| **Title: GxP Assessment for <System Name>** | | Page 1 of 10 |
|---|---|---|
| **Document No.** | <Document No.> | |

# GxP Assessment for <System Name>

**[Appendix 2e-Template of GxP Assessment]**

## APPROVAL PAGE

**Prepared By:**

| Name | Designation | Department | Signature | Date |
|---|---|---|---|---|
| | | | | |

**Reviewed By:**

| Name | Designation | Department | Signature | Date |
|---|---|---|---|---|
| | | | | |
| | | | | |
| | | | | |
| | | | | |

**Approved By:**

| Name | Designation | Department | Signature | Date |
|---|---|---|---|---|
| | | | | |

**[Appendix 2e-Template of GxP Assessment]**

## TABLE OF CONTENTS



## REVISION HISTORY

| Revision No. | Effective Date | Reason for Revision |
|---|---|---|
| | | Initial Document |

**[Appendix 2e-Template of GxP Assessment]**

## 1.0 INTRODUCTION:

## 2.0 PURPOSE:

## 3.0 SCOPE:

## 4.0 RESPONSIBILITIES:

## 5.0 REFERENCES:

## 6.0 DOCUMENT PROCEDURES:

## 7.0 GxP ASSESSMENT CHECKLIST:

This document consists of check list for below listed items:

1. GENERAL INFORMATION
2. GxP ASSESSMENT
3. ELECTRONIC RECORDS APPLICABILITY
4. ELECTRONIC SIGNATURE APPLICABILITY
5. SYSTEM NATURE (OPEN/CLOSE)
6. COMPUTERIZED SYSTEM (SOFTWARE) CATEGORIZATION AS PER GAMP5
7. HARDWARE CATEGORY

(Tick mark "✓" whichever/ wherever is applicable in this document).

**SECTION-A: GENERAL INFORMATION**

| QUESTION | RESPONSE |
|---|---|
| **INSTRUMENT** | |
| 1. Does the system have an instrument? (Respond as Yes/No) | Yes |
| Answer 2 and 3 if 1 is Yes, otherwise mark as NA | |
| 2. Instrument Manufacturer Name and Model No. | Instrument/Equipment Manufacturer:<br>Instrument/Equipment Model No.: |
| 3. Brief description of the Instrument/Equipment | |
| **APPLICATION/SOFTWARE** | |
| 4. Does the System have an Application/ Software? (Respond as Yes/No) | |
| Answer 5 and 6 if 4 is Yes, otherwise mark as NA | |

**[Appendix 2e-Template of GxP Assessment]**

| QUESTION | RESPONSE |
|---|---|
| 5. Application/ Software Name and Application/ Software Version No. | Software Name:<br>Software Version: |
| 6. Brief description of the Application/ Software | |

**[Appendix 2e-Template of GxP Assessment]**

**SECTION-B: GxP ASSESSMENT**

| Q. No. | