**Document approval**

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# Purpose

The purpose of this Standard Operating Procedure (SOP) is to provide guidance on how to handle Deviations and Nonconformances at Company CDE.

# Scope

This SOP is valid at Company CDE for all Organization. The respective training shall be given in accordance with **SOP-10 CDE Training Management***.*

# Responsibilities

Responsible for the content of this SOP is e.g., Quality Management Director.

|  |  |
| --- | --- |
| **Role** | **Definition/Task** |
| Quality Organization | * Responsible for this SOP and management of Deviation and Nonconformance Management process
* Registers all submitted Deviation and Nonconformance Notifications
* Overseeing the investigation, as appropriate
* Ensuring appropriate actions are taken (e.g., putting product under quarantine)
* Ensuring an appropriate Root Cause analysis, as appropriate
* Determines investigators who will take part in particular investigation
 |
| e.g., Quality Management Director | * Approves Deviation and Nonconformance Investigation Report.
 |
| Department Heads / Team Leads | * Oversee their working areas and to work with Quality Organization to resolve Deviations and Nonconformances through timely and evidence-based investigation, evaluation, segregation, disposition of all affected product.
* Initiate the Deviation and Nonconformance Notification (Originator role).
* Review Deviation Reports.
 |
| Investigators | * Perform Deviation or Nonconformance investigation, analyze probable Root Cause, review investigation related data, propose CAPA measures to escalate Deviation or Nonconformance, prepare Deviation and Nonconformance Investigation Report.
 |
| Observer | * Notifies their Line Manager regarding occurred Deviation or Nonconformance.
* Provides all information related to Deviation or Nonconformance.
 |
| Originator | * Notifies Quality Organization about occurred Deviation or Nonconformance.
* Submits Deviation and Nonconformance Notification to Quality Organization.
 |

# Definitions, terms and abbreviations

|  |  |
| --- | --- |
| **Term/abbreviation** | **Definition at Company CDE** |
| Critical Deviations or Nonconformances | Serious Deviations or Nonconformances with potential implications on the product or process integrity that cannot be contained within **Company CDE.** |
| Discovery Date | The date Company CDE becomes aware of a Deviation or Nonconformance. |
| DNRN | Assigned Deviation / Nonconformance Reference Number |
| Major Deviations or Nonconformance | Process or product impact may occur, but the Deviation or Nonconformance can be controlled, and issues can be resolved within Company CDE. |
| Minor Deviations or Nonconformances | Deviations or Nonconformances from existing procedures or expectations, without serious impact on product, process, integrity, health, or safety (e.g., documentation errors like ink color or insufficient usage of ALCOA principles of data integrity. |
| Observer | Person observing any unexpected Deviation or Nonconformance from an existing process or requirement. |

# Workflow

# General

The Deviation or Nonconformance reporting process establishes a mechanism for Departments and individuals to report, correct, track/trend, and escalate Deviations or Nonconformances that occur within Company CDE.

Each Department is responsible for ensuring appropriate handling of Deviation process flow.
Deviation and Nonconformance Management process flow is described on ***Figure 1.***

***Figure 1:*** ***Deviation and Nonconformance Management Process***

Examples of Deviations and Nonconformances are given in [***Table 1***](#_bookmark7).

***Table 1: Examples of Deviations***

|  |  |
| --- | --- |
| **Functional Area / Department** | **Examples of Deviations** |
| Manufacturing | * in-process controls are out of specification
* Yield out of range
* Hold or process times out of range
* Wrong material or wrong amount (quantity or volume)
* Incompliance in the manufacturing line or equipment clearance
 |
| Laboratory / QC | * Equipment malfunction
* Calibration missing or failed
* Test record error
 |
| Labelling / Packaging | * Wrong material label or missing labels
* Unapproved packages
* No original or damaged tamper seals
 |
| Transportation | * Temperature ranges not within specification
* No dataloggers
 |
| Documentation | * Missing records (e.g., training, batch, test records)
* Failure to follow Good Documentation Practice
 |
| Facility | * Heating ventilation and conditioning system error
* Temperature excursion
* Pest control abnormalities
 |

# Discovery and Notification

Observer informs the Line Manager of any Deviation or Nonconformance discovered. All discovered unexpected events or results shall be reported to the Line Manager immediately on the day of discovery.

