Guidelines for Good Documentation Practices

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A Larsen & Toubro Group Company

Document Authorization

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Compliance Lead	Swati Kochukulam	Refer to e mail authorization	
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Approver			
Compliance COE - Head	G S Vijayakumar	Refer to e mail approval	

Note: Refer to e-mail approval attached at the end of this document

Document History

Version	Change Description	Author	Date
1.00	*Initial version*	*Swati Kochukulam*	*20 Mar 2020*
1.01	*Document title updated from OLS-06-31G-GDP-Guidelines to OLS_01_04G_GDP_Guidelines*	Swati Kochukulam	27 Aug 2020

Table of Contents

1 Introduction

Good Documentation practices are the set of activities that enables a user to record data and hand-written entries in a legible, traceable and reproducible manner.

FDA's 3 golden rules on Proper Documentation says

1. Rule 1 -If it isn't written down, it did not happen
2. Rule 2 - If it isn't written down correctly, it did not happen either
3. Rule 3 - Do not forget Rule1 and Rule2

1.1 Objective

The purpose of this document is to define Good Documentation Practices including but not limited to the method for recording data, providing signatures on official documents, and making changes or corrections to all documents within the Larson's and Toubro Infotech (LTI) Life Sciences accounts and projects.

To lay down guidelines for good documentation practices based on FDA recommendations and industry best practices.

1.2 Scope

The scope covers all documentation of Life Science projects and specifically paper- based executions generated while working in the Life Sciences Business unit of Larson's and Toubro Infotech (LTI).

1.3 Roles and Responsibilities

- **All resources shall be:**
  - Responsible for GxP documentation, to adhere to this standard and carry out the practices defined in this Guideline.
  - Responsible to record entries contemporaneously.

- **Project Manager shall be:**
  - It is the responsibility of LTI Project Manager to ensure that all responsible personnel are trained on GDP practices and that it is followed when cGxP documentation is executed.
  - Shall be accountable for implementation and compliance of this Guideline.

- **Compliance COE Head shall:**
  - Ensure resources are periodically trained on Good Documentation Practices.
  - Ensure verification to adherence of Good Documentation Practices

2 Terms and Abbreviations

Term/Abbreviation	Description
GDP	Good Documentation Practice
cGxP	Current Good X (Manufacturing, Clinical, Lab) practices
COE	Center of Excellence
FDA	Food and Drug Administration, USA

Term/Abbreviation	Description
ALCOA plus	Attributable, Legible, Contemporaneous, Original, Accurate, Consistent, Enduring, Available, Complete, Credible, Corroborated

3 Guidelines

- All documentation shall follow ALCOA plus principles (See Reference section for details)
- All documentation entries shall be made with indelible Blue or Black ink in clear and legible handwriting.
- Do not use correction fluid, eraser, blade, Gel pen, Pencils in any of the document.
- All entries must be made directly on the documents. Do not use “Post-It” notes or scrap paper.
- Overwriting in document shall be strictly prohibited.
- Do not use ditto marks (“ - ”) to repeat entry information and Bracketing(“}”)in any form to provide the same answer to multiple check points.
- Do not backdate or pre-date entries. Contemporaneous documentation is essential
- Do not leave any column blank/unfilled in the document. If any column/section does not require information, write “N/A” (not applicable) with sign and Date as well. Line out with a single line, unused portions of pages after the last entry with Initial and date.
- Sign all entries on the day and time they were made.
- The person who enters the data is the one who must sign entries. If more than one person records data on a page, each person who enters data must sign.
- The raw data stored on a separate document e.g a data print out, Screenshots, etc., shall be signed, dated and either cross referenced or retained within the relevant record. Documents shall be in pagination format, Document ID and version number of documents shall be included in the document. pagination of original document shall not be erased or overwritten.
- Always refer or use the latest approved, effective version of controlled document for any execution.
- Do not replace any executed or master document.
- During execution of activity while documenting if variation in ink happens due to emptying of ink, change of pen while writing etc., need to be addressed with appropriate note.
- When a document requires an entry upon completion of an activity and the activity was performed but not documented contemporaneously, an explanation (by the performer of the activity) as to why there was an omission must be included, signed and dated
- All documents requiring review and approval signatures shall contain the original handwritten signature and date signed. Signature made by rubber stamp or pre-printed labels are not permitted.
- For remote approval, a readable scanned copy with the approval signature on the document or an email approval will be accepted in lieu of an actual wet signature page

- Test results shall not be appended, or modified using objective evidence collected at any other time outside of the script testing

3.1 Signatures/Initials

- A signature/Initial followed by date to be done to authorize all documents as per the requirement.
- Electronic signature as per the document demand shall be carried out if applicable

3.2 Date and Time Recording format

- The recording of dates must be performed consistently and be defined in procedures. The following formats should be used as represented below:
  20-MAR-2020 or 20 MAR 2020 or 20MAR2020.
  Where alternative date formats are used a clear definition of the date format must be specified within the document impacted and any corresponding local procedures.
- The recording of time must be performed consistently and be defined in local site procedures. Time should be recorded in a 24-hour format e.g. 15:00. Where a 12 hour clock time is used this should be clearly defined within the document impacted and any corresponding local procedures and the time must indicate AM or PM e.g. 3:00 PM.

