LifeScience Compliance Audit 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*	*20 Mar 2020*

Version	Change Description	Author	Date
1.01	*1.Section 3.4 updated to include note on sampling criteria* *2. References updated in section 4.1 and 4.2* *3. Document title changed from* *OLS_01_04P_ Life Science Audit SOP_Procedure* *OLS_01_01C - Compliance Audit_Checklist* *OLS_01_09T - Compliance Audit Tracker_Template* *To below* *OLS-04-00P - Life Science Audit SOP-Procedure* *OLS-04-01C - Compliance Audit-Checklist* *OLS-04-02T - Compliance Audit Tracker-Template*	*Swati Kochukulam*	*26 Aug 2020*

Table of Contents

1 Introduction

This document provides the procedure to be followed for managing the internal Audit cycle for Life Science specific GxP projects.

Auditing is a systematic and independent examination of various activities, intended to determine compliance with the standard set by the client and with the process set within each account. In a process-oriented approach, two key tasks are process definition and process implementation.

Effectiveness of every defined and implemented process has to be periodically assessed through several mechanism of which Audit is an important process Which involves
Effective assessment of GMP compliance Inspection readiness (self-inspection to ensure current Good Manufacturing practices compliance)

Compliance Team involves in reviewing and auditing the project & support function activities with intent to verify that they comply with the applicable procedures and standards. It provides project management team with the visibility as to whether the project is adhering to its established plans, standards, and procedures.

Internal audit is an independent objective assurance and consulting activity designed to add value and improve project operations.

1.1 Executive Summary

Audit SOP elaborates the process for auditing projects in LifeScience account in a structured manner to ensure they adhere to LTI LS specific process, Customer process and Regulatory guidance.

1.2 Objective

Internal Compliance Audit process is designed to verify each project to ensure the adherence to Regulatory requirements as well as Client SOP requirements and to any specific process defined in the account.

Effective audits are the key to ensuring that process implemented is running well and is able to deliver benefits to the projects, clients and the Organization. The major objectives include the following

- To independently and objectively verify compliance and implementation effectiveness of mandated processes.
- To provide insight to Senior Management about the compliance and status of the implementation of applicable processes.
- To ensure client gets a quality product/ service.
- To identify good practices that can be shared with other projects and/or institutionalized within the organization.

- To identify process areas that needs improvement.
- To ensure that processes set are understood and followed in the organization.
- To assure compliance with all relevant rules and regulations
- To undertake workshops for training and awareness

Audits also provide opportunities to identify Areas of Improvement. Audits also serve as early warnings systems and alerts when periodically and properly performed.

Compliance Head will ensure that the auditor has good knowledge on pharma regulations and has the skills and relevant experience to carry out effective audits.

While the main objective of each audit remains the same, the key focus and check points of each audit will depend on the type of project being audited.

1.3 Scope

This audit procedure is applicable for all GxP projects executed by LTI in life science account any exception will be approved by Compliance head and the same will be documented in the Compliance Audit Tracker referenced in section 4.1

The scope of this document is limited to auditing of projects to ensure project and process adherence.

The scope of this compliance audit is to ensure conformance to standards, requirements, or procedures for specific process(es) like Validation, Testing, Change Control etc.

To define role/responsibility of various functions responsible for Internal audit

1.4 Roles and Responsibilities

- **Compliance Head**
  - Head the Compliance COE team
  - Involve in selection of appropriate Auditor and Qualification
  - Govern the overall audit process as per plan
  - Continually improve the process

- **Delivery Manager/ Key Delivery Manager**
  - Head the project team
  - Support the audit process by committing to schedule and appropriate mindset
  - Help adhere to the audit plan
  - Participate in audit as required and provide supporting evidences
  - Govern conformance to requirements

- **Compliance COE Team (Compliance Auditor)**
  - Involve in Audit planning
  - Ensure the audits are executed as per plan
  - Document all observations found
  - Ensure the closure of all observation as per the dates mentioned

- **Project Manager / Project team (Auditee)**
  - Representative from Project team or Project PM will be assigned as an auditee
  - Support conducting the audit in coordination with the Compliance Auditor
  - Implement correction, corrective and preventive action
  - Ensure the closure of all findings as per the SOP and dates committed

