CAPA SOP

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A Larsen & Toubro Group Company

Document Authorization

Role	Name	Signature	Date
Author			
Compliance Lead	Swati Kochukulam	Refer to e mail authorization	
Reviewer			
Compliance Manager	Anjana Gopalakrishnan	Refer to e mail authorization	
Approver			
Compliance COE -Head	G S Vijayakumar	Refer to e mail approval	

Note: Refer to e-mail approval attached at the end of the procedure.

Document History

Version	Change Description	Author	Date
1.00	Initial version	*Swati Kochukulam*	*26 May 2020*
1.01	*Document title changed from OLS_07_00P_ CAPA SOP_Procedure OLS_07_01T_CAPA Log_Template OLS_07_02T_CAPA Form_Template* *To below OLS-07-00P- CAPA SOP-Procedure OLS-07-01T-CAPA Log-Template OLS-07-02T-CAPA Form-Template*	*Swati Kochukulam*	*26 Aug 2020*

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1 Introduction

Organizations working in the Life Sciences industry have to implement and maintain an effective Quality management system to provide safe and effective product and services meeting customer and regulatory requirements. Should a non-conformity, deviation or incident happen in a process or product, the organization shall take adequate corrective and preventive actions (CAPA) to control the impact of the event as applicable. This document intends to describe the procedure for management and tracking the corrective and preventive actions as applicable.

1.1 Executive Summary

As per GAMP5 guidelines there should be a documented process for CAPA management. This procedure will ensure that CAPA needs to be documented and action items listed for the same are tracked and closed in a timely manner.

1.2 Objective

The objective of this SOP is to ensure that system non-conformances, deviations or incidents if any are identified as early as possible, reported, assessed, investigated and appropriate actions are taken as applicable to:

- to provide safe and effective product and services meeting customer and regulatory requirements.
- Ensure effective corrective and preventive action are taken.
- Prevent reoccurrence of quality problems
- Preventing or minimizing failures

1.3 Scope

This SOP shall be applicable to handling of internal GxP relevant systems of LTI or GxP projects executed for Life Sciences customers. The scope of this SOP shall be to establish an effective CAPA procedure to deal with handling of events like non-conformance, deviations, operational incidents etc., either detected internally via LTI's review and audit mechanisms, or specifically reported and triggered by a customer event.

1.4 Roles and Responsibilities

- **Process Owner is responsible for the following:**
  - Pre and Post approval of CAPA form
  - Approve/ reject justification for extension to CAPA closure date

- **Compliance Team member is responsible for the following:**
  - Issue and allocation of Number to CAPA form
  - Review of CAPA form
  - Update and maintain CAPA log
  - Follow up on outstanding CAPA issues
  - Review CAPA log periodically
  - Pre and Post Approval CAPA Form

- Ensure adherence to this SOP
- Approve/ reject extension request to CAPA closure date

- **CAPA Owner is responsible for the following:**
  - Acknowledge the CAPA and take responsibility as CAPA owner
  - Provide the target date of CAPA closure
  - Implement the proposed CA and PA
  - To initiate, investigate (if required) the observation and define the corrective and/or preventive action with the required details such as reason/source of CAPA.
  - To initiate CAPA extension request

2 Terms and Abbreviations

Note: The term CAPA used in this SOP and in the LifeScience's industry is mostly as per the below table definitions while it is also recognized that this same term is referred as Correction and Corrective Action respectively by ISO 9001:2015 standards. For easier alignment with LS customers, the below context is adopted by LTI Lifesciences as the Pharma industry is yet to fully adopt the latest ISO 9001: 2015 standard definitions.

