# non-conformance management

## Purpose & SCOPE

The purpose of this standard operating procedure is to describe the procedures and responsibilities for the management of non-conformances and deviations (planned and unplanned) by *(Insert manufacturer’s name)*. This procedure relates to non-conforming products, materials, processes, procedures (documentation), environment, facility and equipment.

## Responsibilities

The responsibilities of the Quality Manager, Quality Coordinator and Facility Director for the Compliance Management system are documented in *Quality Management.*

Specific non-conformance responsibilities:

* Quality Management staff, the Facility Director, the Scientist in Charge and if appropriate, the Medical Director are responsible for coordinating and actioning non-conformance procedures in a timely manner.
* The Quality Manager (or delegate) is responsible for:
* approving deviations and any actions taken
* determining the requirement for CAPA

All employees are responsible for raising non-conformance reports in any instance where a requirement is not fulfilled, segregating incoming material found to be non-conforming ad implementing the actions required to address the non-conformance, as instructed by the Facility Director and/or Scientist in Charge.

## DEFINITIONS

**Non-conformance:** Non-conformances are defined as the non-fulfilment of a specified requirement.

**Planned deviation:** A planned procedural deviation is a pre-planned change to a documented procedure which is needed to fulfil the requirements of a finished product. Such changes must not have an adverse impact on the end product.

**Adverse Event:** Any clinically significant adverse event that occurred during or immediately following administration of the therapeutic product. All aspects of the processing procedure related to the adverse event or unexpected outcome are to be evaluated and corrective actions and/or process improvements recorded.

**Audit Non-Conformance:** Failure to comply with regulatory requirements or a failure to follow documented procedures identified during an internal audit. The non-conformance should be expressed in the words of the relevant standard or documented procedure, if possible. A deficiency identified by an external audit may be recorded on a CM to aid evaluation and monitoring.

## non-conformance Procedure

All steps of non-conformance procedures are documented using the Compliance Management module in *(Insert name of quality software application)*, refer to *(Insert name of quality software application document)* for further instructions. If *(Insert name of quality software application)* is unavailable, a *Compliance Management Form* is used to manually record the relevant information. The information is then transferred the *(Insert name of quality software application)* as soon as possible.

### Identify Non-conformance

Products, materials, processes, procedures (documentation), environment, facility or equipment may be identified as non-conforming at any stage. Material non-conformance is generally identified at incoming inspection. Product non-conformance is generally identified at incoming inspection or during the production cycle. Process and documentation are most likely to be identified as non-conforming during the implementation procedure.

Once a non-conformance is identified, immediately notify the Quality Manager (or delegate).

### Quarantine Product/Material

Quarantine non-conforming materials and products (where possible) whilst the non-conformance is being investigated. Identify quarantined items by the addition of a hold sticker or by placement within a designated quarantine area.

### Initiate Non-conformance Report

Initiate a Non-conformance report using the Compliance Management module in *(Insert name of quality software application)*, refer to *(Insert name of quality software application document)*. Any staff member may initiate a non-conformance report. Record the following information:

* Date of non-conformance
* Originator’s name
* Source (e.g. Adverse Event, Audit (internal/external), Customer Feedback, Planned Deviation, Internal, Recall, Safety Suggestion or Supplier)
* Category (e.g. Computing, Documentation, Equipment, Material, Personnel Management, Processing, Record, Testing)
* Process (e.g. Collection/Receival, Facility Management, Manufacturing, Process Controls, Quality Management)
* Product (e.g. HPC)
* Description of the non-conformance

### Implement Immediate Corrective Action

The Quality Manager is to review the information, and consult with the Facility Director and/or Scientist in Charge to determine any immediate actions to be taken.

The following actions may be implemented:

* Use as is (exceptional release required)
* Discard
* Reprocess
* Repair/service
* Return to supplier
* Review process or document
* Other

For Customer complaints the following actions are implemented:

* Acknowledge complaint with customer
* Investigate complaint
* Determine resolution
* Contact customer on outcome
* Implement resolution
* Schedule courtesy follow-up call for customer

### Determine Severity

The Quality Manager is to assess the severity of the non-conformance as critical, major or minor:

* **Critical:** a direct and adverse impact on the integrity, quality or safety of a product.
* **Major:** has the potential to affect the integrity, quality or safety of a product.
* **Minor:** does not have the potential to affect the integrity, quality or safety of a product

### Assess Implications/Impact

The Quality Manager is to consult with the Facility Manager, Scientist in Charge and, if required, the Medical Director to determine the implications of the non-conformance.

For major non-conformances, perform a risk analysis, refer to *Risk Management*.

If required, complete a *Risk Management Form*.

### Root Cause Analysis

The Quality Manger is to consult with the Facility Director, the Scientist in Charge and relevant staff members to determine the root cause(s), refer to *Root Cause Analysis*.

Where possible, categorise root causes as follows:

* Documentation
* Personnel
* Process
* System
* Workload

### Initiate CAPA (if required)

The Quality Manager is to review the non-conformance and consult with the Facility Director and/or Scientist in Charge to determine if further corrective or preventative actions are required.

Initiate CAPA procedures (refer to *Corrective & Preventative Action*)if the:

* severity of the non-conformance is classified as major
* root cause analysis investigation indicates that the non-conformance has the potential to occur again
* non-conformance raised is a repeat occurrence

1. Follow up Evaluation

The Quality Manger is to review the non-conformance and assesses the appropriateness and effectiveness of any actions taken.

1. Management Review

The *(Insert manufacturer’s name)* Management team is to review all non-conformances prior to closure, refer to *Compliance Management*.

Following management review further actions or investigations may be initiated.

1. Closure

The Quality Manger (or delegate) may close the non-conformance report upon completion of all of the above stages.

## planned deviations

Planned deviation are categorised as non-conformances, as the deviation involves a change to a documented procedure, refer to *Compliance Management*.

Follow the non-conformance procedure outlined above.

## Documents

*Compliance Management* DOC148

*Correction & Preventative Action* DOC154

*Product Review* DOC152

*Quality Software Application* DOCXX

*Quality Management* DOC50

*Risk Management* DOC53

*Root Cause Analysis* DOC156

## forms

*Compliance Management Form* FORM79

*Risk Management Form* FORM133

## Records

Maintain all non-conformance records in accordance with *Record Management* and file in the CM Report files stored in the office of the Scientist in Charge.

## Procedure History

| Revision | **Date** | **Modification** | **Approved** | **Implemented** |
| --- | --- | --- | --- | --- |
| 1.0 | *(Insert date)* | Originally drafted by (*Insert name*) | (*Insert name*) | (*Insert date*) |
| 2.0 | *(Insert date)* | Revised by (*Insert name & description of changes*) | (*Insert name*) | (*Insert date)* |