2 Terms and Abbreviations

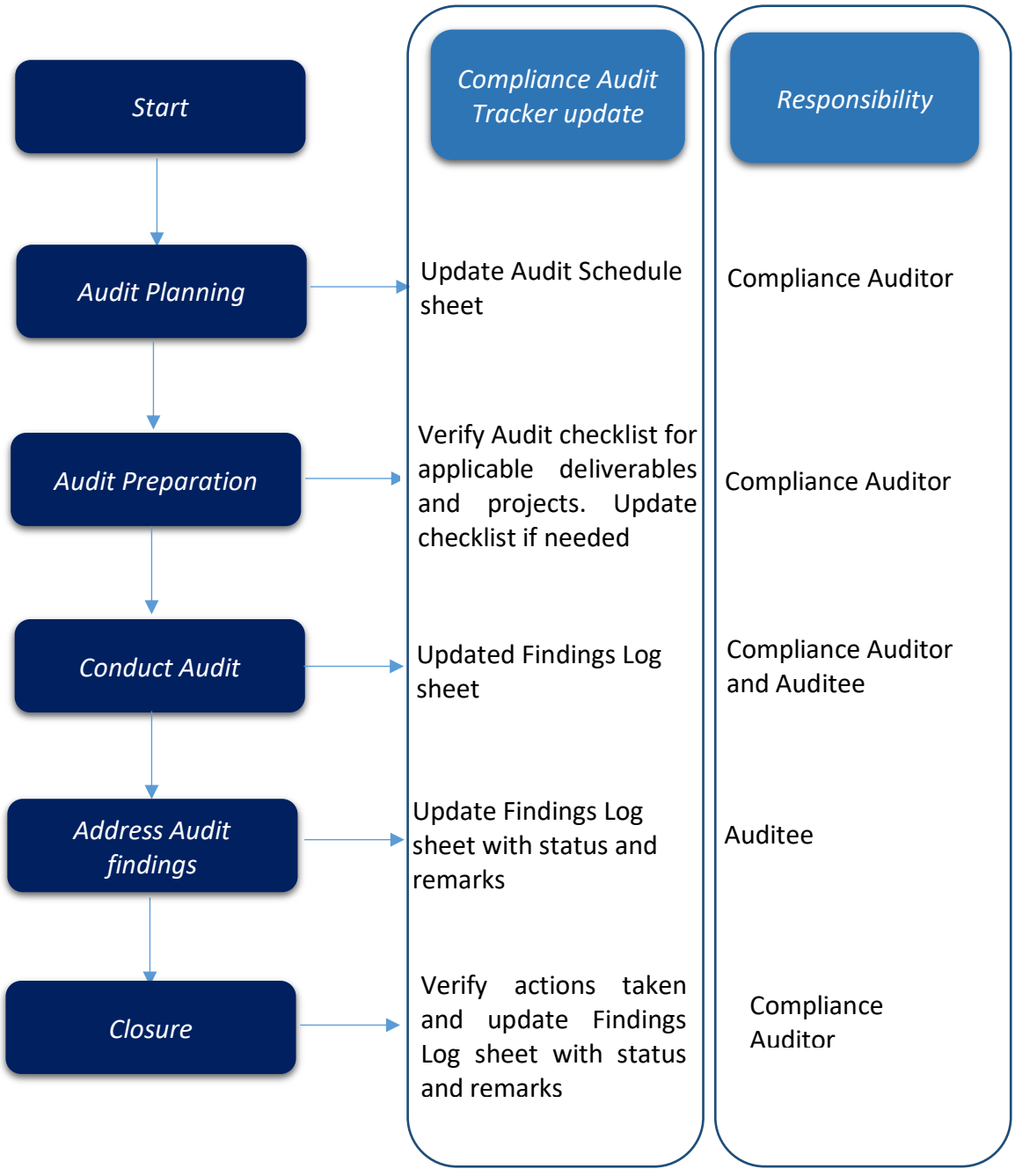
Term/Abbreviation	Description
CAPA	Corrective Action and Preventive Action
CA	Corrective Action
COE	Center Of Excellence
LS	Life Science
cGxP	Current Good x (M=Manufacturing, L= Laboratory, C= Clinical, D= Documentation) Practice
MoM	Minutes of Meeting
QMS	Quality Management System
QA	Quality Assurance
SOP	Standard Operating Procedure
TM	Team Member

3 Process

3.1 Tasks Steps

Sub-Process	*Responsibility*	*Output*
Audit Planning		
• Prepare internal Compliance audit schedule for all projects with Audit date, project team SPOC and Compliance SPOC • Communicate the plan to all stakeholders	Compliance Auditor	Audit schedule Sheet – OLS-04-02T - Compliance Audit Tracker
Audit Preparation		
• Go through the document/references if already made available by PM • Review previously logged findings • Review audit checklist for the deliverables and update the checklist if needed • Set up meetings as the audit schedule defined	Compliance Auditor	Audit checklist - OLS-04-01C- Compliance Audit Checklist
Conduct Audit		
• Gather understanding from project team on their overall activities • Verify relevant documents / process • Check all supporting evidences • Verify closure of earlier logged findings • Verify implementation of corrective and preventive actions suggested • Raise non-conformance wherever there is a deviation observed • Discuss all issues in detail with the project team SPOC • Log audit findings in Audit log	Compliance Auditor and Auditee	Findings log sheet - OLS-04-02T- Compliance Audit Tracker
Address Audit findings		
• Analyze the root cause and update the tracker accordingly • Make correction as suggested • Implement corrective and preventive measures • Track the progress • Ensure closure of all findings before due date • Report to compliance team in any issues faced during addressing the findings • Discuss with auditor in case of any concerns in addressing the issues	Auditee	Findings log sheet - OLS-04-02T- Compliance Audit Tracker
Closure		
• Verify the corrections made • Verify the corrective and preventive actions implemented • Verify effectiveness of CAPA • Suggest any further action required • Updated the status in audit log	Compliance Auditor	Findings log sheet - OLS-04-02T- Compliance Audit Tracker

3.2 Process Flow Chart



Flow Diagram for Process Steps

3.3 Auditor Selection and Qualification

- The Compliance Head will identify and qualify auditors based on the auditor's knowledge, training, and experience. If additional training is required to properly conduct the audit, the training will be defined and documented by the Compliance Head
- All consultants identified by LTI to conduct an audit, in addition to documentation of reading and understanding this SOP, must provide a CV showing applicable auditing experience. The CV will be maintained as part of the auditing files.
- The Compliance Head will assign other specialist as an audit team member depending on the scope of the audit.