Term/Abbreviation	Description
CA	Corrective Action
CAPA	Corrective Action and Preventive Action
PA	Preventive Action
SOP	Standard Operating Procedure
QMS	Quality Management System
cGxP	Current Good x (M=Manufacturing, L= Laboratory, C= Clinical, D= Documentation) Practice
LTI	Larsen and Toubro Infotech
MSA	Master Service Agreement
GAMP	Good automated manufacturing practice
COE	Center of Excellence
Corrective Action	Action to eliminate detected non-conformity or other undesirable situation
Preventive Action	Action to eliminate the cause of the potential nonconformity or other potential undesirable situation

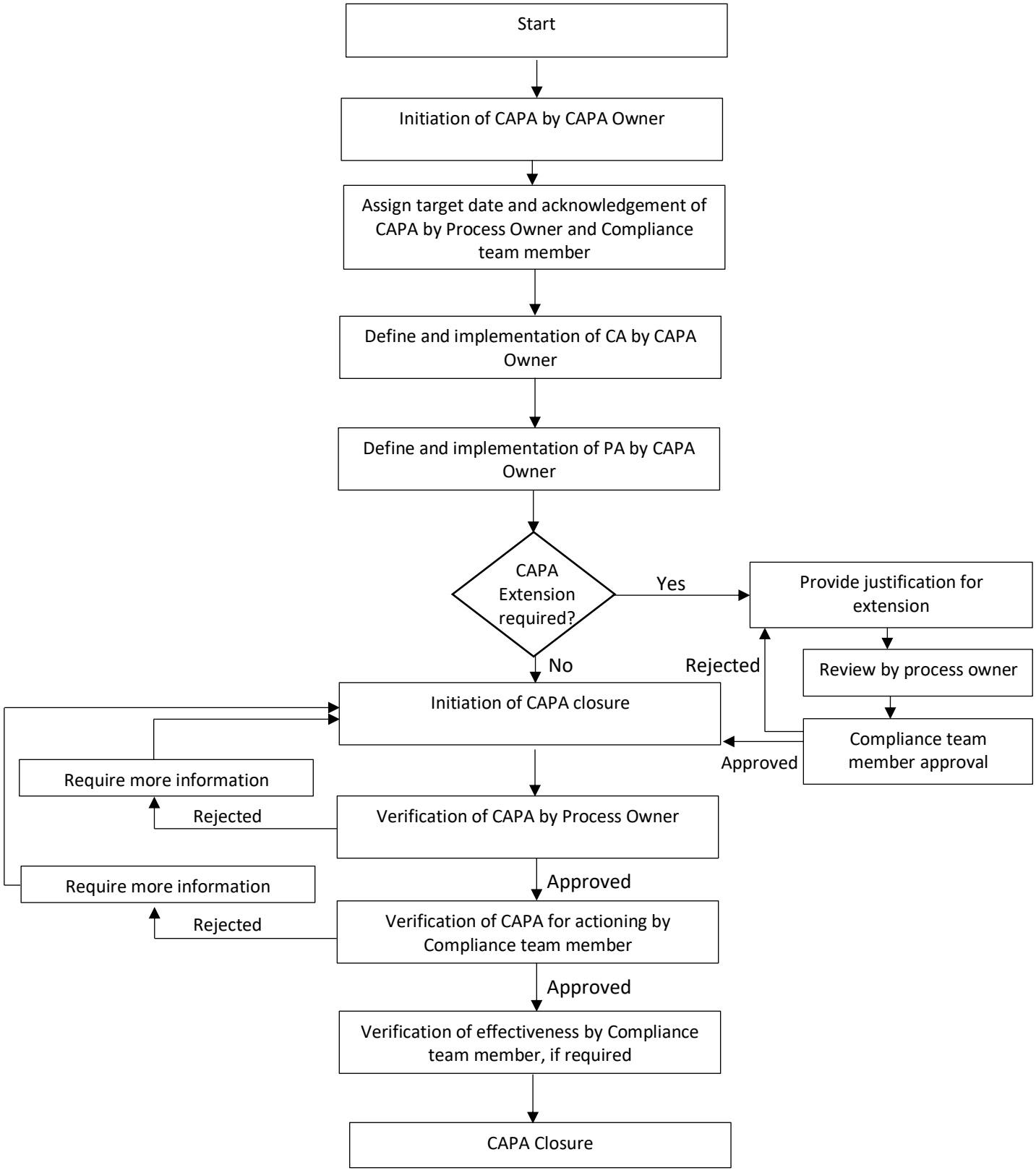
3 Process

3.1 CAPA Management Process

- Corrective and preventive action (CAPA) consists of improvements to an organization's processes taken to eliminate causes of non-conformities or other undesirable situations.
- A CAPA shall be initiated from the actions listed below (but not limited to):
    - Internal reviews/audits (part of LTI global QMS)
    - Regulatory/Customer audits (LifeScience specific)
    - Unplanned Deviations (LifeScience specific)
    - Incident investigation - internal or customer triggered (LifeScience specific)
    - Any other source requiring investigation and actions thereof
- A CAPA shall be documented in CAPA form (OLS-07-02T-CAPA Form-Template) and shall cover following:
    - Remedial correction of an identified problem or potential problem.
    - Prevent action to avert recurrence of a similar potential problem.
- CAPA closure need to be done within 60 Calendar days.

Below is the flow diagram for CAPA Management process:

Figure 1: Flow Diagram for CAPA Management



3.1.1 Initiation of CAPA

- For CAPA related to LTI internal audit by Delivery excellence team and Compliance Audit by Compliance team the relevant CAPA flow as per the respective audit SOPs shall be followed
- This specific process described herein shall apply to CAPA triggered by events other than the audits mentioned above
- CAPA management process shall happen through a CAPA system when such solutions are available and validated. In the absence of such a system, the following paper-based implementation shall be adopted.
