PRISM LIFE SCDCIENCES LIMITED

SOP – Corrective & Preventive Action

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Version number	Release Date	Change Reason

This CAPA Policy is the Final, based on this submission. This policy was created by IT for PLSL. There is no prior approval taken/required as this directly relates to processing of information. If anyone would like to contribute a new policy or updated version of this policy, please send email to shibu@prismile.com. When a request for change is contemplated, the change management plan governs what steps must happen before the change is considered and before it becomes approved and implemented.

1 CONTENTS

CORRECTIVE & PREVENTIVE ACTION PLAN

MANAGEMENT APPROACH

1.1 PURPOSE/ SCOPE

To establish a system that defines the criteria and methodology for taking corrective and preventive action on identified problems or negative trends identified through analysis of quality records.

This procedure applies to internal or external concerns relating to quality, reliability, safety, or performance of any data or information. Specifically, the procedure covers action taken regarding nonconformance to any processes or set procedures, complaints, audits findings, and negative trends identified from analysis of quality.

Specific actions are not covered as part of this procedure because of the uniqueness of the issues. The corrective and preventive action for each problem/issue will be determined based upon its severity.

Problems deemed to be “critical” are verified for effectiveness upon completion. All others will be reviewed during the next internal audit of the system and/or area.

1.2 RESPONSIBILITIES

The Head of Department or the designee is responsible for establishing, implementing, and maintaining the ongoing effectiveness of the corrective action/ preventive action (CAPA) system.

All employees have the responsibility to initiate corrective/preventive action requests as it relates to their job function. Any employee can request that a CAPA be opened.

Management will assign CAPA and resources based on the severity of an incident and/or trending instruction from that process or procedure issue. The term “severity” in this procedure refers to efficacy issues. A Corrective/ Preventive Action Log will be maintained and will be reviewed during regularly scheduled management review meetings.

REFERENCES & DEFINITIONS

1.3 REFERENCES

21 CFR Part 820	Quality System Regulations
ISO 9001:2000	ISO Manual as in ITIL

1.4 DEFINITIONS

1.4.1 CORRECTIVE ACTION:

An action taken to eliminate the cause(s) of existing nonconformity's (problems) or any other undesirable situation to prevent recurrence.

1.4.2 PREVENTIVE ACTION:

An action taken to eliminate the cause(s) of potential nonconformity's (problems). Sources of information for preventive actions may include work operations, audit results, quality records, management reviews, or customer complaints.

1.4.3 REMEDIAL ACTION:

An action taken to alleviate the symptoms of existing nonconformity's or any other undesirable situation.

1.4.4 ROOT CAUSE:

A fundamental deficiency that results in a nonconformance and must be corrected to prevent recurrence of the same or similar nonconformance.

1.4.5 CORRECTIVE ACTION SEVERITY LEVEL:

This refers to the criticality of the corrective action. It will be determined by the following guidelines:

Critical-Related to safety or regulatory issue.

Major-Related to a failure of product or system but will not impact safety of the product.

Minor-Related to a cosmetic type issue.

1.4.6 8-D

This refers to the process of the 'eight steps' or disciplines followed in the identification, investigation, and resolution of CAPA

NORMS & PROCEDURES

1.5 CRITERIA FOR OPENING AND CLOSING OF CAPAS

1.5.1 OPENING OF A CAPA:

The groups below represent possible reasons for initiating a corrective/ preventive action. Corrective actions may be initiated to address any other issues where a corrective/preventive action is deemed necessary.

1.5.2 COMPLAINTS:

A CAPA can be issued to address trends involving customer complaints. The issuance of a CAPA will depend on the severity and/or frequency of the complaint.

1.5.3 NON-CONFORMANCES:

A CAPA can be issued to address repeat non-conformances or to address trends involving non-conformances. The issuance of a CAPA will depend on the severity and/or frequency of the non-conformance

1.5.4 QUALITY AUDIT FINDINGS:

Audit observations, which cannot be resolved before a response is issued to the auditor(s), will be assigned a corrective action. This CAPA will be assigned to the area that was audited. Note: A log of audit corrective actions will be maintained separately from other corrective actions.

1.5.5 SUBCONTRACTOR CONTROL:

Suppliers and subcontractors who perform (score) below acceptable levels (74.99 points) require a CAPA to address their deficiencies. This CAPA (also known as a Supplier Corrective Action Report or SCAR will be assigned to the vendor.

1.5.6 MANAGEMENT REVIEW:

During management review, the management may issue a CAPA to address a deficiency or trend identified. This CAPA will be assigned to the area that is most responsible for the deficiency or trend.