3.4 Sampling Criteria

Following sampling criteria will be applied

Project Type	*Sample Size*	*How to select the sample**
Development Project	If the number of work products is less than 5 then select all the work products	In case where number of work products is less than 5 then ensure that 100% of work products are selected.
	If the number of work products is greater than 5 and less than 20 then select 25 % of the total number of work products	In case where number of work products is greater than 5 and less than 20 select samples on random basis.
	If the number of work products is greater than 20, ensure that sample size should be 25 % of total number of work products	Ensure adequate number of samples across all categories of work product or a weighted selection based on the category size
Support Project	If the number of tickets is less than 20 or equal to 20, sample size should be 50 % of total number of tickets	Classify the entire set of tickets into groups as per criticality
	If the number of tickets is greater than 20 total number of sampled tickets should be 25%.	Select more samples from these groups, Critical/High

* This sampling criteria to be applied to an appropriate data set of the population using risk-based approach typically for engagements which handle ticket resolution.

3.5 Audit Findings

An audit finding is an outcome of an audit. An audit finding can be classified into:

- Critical
- Major
- Minor
- Opportunity for Improvement
- Good Practices

Severity	*Details*	*Some Examples (but not limited to)*
Critical	Critical GxP failure occurs when a deviation could give rise to a product which would be harmful to the patient or	1. Critical Defects identified in Traceability Matrix

Severity	*Details*	*Some Examples (but not limited to)*
	animal, or which has produced a harmful product, impacts potency, purity, patient treatment, or adversely affects the rights, safety or well-being of patients/ subjects, poses a potential risk to public health, jeopardizes the quality and integrity of data, or contribute to withholding information that may constitute a fraud or falsification of products or data; A deficiency in complying with Company and Client Standards, applicable Regulatory requirements etc., in GXP space. A combination of major observation, which indicates a serious system failure, may also be classified as a critical observation. Observations that would result in a failure of the quality system that would have an effect on the finished product quality or may result in not achieving management system certification	2. Requirements for Audit trail not captured for GXP system 3. Untrained staff performing GMP projects 4. Missed / late approvals in change controls
Major	An observation may be classified as major for the following reasons: • Non-critical observation which has produced or may produce a product, which does not comply with GxP/ GCP guidelines that which can potentially turn critical if not addressed in a timely manner • a combination of several "other" deficiencies, none of which on their own may be major, but which may occur in a particular area together represent a major observation • Repeated minor deviations in the same area that could lead to system failure	1. OQ not pre-approved fully before OQ started 2. VP not created for any change on the execution plan
Minor	• An observation that is less serious and isolated in nature which cannot be classified as either critical or major, but which indicates a departure from good manufacturing practice. • Inconsistency or missing link in a process not expected to adversely affect the rights, safety or well-being or jeopardizes the quality, integrity of data • Observations that would result in a failure of one or more quality system processes that may have an effect on the finished product quality or may result in problems achieving management system certification.	1. Screenshot template does not have initials and dates mentioned 2. VP was not signed before OQ
Opportunity for Improvement	An opportunity for improvement relates to a matter about which the Auditor is concerned but which cannot be clearly stated as a non-conformity. Observations also indicate trends which may result in a future non- conformity.	1.Maintenance of review log 2. Maintenance of MoM for all interactions with client
Good Practices	A practice in a project/program/account which has a positive impact on the project/program/account objectives respectively viz. schedule, effort, defects, client satisfaction, employee satisfaction etc.	1. Review checklist maintained for all deliverables

Severity	*Details*	*Some Examples (but not limited to)*
		2. Log maintained for all comments received

3.6 Audit Frequency and Timelines

Compliance Audit shall be performed at monthly intervals for all GXP projects. The applicable list of projects will be defined by Delivery Managers/Key Delivery Manager for each account. In case of any deviation from this, appropriate approval shall be taken from the Compliance Head/ Delivery Head with proper justification.

The audit findings shall be shared with the auditee within a week of the audit.

The auditee shall respond with appropriate CAPA plan within two weeks of sharing the findings. While timeline for action is proposed by the auditee depending upon criticality and feasibility of the actions and their dependencies, adherence to the following timelines are desirable:

1. **Critical** findings to always include correction, corrective and preventive actions. While corrections are to be done immediately, corrective and preventive actions are to be applied within a month of getting notified
2. **Major** findings to always include correction and corrective actions. Necessity for preventive actions shall evaluated by the auditor/ Compliance Head as appropriate. Actions to be targeted to be closed within two weeks of getting notified
3. **Minor** findings to always include corrections within 5 working days. Necessity for Corrective and preventive actions shall be evaluated by the auditor as appropriate and targeted to be closed within a week.

3.7 Control Mechanism

All findings are tracked to closure by the auditee and verified by auditor within the agreed date. The verification for closure of all findings will be based on the dates provided in the audit log.

