.2.5. If a deviation leads to a CFI, corrective and preventive actions should be determined and follow up tasks should be assigned to area representatives. Follow up tasks should be completed within 30 business days of the observation of deviation. If a deviation with CFI can not be completed within 30 business days, an interim report should be generated detailing the reason for the delay and the progress so far. The interim report should be attached with the DR after QA review. After successful completion of the Follow up tasks DR should be completed and attached with the Batch Report (MI sheet) /Audit report/ Product complaint report /EHS investigation report as appropriate.
- 2.2.6. A CFI team should be initiated by QA if:
  - The observation is of critical or Serious in nature. (See definition above)
  - The cause of the deviation can not be determined by the department manager of the area where deviation occurred.
  - There is a probable cause based on the available evidence, but the cause is not confirmed. This is at the discretion of the QA manager.
  - A deviation demonstrates repeated trends, or there are repeated complaints.