- As soon as a need arises to trigger a CAPA based on discussion with Compliance team, Compliance Team Member shall issue a CAPA in the name of CAPA owner of respective department making relevant entries in CAPA log (OLS-07-01T-CAPA Log-Template).
- CAPA shall be numbered as “CAPA/YY/XXX”, where YY is the current year and XXX is the serial number starting from 001.
- CAPA owner and process owner shall acknowledge the CAPA by verifying the information mentioned in CAPA form.

3.1.2 Execution and implementation of CAPA

- CAPA owner shall create applicable QMS document (e.g. Change Control, Incident, Service request, etc.) to complete the action plan of CA/ PA, if required.
- CAPA owner shall define CA and/or PA based on RCA, if required. Investigation activity shall be recorded on CAPA form (OLS-07-02T-CAPA Form-Template).

3.1.3 Verification & Closure of CAPA

- CAPA owner shall attach supporting document as an evidence and share the document with Compliance Team member and Process Owner for review
- Compliance Team member and process owner shall verify the CAPA form for adequacy and accuracy by verifying the reference document (s) as stated in the CAPA form.
- On successful verification, CAPA owner shall put his/her comments, signature with date and submit CAPA form to process owner for approval
- Process owner shall sign CAPA form with date as approver
- CAPA owner shall then submit the form to Compliance Team member for closure and approval.
- Compliance Team member shall sign CAPA form as approver
- Closed CAPA form shall be uploaded at “LTI share point” by CAPA Owner and then shall be submitted to Compliance Team member.
- Compliance Team Member after verifying the closed CAPA form and its availability at LTI share point shall destroy the CAPA form.
- Verification of the effectiveness of CAPA wherever required, shall be performed after about 3 months by the Compliance Team member during internal Compliance audits appropriately.

3.1.4 Extension of CAPA

- CAPA owner shall initiate CAPA extension request providing justification for the extension in CAPA form (OLS-07-02T-CAPA Form-Template).
- Process owner shall review the extension request.
- Compliance Team member shall approve the extension request.

