Standard Operating Procedure

Title: Deviation Report System

Department	Quality Management		Document no	QMS-035	
Prepared by:		Date:		Supersedes:	
Checked by:		Date:		Date Issued:	
Approved by:		Date:		Review Date:	

Document Owner

Quality Assurance Manager

Affected Parties

All Site colleagues

Purpose

To define the procedures to be followed and the responsibility for raising and documenting Deviation Report (DR) where material/product or process do not comply with organization/regulatory requirements.

NOTE: The aim is to segregate product linked with a Quality concern, determine the root cause, assign Corrective Action responsibilities, and whenever possible, actions that lead to prevention.

Scope

This procedure applies to all personnel who carry out operations with the potential to impact upon product quality, Quality System requirements, safety or the environment.

This procedure relates to any material purchased by Site or supplied to Site for use in the contract manufacture for a customer. This procedure relates to any product (or intermediate) produced by Site, distributed under Site's name, or any product produced under contract for a customer.

Definition

Author	Any person identifying an issue that raises concerns with respect to quality, safety or the environment.
Non-conforming Material	Any incoming, intermediate or finished goods material, which fails to comply with the specifications or tests as defined in Site approved documents relating to that material/product.
Non-conforming Process	Deviation from the requirements of approved documentation including, procedures, policies, test methods etc, independent of material product conformity.
Reject material	Any manufactured finished good, packaging, raw material/ component or imported finished good which requires rejection, superseding or has been made obsolete
Deviation Report (DR)	Documentation system for recording, investigation and analysing material and processes that do not comply with Site requirements.
Description	Description of the occurrence that gave rise to the DR.
Follow up Tasks	Follow up tasks are raised to address the immediate concern (Corrective Actions) and where required the long-term Preventative Actions. Follow up tasks are raised to assign the persons responsible for performing the tasks.
Corrective Action	Actions intended to overcome a particular problem
EHS Hazard (Environmental Health and Safety)	An 'EHS situation' is a set of circumstances with the potential to cause an accident or environmental harm. An 'EHS incident' is a 'near miss' or a minor accident.

- The occurrence of an event and observation suggesting the existence of a real or potential quality related problems. Frequent events are identified and listed in section 1.2. of the form.

2.1.2. When a trend of deviations noticed that requires further investigation.

2.1.3. All batch production deviations (planned or unintended) covering all manufacturing facilities, equipments, operations, distribution, procedures, systems and record keeping are covered by this procedure.

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 manger 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.

If a critical or serious 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 /Safety investigation report as appropriate.

6. Numbering System of a Deviation Report

Upon receipt of the DR, QA representative should assign a unique DR number which can be in the format of DRX -YYYY where, X represents the deviation category as described in section “Major Areas Where Deviation Might Occur’. YYYY represents the DR number sequentially assigned for the unique category. i.e. DR1-0010 Batch related deviation number 10 for the year.

7. How Does QA Assess the Level of Risk from a Deviation

QA delegate has to conduct a primary Investigation on the deviation reported and evaluate the following information

- Scope of the deviation – batch affected (both in-process and previously released)
- Trends relating to (but limited to) similar products, materials, equipment and testing processes, product complaints, previous deviations, annual product reviews, and /or returned goods etc where appropriate.
- A review of similar causes.
- Potential quality impact
- Regulatory commitment impact
- Other batches potentially affected
- Market actions (i.e. recall etc)

8. Risk Matrix – An Effective way to Assess Risk

Following is simple risk matrix which can be used effectively to assess risk of a deviation. The matrix is based on two variables. On the vertical axis the variable is the impact of deviation on the product quality and GMP. The horizontal axis is based on the probability of deviation recurrence and delectability of deviation.

After the depth of the deviation is analysed QA representative has to determine wither a CFI is necessary. If the deviation is of standard type QA rep. has to send the report to the area where the deviation was observed in order to complete the management response tasks. Report should be sent in 1 business day. Area manager and his delegate has to confirm that the deviation is understood and write any urgent corrective action was made to resolve the issue. Area manager can suggest in writing any Preventative action in the follow up tasks section of the report. Deviation should be sent back to QA within two business days for QA approval.

QA Representative has to review the report and justify the corrective actions if any. Check any preventative action is necessary in the follow up task. List all corrective and preventive actions from the follow up tasks referring the DR number into a spread sheet and send the report to QA manager for approval.

QA manager should review the data for potential impact to the product quality, validation and regulatory requirement. If satisfactory approve the deviation report. The approved deviation report has to be placed in the 'Completed Deviation Report folder' if there is no corrective or preventative action necessary.

Follow up tasks should be reviewed and completed within 30 business days from the time of generation. If the tasks can not be completed within 30days, an interim report should be generated by the area manager and send to QA for approval. QA manager should justify if more time is necessary and approve or reject time extension up to 90days.

After all the follow up tasks have completed, assignee to confirm, sign and date. Send the report again to QA manger for final review and approval. Place the completed report into 'Completed Deviation Report folder' in QA Office.

10. Trending of Deviation

QA has to review all Deviation Reports from time to time and the corrective and preventative actions listed in a full year in the spread Sheet.

If a trend is identified a Cross Functional Investigation (CFI) will be initiated.

11. When does a CFI is Necessary

A Cross Functional Investigation (CFI) is necessary if:

- The observation is of critical or Serious in nature (Level 3 deviation). (See definition above)
- The cause of the deviation can not be determined by the QA or Line 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.

QA Management should organise an Investigation Meeting with all relevant parties within 5 working days of the generation of the deviation Report. Management response tasks and Follow up tasks are raised for the appropriate persons. Management response tasks are to be completed by the Area Manager where the deviation occurred and QA management after the investigation will be completed.

- Compliance Aspects such as violation of cGMPs, or deviations from revalidation / re-qualification requirements.

Develop corrective/preventive actions (CAPA); determine need for new data.

- Develop corrective actions to support affected batch or batches. Corrective actions relating to batch disposition are documented in the Management Response Tasks of the DR (i.e. confirm rejection of the batch).
- Develop preventive actions to avoid recurrence.
- Corrective and preventive actions must be monitored to completion.
- All other Corrective actions and Preventive actions are documented in the follow up tasks of the DR and monitored until completion.

Trend causes – add all the investigation outcomes including the root cause/s, corrective and preventive actions on a spreadsheet for the current year to facilitate in trending the repetitive issues.

14. Completion Period of a Deviation Report (unplanned deviation)

14.1. Print a copy of Deviation Report Form (**Form-450**). Write a short description of the fact with a title in the table on the form. Notify Quality Assurance within one business day of identifying the deviation. QA should review the DR and either approve the initiation or send back for more information. Follow the following table for prioritising different types of deviation.

Prioritising Deviation Report

Priority	Relative End Date	Priority Text	End Date Unit
Deviation Report Types 1, 5,7,8			
1	1	Very high	DAY
2	3	High	DAY
3	5	Medium	DAY
4	7	Low	DAY
Material Complaint Quality Notification (QN2)			
A	14	Raw Material Reject	DAY
B	14	Component Reject	DAY
C	14	Imported finished goods damage /reject	DAY
D	14	Finished goods Reject	DAY
EHS Deviation Report (DR2)			
1	1	Extreme Risk	DAY
2	5	High Risk	DAY
3	20	Significant Risk	DAY

16. Summary of Changes

Version #	Revision History
QMS-035	New