1.5.7 CLOSING OF A CAPA:

The CAPA must contain a thorough investigation and documentation for all sections of the CAPA. All data and analysis should be put in measurable terms to support the corrective action and future verifications.

1.5.8 TIME FRAMES FOR CAPAS:

A proposed due date will be agreed upon between the Management and the assignee charged with gathering the problem analysis data. A one-time extension of the proposed due date can be requested, and must be approved by Management.

1.6 PROCEDURE

1.6.1 If a CAPA is initiated, it should be documented on the Corrective Action /Preventive Action (CAPA) LOG.

The CAPA number should be located in the left side on the top of the Log.

1.6.2 To address a CAPA will be following the 8-D process.

THE 8-D process contains 8 basic steps:

- D1 - Description of Problem
- D2 - Team Members
- D3 - Containment Actions
- D4 - Root Cause Analysis and Root Cause Identification
- D5 - Corrective Action(s)
- D6 - Verification of Effectiveness
- D7 - Prevention
- D8 - Closure

1.7 DOCUMENT THE CAPA USING THE 8D STEPS AS SUITABLE AND BASED ON BEST PRACTICE

D1 - DESCRIPTION OF PROBLEM

Draft a statement describing the actual problem (issue). Include the source that identified/raised the issue to our attention; the severity of the issue; and relevant information. The description should include 'is' and 'should be' statements. Provide pictures where necessary

D2 - IDENTIFY THE TEAM

Identify the team members assigned to address the CAPA and their titles. Identify the team member responsible for completing the CAPA

D3 - CONTAINMENT ACTIONS

Identify the actions taken to isolate the issue immediately. Where possible, complete Containment Checklist (Form F-0123)

D4 - ROOT CAUSE ANALYSIS AND ROOT CAUSE IDENTIFICATION

Identify the primary reason(s) the issue occurred. Document the root cause analysis tools used such as Fish Bone Analysis. Assess each potential root cause to ascertain whether it is responsible for the failure mode.

D5 - CORRECTIVE ACTIONS

Identify corrective measure(s) to address the root cause of the issue as identified in the root cause analysis.

D6 - VERIFICATION OF EFFECTIVENESS

For each corrective action taken (6.3.5), identify how each action will be measured. Identify the indicator and acceptable criteria.

D7 - PREVENTION

Identify and establish actions to prevent issue from recurring. Prevention should address the real root cause for the issue.

D8 - CLOSURE

Document the proposed date the CAPA is targeted to be closed.

Document the actual date the CAPA is officially closed.

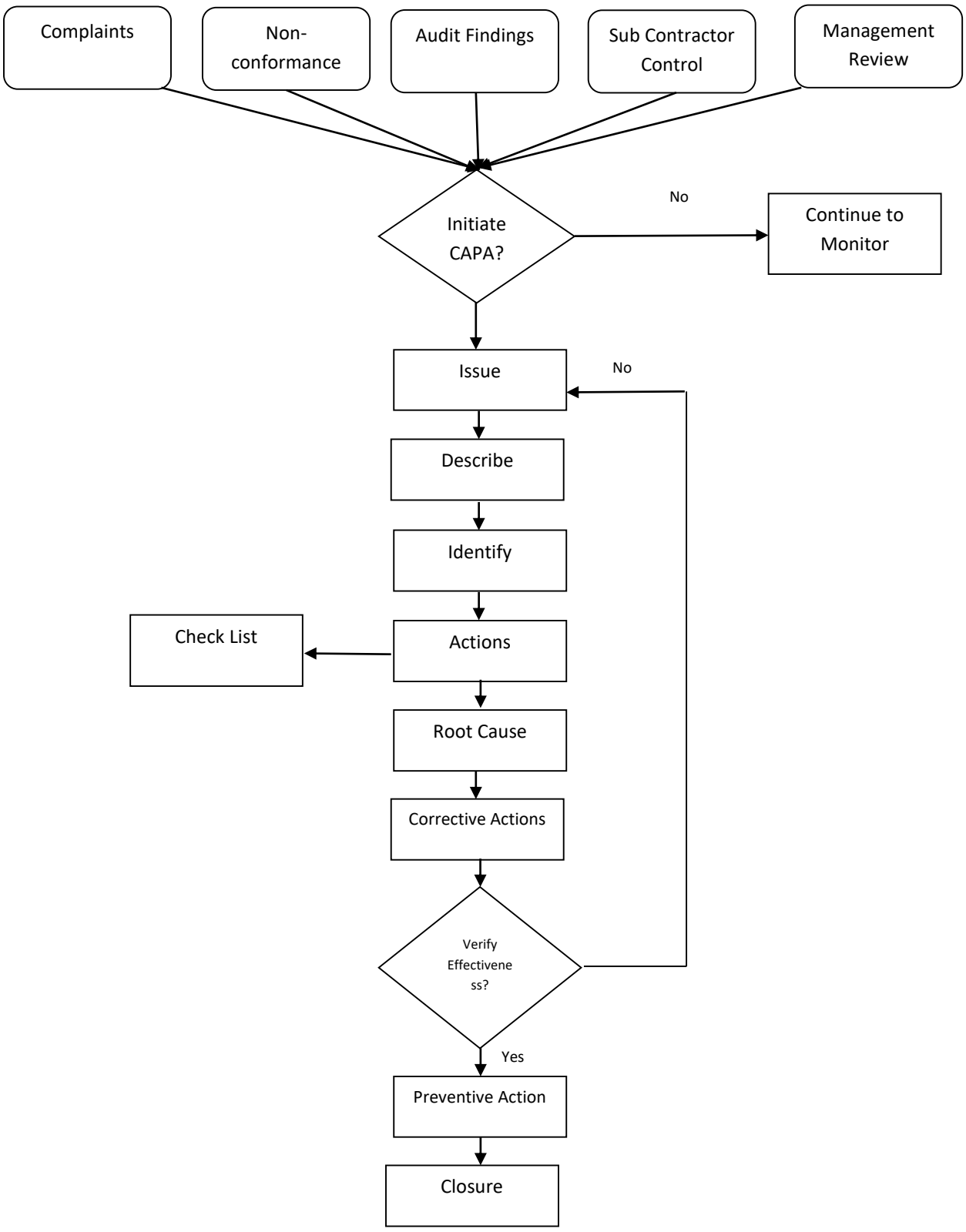
Quality Management or their designee should sign the CAPA for closure.