3.1.5 Periodic review of CAPA Log

- Compliance Team member shall check and follow up with Process owner team member or CAPA owner to close the document as per the timeline defined.
- The "CAPA Log" (OLS-07-01T-CAPA Log-Template) shall be reviewed by Compliance Team member, twice in a year to check for correctness and completeness of records.
- If needed, then the action item shall be done as suggested by Compliance Team member

3.2 References

- GAMP 5 A Risk Based Approach to Compliant GxP Computerized System
- SOP on SOPs: OLS-02-00P - SOP on SOP-Procedure

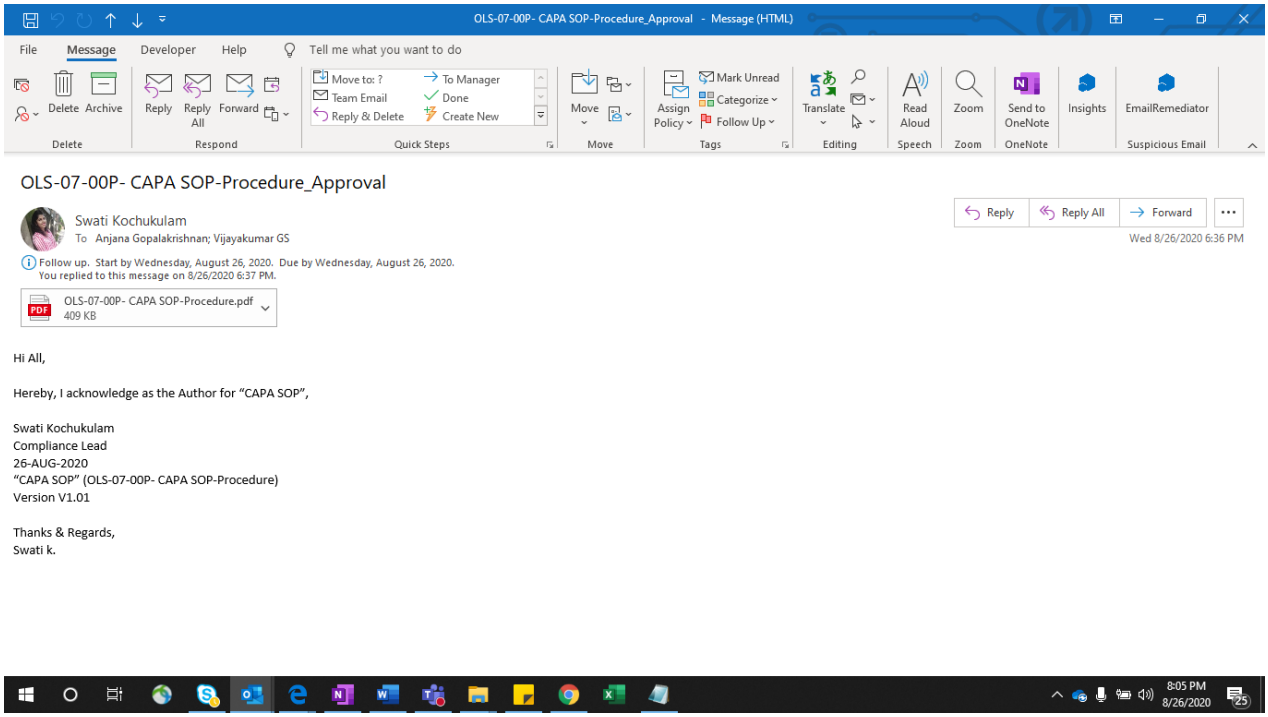
4 Annexures

4.1 Templates, Tools and Checklists

Sr. No.	QMS Template Number	Annexure Name
1.	OLS-07-01T-CAPA Log-Template	CAPA Log Template
2.	OLS-07-02T-CAPA Form-Template	CAPA Form

4.2 References

- GAMP 5 A Risk Based Approach to Compliant GxP Computerized System
- SOP on SOPs: OLS-02-00P - SOP on SOP-Procedure
- QMS templates related to CAR process
    - UM-03-06-Prevention Action Log
    - UM-06-03-Fish-Bone-Template
    - UM-06-01-CAR-guidelines
    - UM-06-04-Hypothesis test
    - UM-06-02-CAR-report
    - UM-06-05-Five-Why-Template
    - UM-06-06-CAR-Review-Checklist
    - UM-06-CAR
    - UM-06-07-Why-Tree-Template



OLS-07-00P- CAPA SOP-Procedure_Approval - Message (HTML)

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OLS-07-00P- CAPA SOP-Procedure_Approval

Swati Kochukulam
To Anjana Gopalakrishnan; Vijayakumar GS

Reply Reply All Forward

Wed 8/26/2020 6:36 PM

Follow up. Start by Wednesday, August 26, 2020. Due by Wednesday, August 26, 2020.
You replied to this message on 8/26/2020 6:37 PM.