Any Unresolved issues will be escalated to Compliance Head and Delivery Manager/ Key Delivery Manager

3.8 Output of the Audit

- Compliance Audit Checklist - OLS-04-01C- Compliance Audit Checklist
- This will be maintained in LTIs Sharepoint by respective Compliance Representative

4 Annexure

Not Applicable

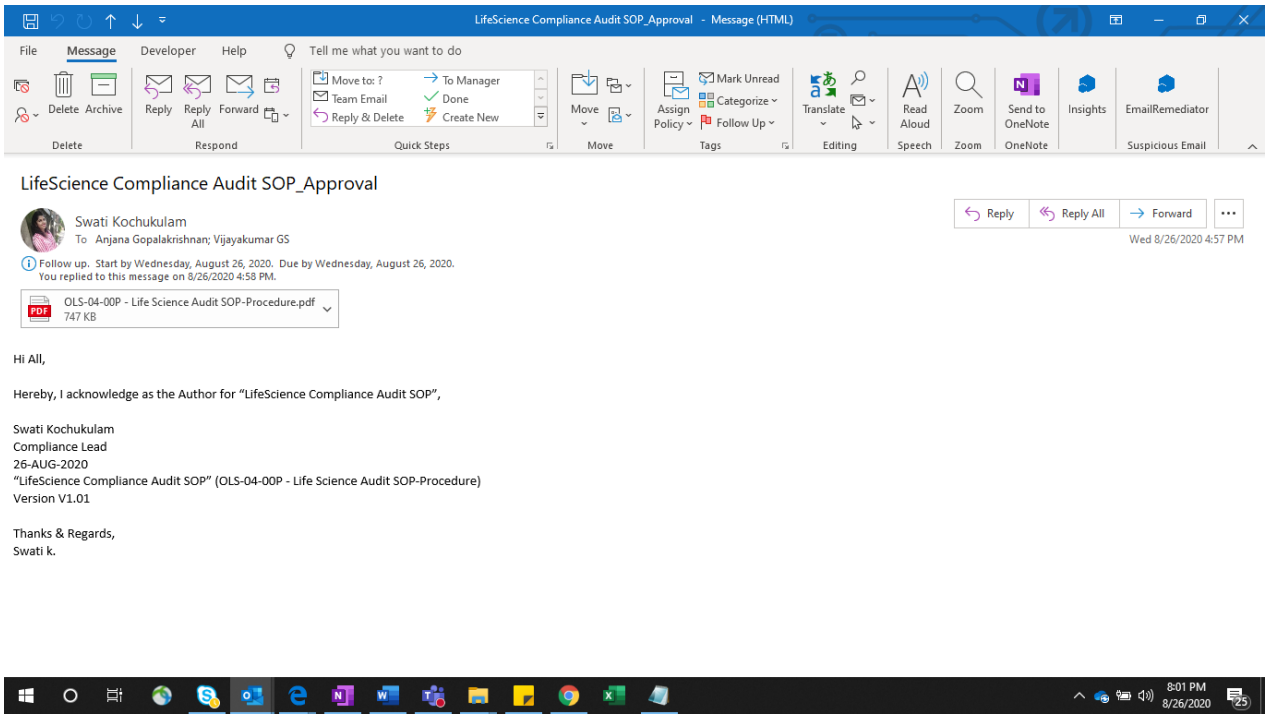
4.1 Templates, Tools and Checklists

Sr. No	*Document Name*	*Type*	*Location*
1	OLS-04-02T - Compliance Audit Tracker-Template	Template	QMS
2	OLS-04-01C - Compliance Audit-Checklist	Template	QMS

4.2 References

Item	*Document Name*	*Location*
LTI's internal audit process document	QA-06-Audit	LTI's QMS*
CAPA SOP	OLS-07-00P- CAPA SOP-Procedure	LTI's QMS*
Deviation Management SOP	OLS-05-00P- Deviation SOP_Procedure	LTI's QMS*
CSV SOP	OLS-06-00P-CSV SOP-Procedure	LTI's QMS*
SOP on SOPs	OLS-02-00P - SOP on SOP-Procedure	LTI's QMS*

*LTI's QMS:
https://lntinfotech.sharepoint.com/sites/QMS/Pages/default.aspx



LifeScience Compliance Audit SOP_Approval - Message (HTML)

File Message Developer Help Tell me what you want to do

Delete Archive Reply Reply All Forward Move to: ? To Manager Team Email Done Reply & Delete Create New Move Assign Policy Mark Unread Categorize Follow Up Translate Read Aloud Zoom Send to OneNote Insights EmailRemediator

Delete Respond Quick Steps Move Tags Editing Speech Zoom OneNote Suspicious Email

LifeScience Compliance Audit SOP_Approval

Swati Kochukulam
To Anjana Gopalakrishnan; Vijayakumar GS

Reply Reply All Forward
Wed 8/26/2020 4:57 PM

Follow up. Start by Wednesday, August 26, 2020. Due by Wednesday, August 26, 2020.
You replied to this message on 8/26/2020 4:58 PM.