NOTE: The CAPA will be officially closed after verification has been performed. The verification will be within the next 3 production lots with no re-occurrence and/or 90 days after preventive actions had been implemented (whichever comes first).

IF THE REVIEW OF THE CORRECTIVE/PREVENTIVE ACTION INDICATES THAT THE CAPA WAS INEFFECTIVE, A NEW CAPA IS TO BE OPENED. THE NEW CAPA SHOULD REFERENCE THE ORIGINAL CAPA.

MANAGEMENT WILL REVIEW THE STATUS OF ALL CAPAS AND THE EFFECTIVENESS OF THE CORRECTIVE ACTION PROGRAM AT LEAST ONCE A YEAR.

FLOW CHART


Complaints
Non-conformance
Audit Findings
Sub Contractor Control
Management Review
Initiate CAPA?
No
Continue to Monitor
Issue
No
Describe
Identify
Check List
Actions
Root Cause
Corrective Actions
Verify Effectiveness?
Yes
Preventive Action
Closure

1.8 CORRECTIVE AND PREVENTIVE ACTION

<table>
<tr><td></td><td colspan="4">CORRECTIVE AND PREVENTIVE ACTION</td><td>Doc. No:
ITC_F_12_00
Issue No:01
Rev. No:00
Date:</td></tr>
<tr><td colspan="6">Identification of Problem:</td></tr>
<tr><td colspan="6">Correction/ Containment Action:</td></tr>
<tr><td colspan="6">Why-Why Analysis</td></tr>
<tr><td>Why1</td><td colspan="3"></td><td colspan="2">Ans.</td></tr>
<tr><td>Why2</td><td colspan="3"></td><td colspan="2">Ans.</td></tr>
<tr><td>Why3</td><td colspan="3"></td><td colspan="2">Ans.</td></tr>
<tr><td>Why4</td><td colspan="3"></td><td colspan="2">Ans.</td></tr>
<tr><td>Why5</td><td colspan="3"></td><td colspan="2">Ans.</td></tr>
<tr><td>RC(Root cause)</td><td colspan="5"></td></tr>
<tr><td colspan="6">Implementation of Action plan</td></tr>
<tr><td>Corrective Action</td><td></td><td>Target Date</td><td></td><td>Responsibility</td><td></td></tr>
<tr><td>Preventive Action</td><td></td><td>Target Date</td><td></td><td>Responsibility</td><td></td></tr>
<tr><td colspan="2">Verification of Implemented Action plan:</td><td colspan="3"></td><td>Sig.</td></tr>
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1.9 CORRECTIVE AND PREVENTIVE ACTION

The purpose of this change management plan is to set forth the plans and procedures for monitoring and controlling changes to the live projects, project documents and deliverables in Prism Life Sciences Limited. **No changes will be permitted unless a request for change is processed in accordance with the set procedures**.