OLS-07-00P- CAPA SOP-Procedure.pdf
409 KB

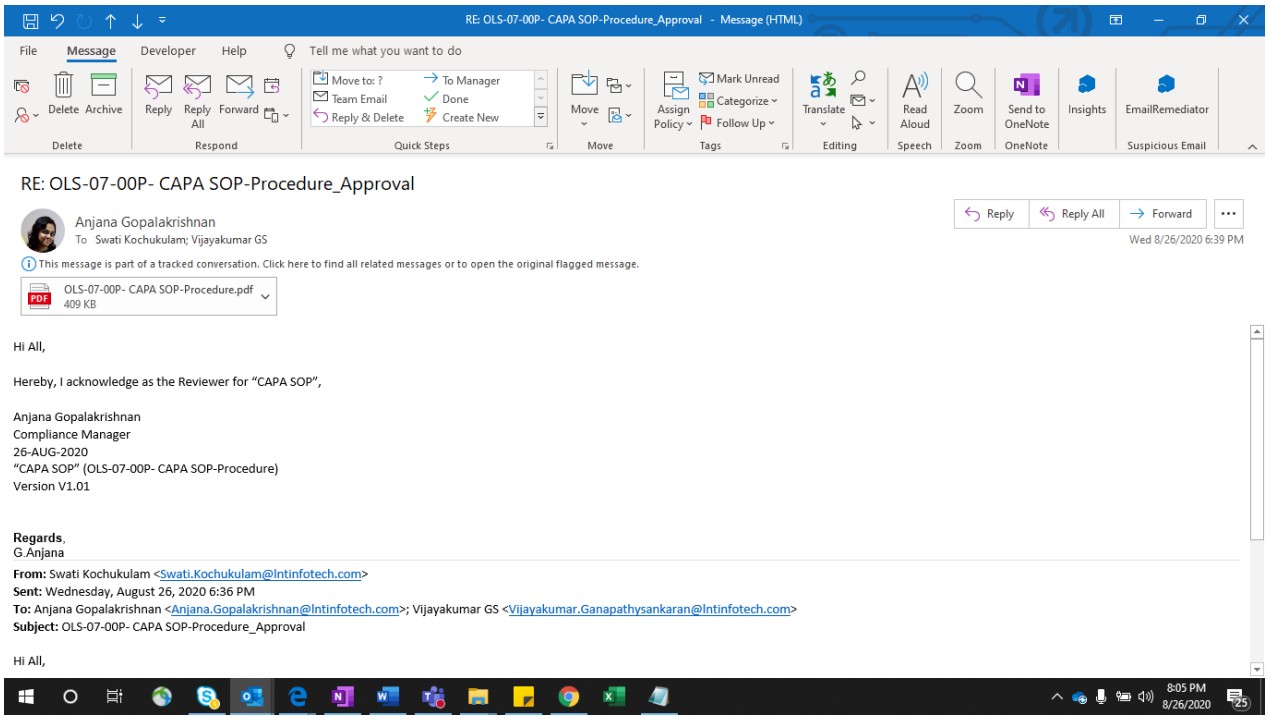
Hi All,

Hereby, I acknowledge as the Author for "CAPA SOP",

Swati Kochukulam
Compliance Lead
26-AUG-2020
"CAPA SOP" (OLS-07-00P- CAPA SOP-Procedure)
Version V1.01

Thanks & Regards,
Swati k.

