

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 Sydco 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 Sydco or supplied to Sydco for use in the contract manufacture for a customer. This procedure relates to any product (or intermediate) produced by Sydco, distributed under Sydco'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 Sydco 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 Sydco 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	An 'EHS situation' is a set of circumstances with the potential to cause an accident or environmental harm.
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Procedure

1. General – Deviation Report

- 1.1. A deviation is a departure from standard procedures or specifications resulting in non-conforming material &/or processes, or where there have been unusual or unexplained events which have the potential to impact on product quality, system integrity or personal safety. For compliance to GMP and the sake of continuous improvement, these deviations are recorded in the form of Deviation Report (DR).
- 1.2. There are a number of DR examples, but not limited to, the following:
 - Production Deviation (**DR1**) – usually raised during the manufacture of a Batch Production.
 - EHS Deviation (**DR2**) – Raised due to a “EHS Hazard”. See SOP **EHS-010**. in conjunction with this SOP
 - Quality Improvement Deviation (**DR3**) – may be raised if a potential weakness has been identified, and the implementation will require project approval.
 - Audit Deviation (**DR4**) – Raised to flag non-conformance identified during internal, external, supplier or corporate audits. See SOP **QMS-080** in conjunction with this SOP.
 - Customer Service Deviation (**DR5**) – Raised to track implementation measures related to customer complaints.
 - Technical Deviation (**DR6**) – DR can be raised for validation discrepancies, MI (Manufacturing Instruction) sheet changes etc.
 - House-Keeping Deviation (**DR7**) – raised as a result of a housekeeping audit. See SOP **QMS-105** in conjunction with this SOP
 - Material Complaint (**DR8**) - raised to document any issues with regards to non-conforming, superseded or obsolete raw materials/components, packaging, or imported finished goods. See SOP **QMS-055** in conjunction with this SOP
 - System Routing Deviation (**DR9**) – raised to track changes made to BOM (Bill of materials) as a result of an Artwork change.

2. Responsibilities

2.1. All colleagues

- 2.1.1. A hard copy Deviation Report Form (**Form-450**) should be raised when there is:
 - A deviation from methods or controls specified in manufacturing documents, material control documents, standard operating procedure for products and confirmed out of specification results.
 - 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.

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3. What is Deviation

A deviation is a departure from standard procedures or specifications resulting in non-conforming material &/or processes or where there have been unusual or unexplained events which have the potential to impact on product quality, system integrity or personal safety. For compliance to GMP and the sake of continuous improvement, these deviations are recorded in the form of Deviation Report.

4. When to Report Deviation

A Deviation Report (Form-450) should be raised when there is a deviation from methods or controls specified in manufacturing documents, material control documents, standard operating procedure for products and confirmed out of specification results and from the occurrence of an event and observation suggesting the existence of a real or potential quality related problems.

A deviation should be reported if a trend is noticed that requires further investigation.

All batch production deviations (planned or unintended) covering all manufacturing facilities, equipments, operations, distribution, procedures, systems and record keeping must be reported and investigated for corrective and preventative action.

DRs are required to document deviations regardless of final batch disposition. If a batch is rejected a DR is still required.

Form: 450 An example of "Deviation Report Form"

DR Number:	DRX-YYYY	Priority	
Author (Reported by)		Date Reported	Area/Team Responsible
Deviation Type: (Describe the process or area where deviation was found)			
Deviation Title:			
Detailed Description of Deviation Found (Text include every information relating to deviation)			
Initial assessment by Quality Assurance (Text, Investigate initially the impact of the deviation on product quality)			
Management Response Tasks			
1. Area Manager Response Tasks (Describe the facts, corrective actions taken. If a preventative action is necessary list in the Follow up tasks. Sent the report to Second level management for response)			
Name:		Sign:	Date:

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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.

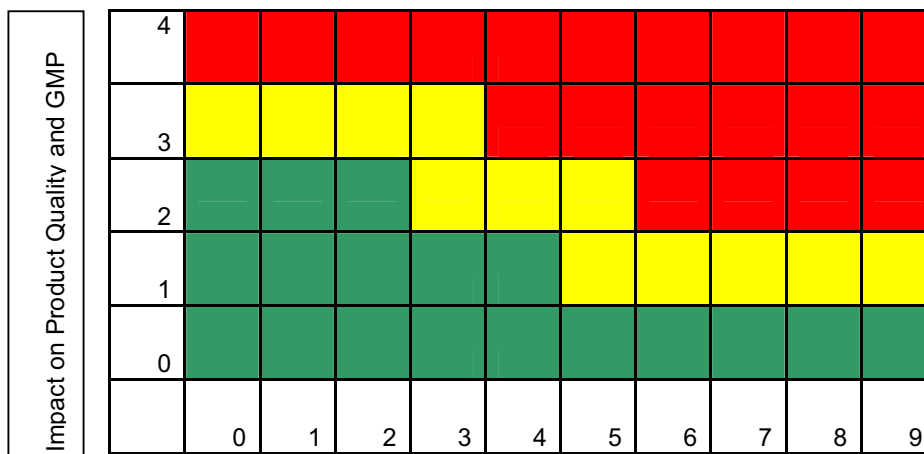
7. How Does QA Assess the Level of Risk from a Deviation

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.