The project Lead will assume overall responsibility for change request management. The people listed below will assume the following change request management responsibilities:

1.9.1.1.1.1 ROLES AND RESPONSIBILITIES

#	Roles	Responsibilities	Names
A	Project Lead	Overall responsibility for change request management	Atanu Bhaumik
B	HOD / Team Lead	Identifies and Asks for the concerned changes to the project scope	Hema, Ketan, Neeraj, Neeta, Prem, Rohit, Sureena [names can change as per records of HODs]
C	Department / Team Member(s)	Identifies and Asks for the concerned changes to the project scope	
D	Change Request Qualifier	Checks w.r.t other SOPs, Validates & Qualifies the CR# for approval/disapproval	(Sureena/Neeta, till such time, when Prism identifies a CRQ)
E	IT Team Lead	Maintains the CR Log and Executes the approved CR in the ERP.	Atanu Bhaumik

2 CHANGE CONTROL BOARD

The following persons are members of the change control board

Board Member Name	Role / Authority	Contact Information
Shri Shibu Kurup		

3 CHANGE CONTROL PROCESS

No change is permitted to the project scope, the project budget, the schedule or to any approved plan, document, or baseline unless a request for change is first submitted in writing and approved by the change control board, in accordance with the processes described below.

3.1 CHANGE REQUESTS

3.1.1.1.1.1 WRITTEN REQUESTS

All requests for change must be submitted in writing on the approved change request form as per the Format no **VLPL/ITM_F_01_00** (Attachment A, below)

A. Who May Submit Change Requests

The following people may initiate changes to the project:

a) Operation Team Lead
b) Operation Team Member
c)
d)

B. Deliver To

All written requests for changes must be submitted to the IT Head, who will log and track each request on the change request log as per Format no **VLPL/ITM_F_02_00** (Attachment B, below).

3.2 REVIEW AND SIZING

The Change Request Qualifier (CRQ) is responsible for analyzing the change requests for impact, on other SOPs and schedules, evaluate the risk v/s the quality of change asked. Once the sizing is complete, the CRQ will electronically submit (email) each change request to all members of the change control board.

3.3 DISPOSITION BY CHANGE CONTROL BOARD

Members of the change control board will evaluate each written change request and decide whether it becomes approved, approved with modifications, rejected or deferred. Once a

decision is reached, the change request is signed by an authorized member of the change control board and emailed to the project manager for planning revisions, communication and implementation.

3.3.1.1.1.1 APPROVED

When a change request is approved by the change control board, the IT Team Lead will track the approval on the change request log found in Attachment B, below. The IT Team Lead will also ensure implementation of the change, as it was submitted and approved.

Where implementation affects changes to the project management plan, the project Lead will revise the plan and distribute notice of the revisions.

3.3.1.1.1.2 APPROVED WITH MODIFICATIONS

When a change request is approved with modifications, the project Lead will track the modified approval on the change request log found in Attachment B, below. The project Lead will also ensure implementation of the change, as it is modified and approved.

Where implementation affects changes to the project management plan, the CRQ will revise the plan and distribute notice of the revisions.

3.3.1.1.1.3 REJECTED

When a change request is rejected, the IT Team Lead will track the rejection on the change request log found in Attachment B, below and provide written notice of the rejection to the party who initiated the change. No further action will be taken.

3.3.1.1.1.4 DEFERRED

When a change request is deferred, the project Lead will track the deferred request on the change request log found in Attachment B, below. The IT Team lead will also notify the party who initiated the change request.

No other action will be taken unless the change control board later approves, approves with modifications or rejects the change request.

4 ASSUMPTIONS

While managing change, it's possible that assumptions will be made. All assumptions regarding change are documented and added here from time to time. If need be can be referred later for all practical reasons and for further management.

Assumption	

5 ISSUES

While managing change, it's possible that issues will be encountered. All issues regarding change are documented here and then can be transferred to the Risk listed below for further mitigating the risk arising out of the issue(s).

Issues	

6 RISKS

While managing change, risks may be identified. All risks regarding change are documented here then referred for further management/mitigation of the risk.

Risks	Date Transferred to Risk Management Plan

7 PLAN APPROVAL

By signing below, I, _____ in my capacity as Project Sponsor approve of this Change Management Plan.

Name:
Title:

_____ _____

Signature Date Approved

8 FORMATS TO BE USED AS ATTACHMENTS

A. CHANGE REQUEST FORM (PLSL/ITC_F_01_00)
B. CHANGE REQUEST LOG (PLSLS/ITC_F_02_00)