8:05 PM
8/26/2020



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RE: OLS-07-00P- CAPA SOP-Procedure_Approval

Anjana Gopalakrishnan
To Swati Kochukulam; Vijayakumar GS

Reply Reply All Forward

Wed 8/26/2020 6:39 PM

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Hi All,

Hereby, I acknowledge as the Reviewer for "CAPA SOP",

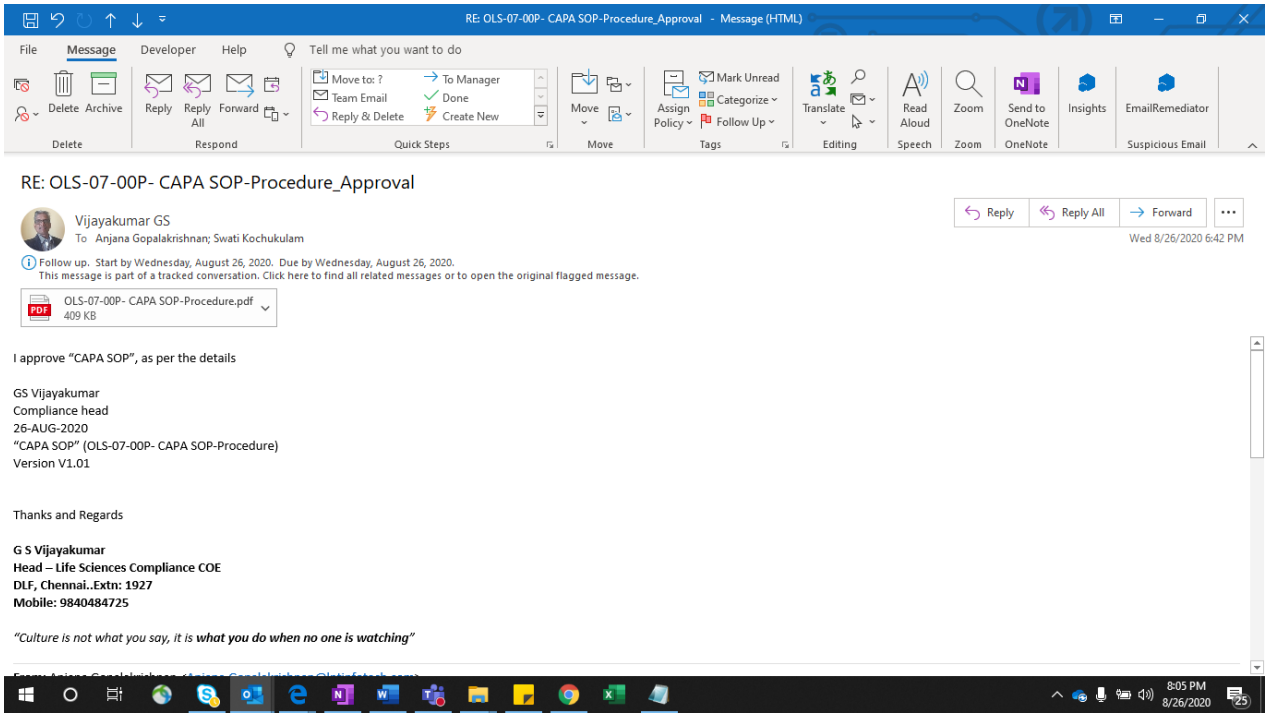
Anjana Gopalakrishnan
Compliance Manager
26-AUG-2020
"CAPA SOP" (OLS-07-00P- CAPA SOP-Procedure)
Version V1.01

Regards,
G.Anjana

From: Swati Kochukulam <Swati.Kochukulam@lntinfotech.com>
Sent: Wednesday, August 26, 2020 6:36 PM
To: Anjana Gopalakrishnan <Anjana.Gopalakrishnan@lntinfotech.com>; Vijayakumar GS <Vijayakumar.Ganapathysankaran@lntinfotech.com>
Subject: OLS-07-00P- CAPA SOP-Procedure_Approval