Probability = Probability of recurrence + Probability of detection

Figure: 1 Risk Matrix

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9.1. An Example

For instance after an initial investigation on a deviation if QA would find the “Impact on Product Quality and GMP” scored 2, “Probability that the deviation will occur again” scored 1 and “Probability that the deviation will be detected if it will occur again” scored 2. Then, the total probability score will be 2+2 = 4.

Plotting this rating for both the variables will assess the risk as level 2 class. This example is depicted in the following figure.

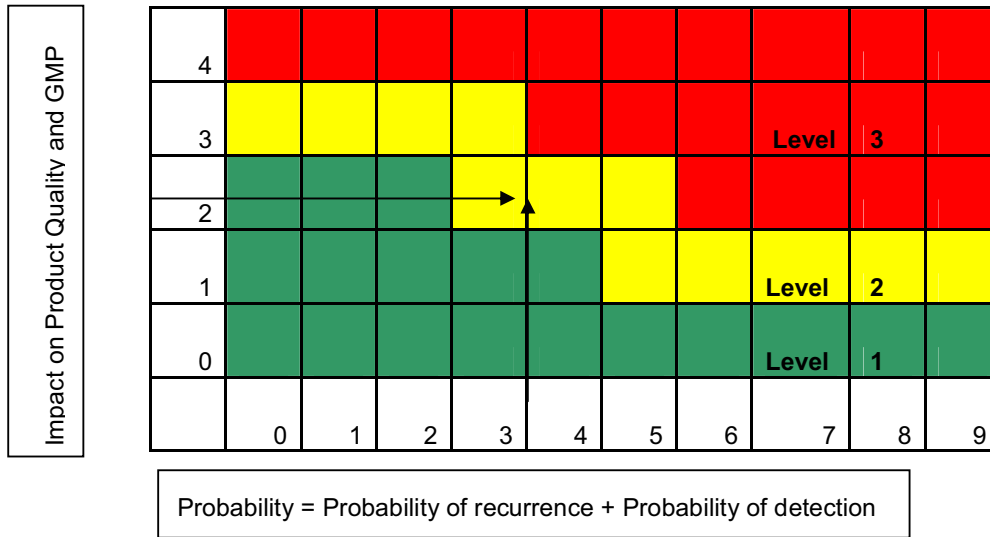


Figure: 1.2 Risk Matrix used as an example to assess deviation risk.

9.2. Next Step After Assessing Risk

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.

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Template: An example template of "Investigation Report "

Investigation Number: YY-INV-XXX

Investigation Type:

This should list the type of investigation (eg. Process Failure, Operator Error, etc.).

Executive Summary

(The executive summary should contain a brief description of the event, root cause found during the investigation and a final summary on product disposition)

Name (Position)	Signature	Date
Prepared by:		
Checked by:		
Authorised by:		
Approved by:		

Events

(Description of event and details to be added here)

Process Line(s), Product Name(s), Product Code(s) and Batch No.(s) to be added here. Initial Scope of the investigation and any immediate action/segregation/blocking of stock for sale should be listed here.

Batch Chronology

(This table is an example of events that may need to be documented in a batch investigation chronology. Table can be customised (or even omitted) to fit the sequence of events in an investigation)

Date dd/mm/yyyy	Time (24 hrs)	Description
dd/mm/yyyy	00:00	Example – Batch planned / scheduled
dd/mm/yyyy	00:00	Example – Batch commenced filling
	00:30	Example – Shipper No at time of event
	05:00	Example – Line Clearance performed after event
	06:00	Example – DR raised at this point

Suspect Causes and Rationales

No.	Cause Description	Primary / Contributing / Unlikely
1	Rationale: This is where you enter your rationale as to why a suspect cause is likely to be correct or why you have discounted this particular cause	
2		

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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.

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.

Investigate each probable cause. Prepare a list of questions and records needed for review. Assign and delegate the gathering of information.

Analyse the information and identify the actual or suspect cause(s). Analysis of data must be objective and logical.

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.

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.
- 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
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issue. Area manager can suggest in writing any Preventative action in the follow up tasks section of the report. Deviation should be send back to QA within two business days for QA approval.

- 14.5. 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 **QA metrics sheet** and send the report to QA manager for approval.
- 14.6. 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. If there are some follow up tasks to complete place the DR in the 'Incomplete Deviation Report folder' until all the follow up tasks are completed satisfactorily.
- 14.7. Follow up tasks should be reviewed and completed within 30 business days from 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.
- 14.8. 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.

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16. Summary of Changes

Version #	Revision History
QMS-035	New