Standard Operating Procedure

Title: Corrective and Preventive Action

Department	Quality Management		Document no	QMS-175	
Title: Corrective and Preventive Action					
Prepared by:		Date:		Supersedes:	
Checked by:		Date:		Date Issued:	
Approved by:		Date:		Review Date:	

A PURPOSE

To define the process for control of non-conformance/deficiencies or quality problems that require corrective and preventive action (CAPA).

B SCOPE

The process applies to identified product, process or system non-conformities. Issues may be identified during manufacture, product reviews, recurrent deviations, customer complaints, and internal or external audits. The procedure applies to all GMP manufacturing sites.

This procedure does not apply to non-conformities identified by third-party suppliers. Corrective actions that have been identified through change control will be managed using the change control system.

C RESPONSIBILITY

1. Quality Assurance / Compliance Manager (or delegate)

- Approves or rejects proposed CAPA
- Review documented root cause and CAPA plan for approval.

2. Quality Assurance Associate

- Allocates CAPA number
- Facilitate the preparation and implementation of CAPA plans
- Track all CAPAs to completion.
- Initiates follow–up verification of completed CAPA for effectiveness check.
- File and maintain all CAPA documentation

3. Quality Assurance Associate (auditor)

- Performs follow-up verification of completed CAPA.

4. Department Manager (or delegate)

- Participate in review or respond to CAPA when requested
- Perform risk assessment if required
- Investigate potential causes of non-conformance.
- Assist in the implementation of the CAPA.

5. Personnel

- Report problems or non-conformance to QA on the CAPA form

D SAFETY AND PROCESS SPECIFIC INFORMATION *(if applicable)*

1 Safety

1.1 All safety requirements for relevant areas at any GMP facility must be followed at all times.

2.3 The QA Manager will notify the originator if a request has been rejected, providing the rationale.

2.4 The QA Associate files the rejected CAPA.

2.5 If the CAPA is approved, the QA Manager documents any immediate action required with a completion date on the CAPA form (Appendix 1).

2.6 The QA Manager determines the responsible department and notifies the Manager. This is documented on the CAPA form.

2.7 The QA Associate takes a copy of the CAPA form and enters details in the CAPA tracker.

2.8 The QA Associate will notify the originator of the CAPA regarding the outcome of their request and who will be responsible for completion.

3 Responsible Department Action

3.1 The responsible department manager (or delegate) must implement any immediate action within the timeframe stipulated on the CAPA form.

3.2 The department manager determines the root cause (QMS-140 Root Cause Analysis Investigation Procedure) and performs a risk assessment.

3.3 A corrective action plan is developed in consultation with QA to eliminate the root cause and prevent recurrence. The plan must include a date for completion.

4 CAPA implementation

4.1 The responsible department manager implements the CAPA plan within the prescribed timeframe.

4.2 Any changes to procedures or processes must be documented and recorded on the CAPA form.

4.3 Communication and training of the changes are performed and documented.

4.4 The responsible department manager (or delegate) collates all objective evidence of completion and attaches it to the CAPA form.

4.5 The CAPA form is signed and dated before being forwarded to the QA Associate.

5 CAPA Follow-up Verification

5.1 The QA Associate assesses the documentation and ensures the objective evidence is complete

5.2 The QA Associate verifies that the corrective or preventative action is effective.

5.3 If the actions are determined to be ineffective, the responsible department manager is notified, and a new plan is devised.

5.4 Once verification of effectiveness is complete, the CAPA form is signed to show completion.

5.5 The QA Associate notifies the responsible department manager and the originator.

5.6 The CAPA tracker is updated to reflect the status of the CAPA as closed.

5.7 All documentation is filed in QA records.

6 CAPA Awareness

6.1 The nature and status of CAPA are reported to site management through the monthly Site Quality Council meetings

H PROCEDURE – CAPA IDENTIFIED THROUGH EXTERNAL AUDIT

1 Tracking CAPA

1.1 The QA Associates prepare a tracking spreadsheet for all non-conformances identified in the formal audit report issued by the regulator.

1.2 The QA Manager (or delegate) convenes a meeting of all managers responsible for closure of non-conformance within 3 working days of receipt of the report.

1.3 Action plans are developed for each nonconformance and will include:

- Person responsible
- Date for completion
- Objective evidence required

1.4 The QA Manager will convene weekly meetings to ensure all non-conformances are closed within predetermined timeframes.

I REVISION HISTORY

Date	Replaces	Writer	Role	Change	Reason for change

Management Action					
Analysis of Root Cause: (if insufficient room please attach)					
If Risk Assessment is required please attach. If not required, please explain					
Corrective Action Plan		Due Date:			
Action				Responsibility	Due Date
Manager		Signature		Date	
QA Approval		Signature		Date	

Quality Assurance Follow up / Verification					
List documented evidence of CAPA implementation					
Name		Signature		Date	
Effectiveness Review					
☐ CAPA Closed					
Name		Signature		Date	