3.3 Correction Procedures

- Corrections shall be made using a clear single line throughout data or record to indicate it is incorrect or erroneous.
- The crossed out data or record shall be followed by the initials of the person making the correction and date on which the correction was made.
- Do not scribble the correction, it should be legible.
- Write the correction or change adjacent to, or as close as possible to, the changed text.
- For all documentation, provide a brief explanation for the correction when not self-evident.
- In the event that a second person must make a correction, the reason for doing so must be explained and corrected as described above.
- The correct entry shall be inserted in a way that clearly indicates that the new entry is a revision on the incorrect entry.
- The abbreviations listed below may be used when appropriate reason :
  - Abbreviation Explanation
  - WE : Writing Error
  - SP Spelling Error
  - CE Calculation Error
  - CL Clarification
- When correcting data, it should be clear what is the Incorrect entry, correct entry, Reason for the correction, Date and person recording the entry.
  Example: ~~01/01/2019~~ Sign/Date Reason
  01JAN2020

- If adequate space to record corrections is not available, reference the comments section if available, a new page and/or location for the correction to be made.
- An asterisk or other symbol (*,#) may be used to reference the explanation provided it is on the same page.
- Multiple errors of the same type may be similarly referenced with unique symbols or footnote numbers.
- If the Recorder is not available to make a correction and a person other than the original Recorder makes a correction, a signature (not initials) and date must be used along with the reason for the correction.

3.4 Guidelines for the Screenshot(s)/Attachment/Annexures/Supporting Documents as objective evidence of Testing

- In Validation activity for successful execution of test script, objective evidence is generally required in the form of screenshot(s) or as per SOP terms. In the absence of any explicit mention in the SOP or protocol, screenshots shall be generated where ever possible.
- The screenshots shall be taken in real time during test step execution by tester.
- The screenshot shall include full screen image of testing device including PC Date / Time.
- The screenshots shall be clear, legible, traceable to test and do not obscure any information.
- Only one monitor shall be used during validation/Testing.
- During validation/ testing other windows shall be closed, else other windows will get captured in screenshots.
- Unique user ID and password, date and time shall be captured for Part 11 related requirements
- When screenshot includes multiple script executions, identify the applicable pages in the test script comment section to support objective evidence requirements
- If Scan copy need to be attached with the master document, reference of the same need to be given in master document and signature and date need to be done with scan copy attachment.
- All the attached annexures adhere to master document need to be signed with date and cross reference for the same need to be present in the master document.
- In case of automated test script execution, evidence shall be provided as attachment in the test management tool as appropriate for review and approval.

3.5 Document Retention

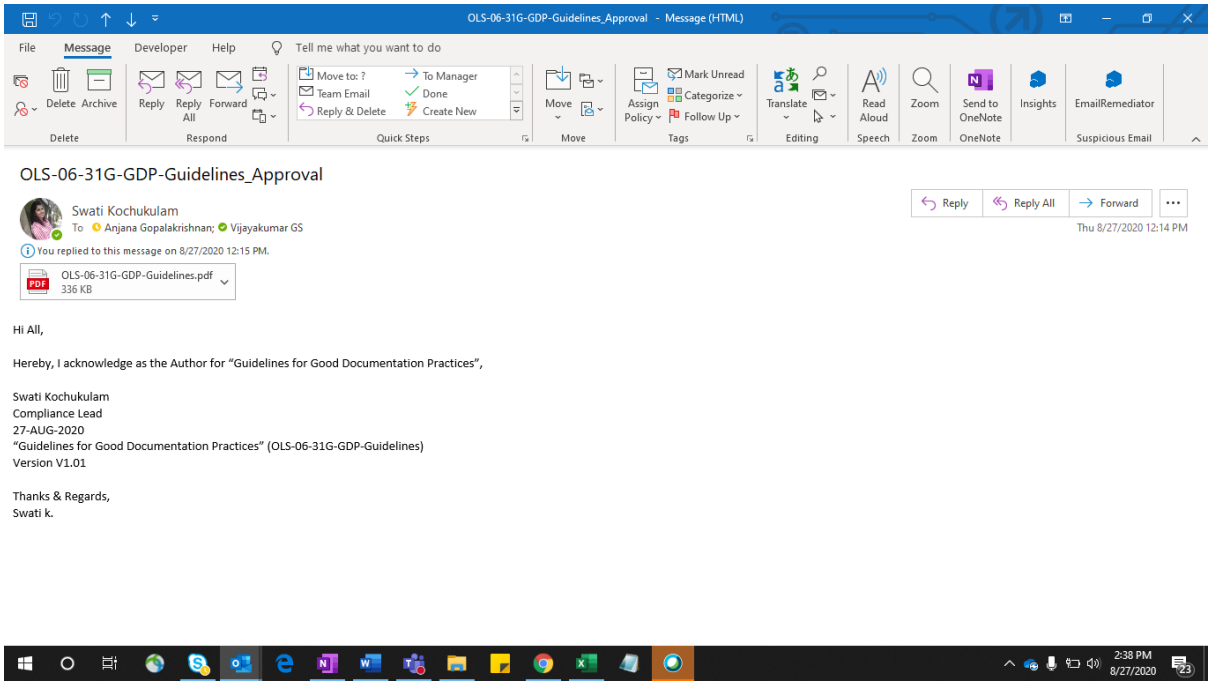
- Document retention shall be performed as per record retention policy defined in “SOP on SOP” for Life Sciences or as specified in the contract.