Line Manager verifies all available data and records related to the event. If there are sufficient grounds Line Manager (Originator) notifies Quality Organization about the event and submits appropriate records **not later than end of next working day** according to **Deviation and Nonconformance Notification Form**. Observer records all witnesses of the incident for the purpose of further investigation.

All appropriate Corrections shall be taken immediately. All appropriate segregation measures shall be taken for Nonconforming Product or Material immediately according to respective procedures.

At a minimum, the following events result in generation of **a Deviation and Nonconformance Notification record:**

* + Failure of a critical control point
	+ Nonconforming Product made available for distribution

Quality Organization representative shall verify completeness of **Deviation and Nonconformance Notification record**, register it and assign DNRN.

# Investigation

Quality Organization registers submitted **Deviation and Nonconformance Notification record**, assigns DNRN and initiates Deviation or Nonconformance investigation. Quality Organization determines and assigns Investigators who will take part in the particular investigation. Investigators may represent different Departments depending on the area of investigation and their SME’s expertise areas.

If Material or Product Conformity is in question, Quality Organization ensures that all involved Materials or Products are segregated (placed in quarantine) until the following steps occur:

* Investigation is completed to determine Conformance/Nonconformance of Product/Material.
* Final decision is made regarding product/material disposition and the decision is approved.
* Quarantine and release status are documented on the **Deviation and Nonconformance Investigation Report**.

# Major and Critical Deviations or Nonconformances

The following investigation shall be done if the Deviation or Nonconformance is classified as Major or Critical:

* + - * Perform comprehensive document review and conduct interviews with Observers.
			* Assess other potential impacted processes or products.
			* Perform a Risk Assessment according to **SOP-09 CDE Quality Risk Management**.
			* Perform Trends assessment and historical record verification for reoccurring issues.

Establish Root Cause by using **Quality Investigation and Assessment Tools Appendix**. Usual Root Causes are poor procedures, training, other systemic errors, etc. "Human Error /Personnel failure" as potential Root Cause may be suspected only in exceptions.

In case of closure timelines exceeding on critical Deviations, escalate to Leadership Team.

# Minor Deviations or Nonconformances

For Minor Deviations or Nonconformances a minimal investigation and appropriate Corrections are required.

# Reporting and Closure

Investigators record the progress of the Investigation and its results in the **Deviation and Nonconformance Investigation Report**. Investigators propose and initiate appropriate suitable CAPA measures for at least Major and Critical Deviations or Nonconformances according to **SOP-07 CDE CAPA Management**.
The final disposition of Nonconforming Product or Material shall be clearly stated in the **Deviation and Nonconformance Investigation Report.**

Departments/Heads or Team/Leads review the **Deviation and Nonconformance Investigation Report** than e.g., Quality Management Director approves the **Deviation and Nonconformance Investigation Report**.

Deviation or Nonconformance Closure is expected within thirty (30) days.

# Escalation

If necessary, Investigators can escalate any Deviations or Nonconformances by informing Department Heads /Team Leads, for example:

* + - * unfavorable trends (e.g., multiple Minor Deviations / Quality Defects on the same issue),
			* Minor Deviation or Nonconformance or group of similar Minor Deviations or Nonconformances.

# Documentation

Quality Organization keeps all approved **Deviation and Nonconformance Notifications, Deviation and Nonconformance Investigation Reports**. Quality Organization timely compiles and updates **Deviations and Nonconformances Tracker.**

The following Deviations and Nonconformances numbering principle applies:

**DNRN/YY/NN**, where **YY** means the year, **NN** means the serial subsequent number (begins with 01 annually).

# Deviations and Nonconformances Metrics

Quality Organization reports Deviation and Nonconformance Management metrics and trends to Company CDE Leadership Team as part of the Management Review process in accordance with
**SOP-04 CDE Management Review.**

# Applicable documents

MD-01 CDE Quality Manual

SOP-01 (CDE) Documentation Management

SOP-10 CDE Training Management

SOP-07 CDE CAPA Management

SOP-04 CDE Management Review

SOP-09 CDE Quality Risk Management

# Appendices

The following appendix(ces) is/are integral part of this SOP: Appendix Deviation and Nonconformance Notification Form

Appendix Deviation and Nonconformance Investigation Report Form

Appendix Quality Investigation and Assessment Tools Appendix

Appendix Deviations and Nonconformances Tracker Form

# Document revision history

|  |  |  |  |
| --- | --- | --- | --- |
| **Version** | **Valid from** | **Description of the revision** | **Reason for the revision** |
| 1 | See header | Document created | QMS implementation |