Hi All,

8:05 PM
8/26/2020



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RE: OLS-07-00P- CAPA SOP-Procedure_Approval

Vijayakumar GS
To Anjana Gopalakrishnan; Swati Kochukulam

Reply Reply All Forward

Wed 8/26/2020 6:42 PM

Follow up. Start by Wednesday, August 26, 2020. Due by Wednesday, August 26, 2020.
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I approve "CAPA SOP", as per the details

GS Vijayakumar
Compliance head
26-AUG-2020
"CAPA SOP" (OLS-07-00P- CAPA SOP-Procedure)
Version V1.01

Thanks and Regards

G S Vijayakumar
Head – Life Sciences Compliance COE
DLF, Chennai..Extn: 1927
Mobile: 9840484725

*"Culture is not what you say, it is **what you do when no one is watching**"*

8:05 PM
8/26/2020

CAPA Log Template

Sr.No	CAPA Initiation Date	CAPA ID	Source of CAPA (If Any)	CAPA Description	CAPA Owner (Sign/Date)	Issued by/Date (DD/MM/YYYY)	Target Date of Closure (DD/MM/YYYY)	Extension Date (If any)	CAPA Closed by/Date (DD/MM/YYYY)	Remark (If any)

CAPA Form

CAPA Form		
Initiation of CAPA		
CAPA ID	*<Specify CAPA ID here>*	
Department	*<Specify Department for which CAPA is initiated>*	
Source of CAPA: _____ _____ _____ _____ _____		
Assigned To - CAPA Owner	*<<Stakeholder to whom CAPA shall be assigned>>*	
Target Date of Closure	*<<Tentative date for closure of CAPA>>*	
Issued by/ Date (DD/MM/YYYY)	*<<Name of person who issued the CAPA and Date when CAPA was issued>>*	
Process Owner Acknowledgement/ Date and Sign (DD/MM/YYYY)	*<<CAPA form shall be acknowledged by Process Owner with required date format>>*	
Compliance Team Member Acknowledgement/ Date and Sign (DD/MM/YYYY)	*<<CAPA form shall be acknowledged by Compliance Team Member with required date format>>*	
Execution and implementation of CAPA		
<<Application/Process name for which CAPA in initiated>>	Version	

CAPA Form

Description: *<<Brief description or outline of the topic/process/problem being documented; can be formatted as a paragraph, numbered list, or bulleted items>>* _____ _____ _____ _____ _____
Corrective Action: *<<Immediate action to a problem that has already occurred or has been identified. Description of the corrective actions taken or planned by the CAPA Owner.>>*
Preventive Action: *<<Taken to eliminate the root cause of a potential problem including the detection/identification of problems. Description of the preventive actions taken or planned by the CAPA Owner.>>*
CAPA Extension Request
Reason for extension: *<<Optional in case no due date is passed for CAPA>>* _____ _____ _____ _____ _____

Requested by/ Date (DD/MM/YYYY)	*<<Date on which extension for CAPA requested and by whom>>*
Revised Target Date	*<<Target date by which CAPA shall be closed>>*
Reviewed by: *(to be signed and dated* (DD/MM/YYYY) by *process owner)*	*<<Review signoff by process owner>>*

CAPA Form

Approved by: *(to be signed and dated* (DD/MM/*YYYY) by Compliance Team Member)*	**Approved/Rejected -** *<< signoff by process owner>>*
CAPA Closure	
CAPA Owner Comments: _____ _____ _____ _____	
Supporting information for closure for CAPA: ☐ Revision of document/SOP ☐ Control established in application ☐ Testing of functionality ☐ Training Records ☐ Others: _____ Reference document number: _____	
CAPA Owner Sign/Date (DD/MM/YYYY)	
Closure of CAPA	
Approved by: *(to be signed and dated* (DD/MM/YYYY) *by process owner)*	**Approved/Rejected -**
Approved by: *(to be signed and dated (DD/MM/YYYY) by Compliance Team Member)*	**Approved/Rejected -**

Note: Remove blue text before final usage of template.