4 Annexure

NA

4.1 References

- Good Documentation Practices- Guidelines – IPA, Feb 2018 - https://www.ipa-india.org/static-files/pdf/event/ipf2018-presentation22.pdf
- WHO publications - Annex 5-Guidance on good data and record management practices - https://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex05.pdf



OLS-06-31G-GDP-Guidelines_Approval - Message (HTML)

File Message Developer Help Tell me what you want to do

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

OLS-06-31G-GDP-Guidelines_Approval

Swati Kochukulam
To Anjana Gopalakrishnan; Vijayakumar GS

Reply Reply All Forward
Thu 8/27/2020 12:14 PM

You replied to this message on 8/27/2020 12:15 PM.

OLS-06-31G-GDP-Guidelines.pdf
336 KB

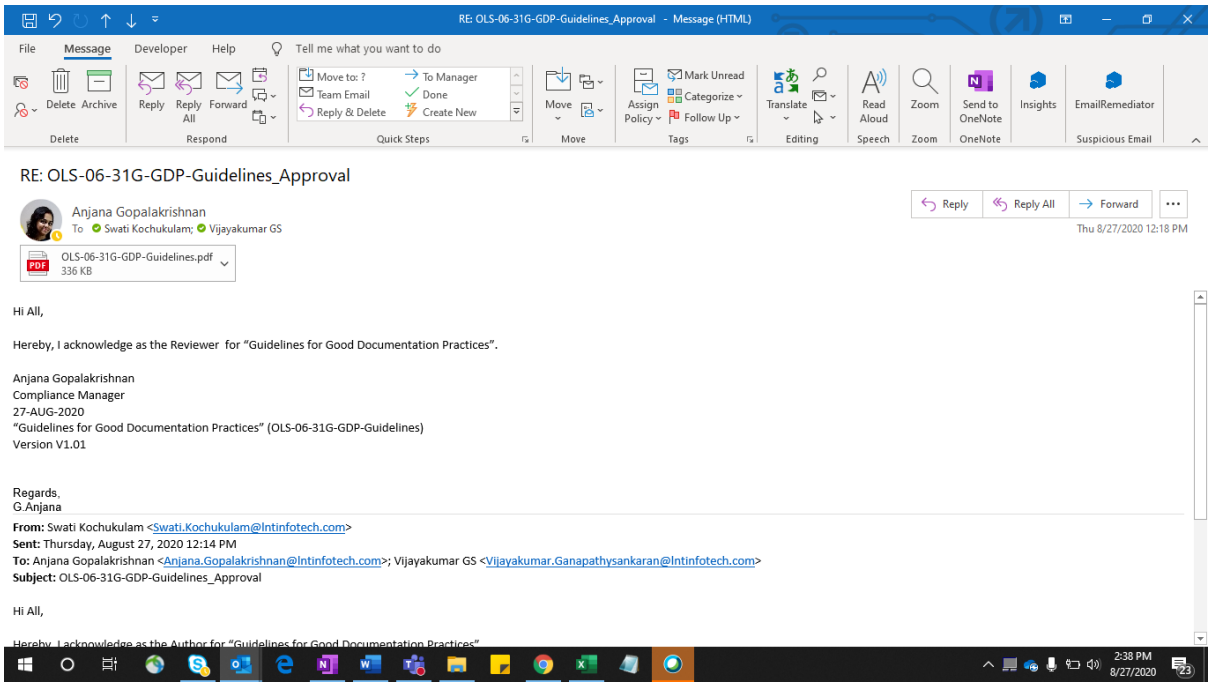
Hi All,

Hereby, I acknowledge as the Author for "Guidelines for Good Documentation Practices",

Swati Kochukulam
Compliance Lead
27-AUG-2020
"Guidelines for Good Documentation Practices" (OLS-06-31G-GDP-Guidelines)
Version V1.01

Thanks & Regards,
Swati k.