OLS-04-00P - Life Science Audit SOP-Procedure.pdf
747 KB

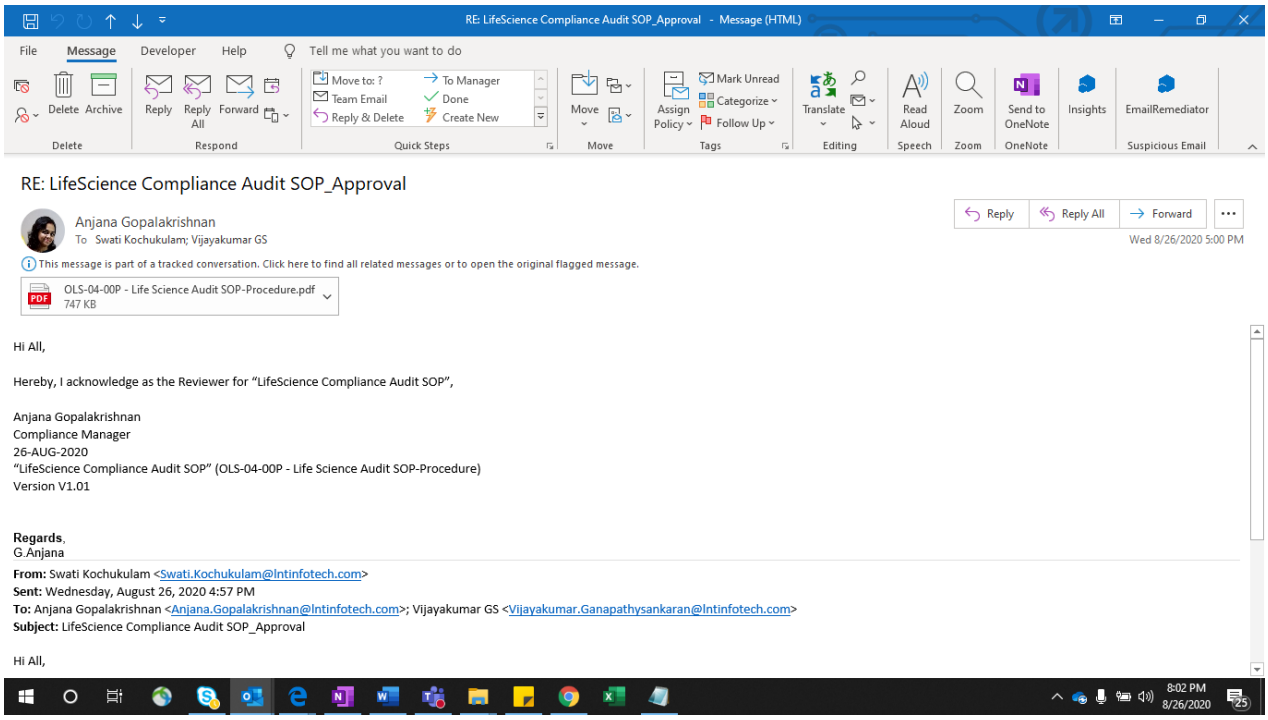
Hi All,

Hereby, I acknowledge as the Author for "LifeScience Compliance Audit SOP",

Swati Kochukulam
Compliance Lead
26-AUG-2020
"LifeScience Compliance Audit SOP" (OLS-04-00P - Life Science Audit SOP-Procedure)
Version V1.01

Thanks & Regards,
Swati k.

8:01 PM
8/26/2020



RE: LifeScience Compliance Audit SOP_Approval - Message (HTML)

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Delete Respond Quick Steps Move Tags Editing Speech Zoom OneNote Suspicious Email

RE: LifeScience Compliance Audit SOP_Approval

Anjana Gopalakrishnan
To Swati Kochukulam; Vijayakumar GS

Reply Reply All Forward
Wed 8/26/2020 5:00 PM

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Hi All,

Hereby, I acknowledge as the Reviewer for "LifeScience Compliance Audit SOP",

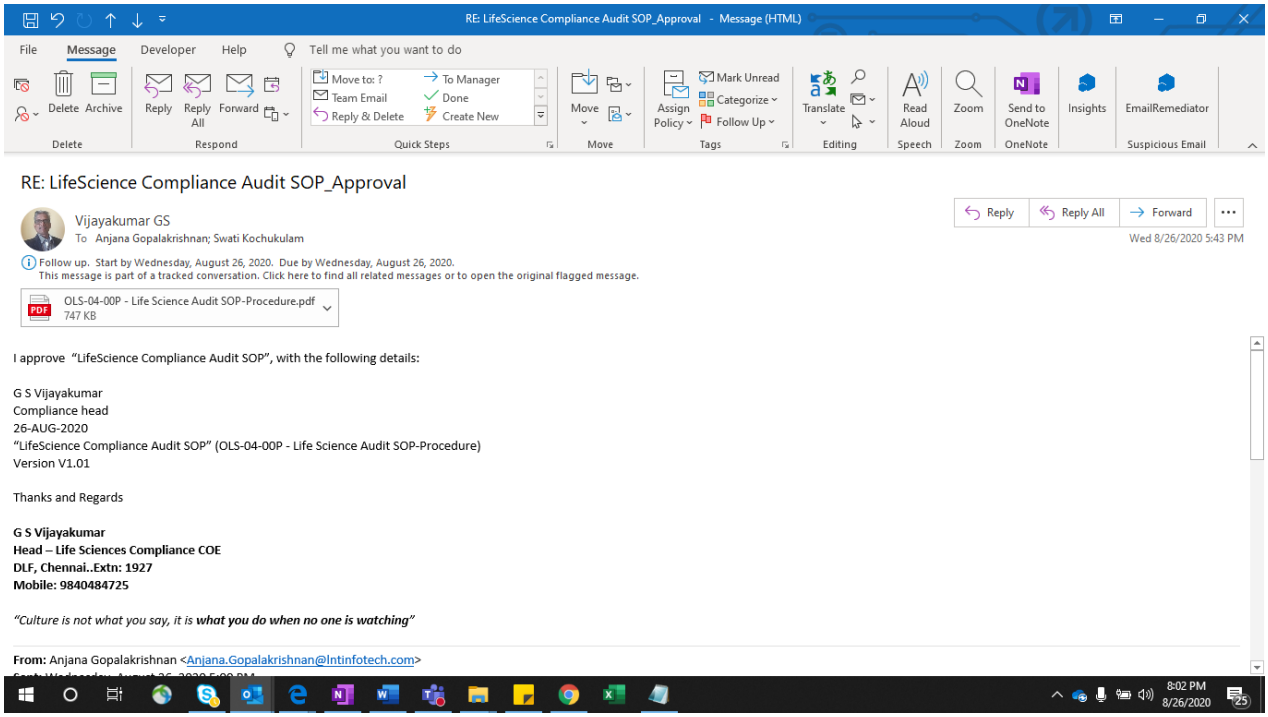
Anjana Gopalakrishnan
Compliance Manager
26-AUG-2020
"LifeScience Compliance Audit SOP" (OLS-04-00P - Life Science Audit SOP-Procedure)
Version V1.01

Regards,
G.Anjana

From: Swati Kochukulam <Swati.Kochukulam@Intinfotech.com>
Sent: Wednesday, August 26, 2020 4:57 PM
To: Anjana Gopalakrishnan <Anjana.Gopalakrishnan@Intinfotech.com>; Vijayakumar GS <Vijayakumar.Ganapathysankaran@Intinfotech.com>
Subject: LifeScience Compliance Audit SOP_Approval

Hi All,

8:02 PM
8/26/2020



RE: LifeScience Compliance Audit SOP_Approval - Message (HTML)

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Delete Respond Quick Steps Move Tags Editing Speech Zoom OneNote Suspicious Email

RE: LifeScience Compliance Audit SOP_Approval

Vijayakumar GS
To Anjana Gopalakrishnan; Swati Kochukulam

Reply Reply All Forward

Wed 8/26/2020 5:43 PM

Follow up. Start by Wednesday, August 26, 2020. Due by Wednesday, August 26, 2020.
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I approve "LifeScience Compliance Audit SOP", with the following details:

G S Vijayakumar
Compliance head
26-AUG-2020
"LifeScience Compliance Audit SOP" (OLS-04-00P - Life Science Audit 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**"*

From: Anjana Gopalakrishnan <Anjana.Gopalakrishnan@Intinfotech.com>

8:02 PM 8/26/2020

Sheet: Project Specific checkpoints

Project Specific Compliance Checkpoint (Applicable for all GxP projects)										
Sr. No.	**Project Type**	**Project Name**	**Auditor**	**Checklist**	**Response**	**Details of documents/activities/ Tickets verified**	**Observations**	**Total Deliverables**	**# of samples verified (atleast 20%)**	**# Samples Compliant**
Project specific checkpoints										
1	*<Project type to be filled in>*	*<Project Name to be filled in>*		*<The checklist has to be created for each project as per the process defined and followed for each project - This has to be created before the start of the audit>*	*<To be filled at the time of audit>*	*<To be filled at the time of audit>*	*<To be filled at the time of audit>*	*<To be filled at the time of audit>*	*<To be filled at the time of audit>*	*<To be filled at the time of audit>*

Sheet: Common Checkpoints

The pointers listed as Checklist can be modified as per the project/account requirement.

Project Specific Compliance Checkpoint (Applicable for all GxP projects)								
Sr. No.	**Project Type**	**Project Name**	**Auditor**	**Checklist**	**Response**	**Details of documents/activities/ Tickets verified**	**Observations**	**Total Deliverables**
1	<Project type to be filled in>	<Project name to be filled in>		Any GDP violation observed?	<To be filled at the time of audit>	<To be filled at the time of audit>	<To be filled at the time of audit>	<To be filled at the time of audit>
				Are all protocols are pre-approved before execution?				
				Availability of training records of activity specific resources (JD, CV and Training Records)				
				Any violation from CSV SOP observed?				
				Is High Level Risk Assessment conducted for the system?				
				List of the GAMP category for the system in scope				
				Is the documents as per the GAMP Category listed in "GAMP Category doc" sheet?				
				If not as per the list, where is the scope of documentation mentioned?				
				Audit the Change Management process and adherence to the formal process (if not covered already)				

Project Specific Compliance Checkpoint (Applicable for all GxP projects)								
Sr. No.	**Project Type**	**Project Name**	**Auditor**	**Checklist**	**Response**	**Details of documents/activities/ Tickets verified**	**Observations**	**Total Deliverables**
				Audit the Release Management process and adherence to the formal process (if not covered already)				
				Audit the Defect/Incident Management process and adherence to the formal process (if not covered already)				
				Usage of correct login ID & password against the executed documents (Log in/ Log Out, No Generic ID, Valid User ID and Password)				
				Deviation from procedures in SOP? If yes, then discuss with Client CSV and E mail evidence maintained and shared with Compliance Auditor				
				Are script errors documented? If not documented, should be logged formally and shared with Compliance Auditor				
				Are validation activities done by CSV trained resources				
				Deliverable calendar updated and maintained for all deliverables (as applicable)				
				Execution Tracker updated and maintained for all deliverables (as applicable)				
				Peer Review done and checklist updated for all deliverables before submitting to QA/CSV review				