2:38 PM
8/27/2020



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RE: OLS-06-31G-GDP-Guidelines_Approval

Anjana Gopalakrishnan
To Swati Kochukulam; Vijayakumar GS

Reply Reply All Forward
Thu 8/27/2020 12:18 PM

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Hi All,

Hereby, I acknowledge as the Reviewer for "Guidelines for Good Documentation Practices".

Anjana Gopalakrishnan
Compliance Manager
27-AUG-2020
"Guidelines for Good Documentation Practices" (OLS-06-31G-GDP-Guidelines)
Version V1.01

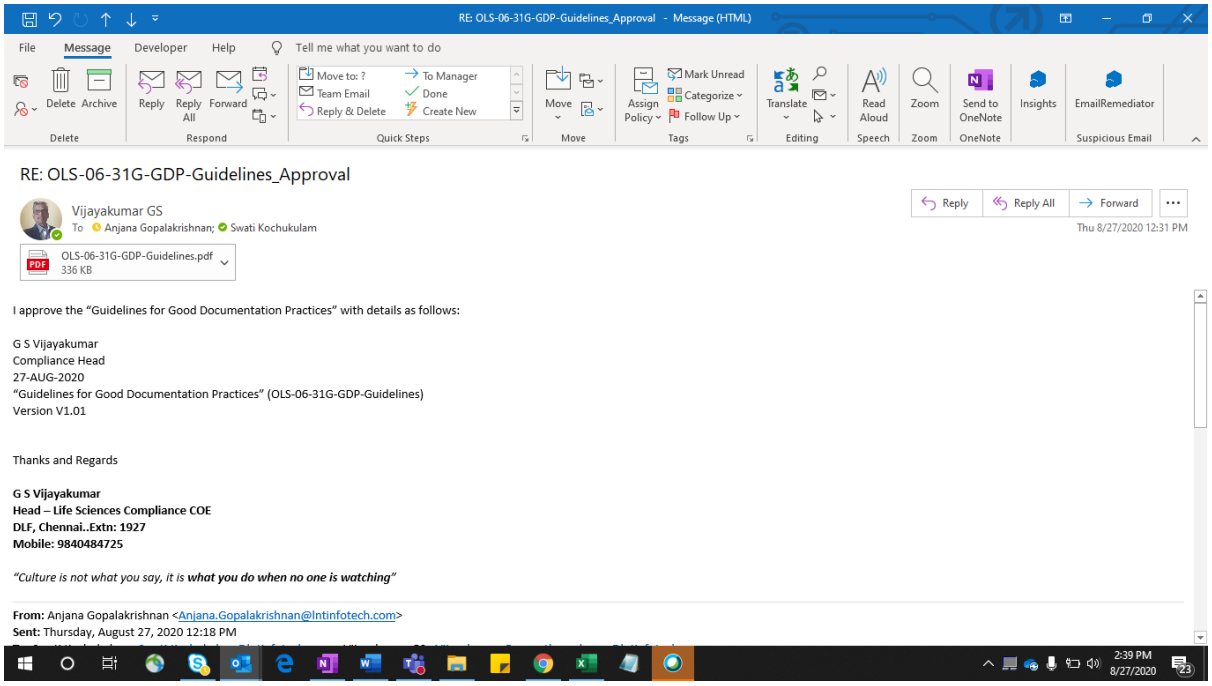
Regards,
G.Anjana

From: Swati Kochukulam <Swati.Kochukulam@Intinfotech.com>
Sent: Thursday, August 27, 2020 12:14 PM
To: Anjana Gopalakrishnan <Anjana.Gopalakrishnan@Intinfotech.com>; Vijayakumar GS <Vijayakumar.Ganapathysankaran@Intinfotech.com>
Subject: OLS-06-31G-GDP-Guidelines_Approval

Hi All,

Hereby, I acknowledge as the Author for "Guidelines for Good Documentation Practices"

2:38 PM
8/27/2020



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

RE: OLS-06-31G-GDP-Guidelines_Approval

Vijayakumar GS
To Anjana Gopalakrishnan; Swati Kochukulam

Reply Reply All Forward

Thu 8/27/2020 12:31 PM

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I approve the "Guidelines for Good Documentation Practices" with details as follows:

G S Vijayakumar
Compliance Head
27-AUG-2020
"Guidelines for Good Documentation Practices" (OLS-06-31G-GDP-Guidelines)
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>
Sent: Thursday, August 27, 2020 12:18 PM

2:39 PM
8/27/2020