Project Specific Compliance Checkpoint (Applicable for all GxP projects)								
Sr. No.	**Project Type**	**Project Name**	**Auditor**	**Checklist**	**Response**	**Details of documents/activities/ Tickets verified**	**Observations**	**Total Deliverables**
				QA/ CSV review process adherence for all deliverables shared with Client				
				Compliance Team SPOC involved during test execution				
				Any new resource without Pharma experience? (Yes/No with resource details)				
				If yes, then is all deliverables by the resource reviewed by CSV resource (Yes/No)				
				Execution in appropriate work environment				
				Is OQ Dry run performed?				
				When screenshot captured, are we making sure other windows are not captured?				
				List project execution SOP name and verify adherence				
				Training Effectiveness check of resources				
				Onboarding process adherence				

Project Specific Compliance Checkpoint (Applicable for all GxP projects)								
Sr. No.	**Project Type**	**Project Name**	**Auditor**	**Checklist**	**Response**	**Details of documents/activities/ Tickets verified**	**Observations**	**Total Deliverables**
				Offboarding process adherence				
				Are the training records for resources available?				
				<Other Account specific pointers to be added further>				

Sheet: CSV checkpoints

The pointers listed as Checklist can be modified as per the project/account requirement.

Project Specific Compliance Checkpoint (Applicable for all GxP projects)							
Sr. No.	**Section Type**	**Section Name**	**Reviewer/ Auditor**	**Checklist**	**Response**	**Details of documents/activities/Tickets verified**	**Observations**
CSV Checkpoints (For project deliverables)							
1	CSV Checkpoints	Approval		Is QA the last approver in all documents?	*<To be filled at the time of audit>*	*<To be filled at the time of audit>*	*<To be filled at the time of audit>*
		Approval		Does all completed test scripts have two sets of approvals – Pre-Execution Approval and Post-Execution Approval?			
		Approval		Is the document approved by Client?			
		Author		Are test protocols authored by CSV resources? Are they trained?			
		Deviation		Is there any deviation logged?			
		Deviation		Has the latest template of "Deviation Report Form (DRF# DEV-01)" used for recording deviation?			
		Deviation		Does the "Deviation Report Form (As per client latest template)" has below details recorded? Test Script ID & Step #, Document # and Deviation #			
		Deviation		Has the Tester signed and added date in "Deviation Report Form (DRF# DEV-01)" ?			
		Deviation		Is the deviation classified as suggested by Client CSV?			
		Deviation		Is the deviation number referenced in the failed step of the script?			
		Deviation		Is the deviation log updated in the script? Are the deviation numbers in sequence?			
		Execution		Is the execution result recorded/ captured on the same day of execution ?			
		Execution		Are all entries done in Blue or black permanent ink ?			

Project Specific Compliance Checkpoint (Applicable for all GxP projects)							
Sr. No.	**Section Type**	**Section Name**	**Reviewer/ Auditor**	**Checklist**	**Response**	**Details of documents/activities/Tickets verified**	**Observations**
		Execution		Is there is back-date or pre-date any entries/signatures?			
		Execution		Is the Date and Time format as per the systemic practice?			
		Execution		Are all blank spaces crossed out (Single strike off)? Is this done by authorized person credentials (Executor)? If initials and date added?			
		Execution		Are appropriate notification sent for DI issues during the execution?			
		Execution		Is the Test protocols reviewed prior and post-execution?			
		Execution		Are there any empty pages left in protocol? Are all empty boxes strikked off?			
		Execution		Are there any Procedure or Expected Results boxes left empty? Are all empty boxes strikked off?			
		Execution		Was the script executed in defined sequence as in test script?			
		Execution		In an executed script, is the actual result (Pass/fail) handwritten?			
		Execution		Are the test results captured directly when testing was done? Is initial and date added to the test step?			
		Execution		Is there any "Ditto" or "Down-arrow" or Other indicators mentioned in the script?			
		Execution		Are specific details mentioned in "Comments" section of the script?			
		Execution		Are relevant Incidents or observations indicated in "Comments" sections? (Even if not directly linked to the script)			
		Execution		Is there any manual correction done to the "expected results" or “Procedure” ?			
		Execution		Are there any minor typographical error's in the script?			

Project Specific Compliance Checkpoint (Applicable for all GxP projects)							
Sr. No.	**Section Type**	**Section Name**	**Reviewer/ Auditor**	**Checklist**	**Response**	**Details of documents/activities/Tickets verified**	**Observations**
		Execution		Are the typographical error's manually corrected (handwritten)? If yes, then do we have confirmation from Client CSV team?			
		Execution		Are the typographical error's manually corrected (handwritten)? If no, then do we have confirmation from Client CSV team?			
		Execution		If the handwritten correction done appropriately? *(Note: Single strike off through the text, correct entry at the top, bottom or next to it* ***or*** *mark any symbol/number next to it, and write the correct entry at the bottom of the page with reference to the symbol/number, initial and date)*			
		Execution		Is there any removals, erasing of data, altering, overwriting, masking or over-writing done?			
		Execution		All details should be in original executed document only? If the original document changed or replaced?			
		Execution		Are the handwritten correction done to the scripts (other than typographical errors)?			
				If yes, If there any deviation logged for this?			
				If yes, then is there any impact to other documents?			
				If yes, then is there a Change Control process followed for updates?			
		Execution		Is the test recordings legible? Is there any Shorthand notations used?			
		Execution		Is the date as per client format?			
		Execution		Is Date & Time of Computer used during execution is restricted?			

Project Specific Compliance Checkpoint (Applicable for all GxP projects)							
Sr. No.	**Section Type**	**Section Name**	**Reviewer/ Auditor**	**Checklist**	**Response**	**Details of documents/activities/Tickets verified**	**Observations**
		Personnel		Has the personal responsible for executing and reviewing the script completed relevant trainings?			
		Personnel		Is the reviewer and executor of the script different?			
		Personnel		Is the author and executor of the script different?			
		Personnel		Is the author also tester, approver or reviewer?			
		Personnel		If the author is also the tester/reviewer, then is that agreed with Client CSV and QA team?			
		Personnel		If the reviewer is also the approver, then is that agreed with Client CSV and QA team?			
		Personnel		If the tester and the test recorder are not the same, then is the "Test executed" by signed by all testers?			
		Personnel		Is there any witness involved? If yes, has the witness also signed the log?			
		Personnel		Has the reviewer reviewed all steps, screenshots, deviations?			
		Personnel		Has the reviewer altered any testcase?			
		Re Execution		Is there any script re executed?			
		Re Execution		The test script which are not fully executed, has the striked out the remaining unexecuted steps of the script and has the tester indicated the reason for the strike out and initial and date in it?			
		Re Execution		The test script is re executed, is that indicated in the first page?			
		Re Execution		Is the step in the test script re executed in accordance with the deviation occurred?			
		Re Execution		Is test execution review done by trained resource?			

Project Specific Compliance Checkpoint (Applicable for all GxP projects)							
Sr. No.	**Section Type**	**Section Name**	**Reviewer/ Auditor**	**Checklist**	**Response**	**Details of documents/activities/Tickets verified**	**Observations**
		Review		Is the CSV review comments captured, executed and tracked for closure (If suggested)?			
		Review		Has the deliverables been reviewed by Client - Business Owner, technical owner, CSV and Quality?			
		Screenshot		Are screenshots available with date and time?			
		Screenshot		Is screenshot captured in relevant steps? Is the attachment# referenced in the step? Is the screenshot clear and readable?			
		Screenshot		Does the hardcopy of the attachment must contain the following information? Test protocol ID #, Test ID #,Step #,Attachment # (Sequential order) ,Page # (incase of multiple screenshot - page x of y format) and Initials & Date at the time of execution			
		Screenshot		Is the attachment log updated?			
		Screenshot		Are the screen shots of different steps combined?			
		Signature		Are any digital image used for signatures?			
		Test Script		Is the test protocols verifying the requirements adequately?			
		Test Script		If the protocol is created for a change? If yes, is the PR for that change, the PR number should be referenced within the protocol?			
		Test Script		Is the test script name and ID mentioned in test script? Note: ID should be in AB-nn format (eg. for IQ document, the test I.D should be IQ-01, IQ-02 and so on. The same applies for the OQ & PQ documents.).			

Project Specific Compliance Checkpoint (Applicable for all GxP projects)							
Sr. No.	**Section Type**	**Section Name**	**Reviewer/ Auditor**	**Checklist**	**Response**	**Details of documents/activities/Tickets verified**	**Observations**
		Test Script		Verify the Specs section, Is the SRS or DS document number or specific requirement number entered? Note: For the test protocols created for system changes, enter PR number, if available. Otherwise, enter NA			
		Test Script		Is Description mentioned stating the purpose of the test script?			
		Test Script		Is the assumptions and pre-requisites specific for the test case mentioned at the Assumptions and Prerequisites section or is N/A mentioned?			
		Test Script		Does the “body” of the test script provide the necessary steps to verify each test case. For each step, is clear instructions and expected results provided?			
		Test Script		Wherever evidences are deemed necessary, are appropriate instructions added in test step accordingly?			
		Test Script		Are all pages present in the protocol?			
		Test Script		Have all resources involved in test execution signed the "Signature Identification Log" prior to performing the activity?			
		Test Script		Is the test script post approved?			
		Test Script		Is the document numbers assigned as per document numbering procedure?			
		Test Script		Is current version used for test protocols, templates and instructions?			
		Test Script		Are the test scripts approved before execution?			
		Test Script		Are the Incident/Deviation status verified before execution of the activity ?			
		VSR		Is the VSR updated to include the details of the completed script?			

Sheet: Audit Schedule

Serial No #	Project ID	Project Name	Auditee	Compliance Auditor	Planned date of audit	Actual Date of audit	Category	Status	Comments

Sheet: Findings Log

Serial No #	Project Name	Auditee	Audit Date	Compliance Auditor	Sampling considered in %	Document's Reviewed	Observation	Severity	Target Closure Date	Root Cause	Impact	Correction	Corrective Action	Preventive action (if any)	Reviewed by	Correction by, Date	Verified and Closed on Date	Status	Remarks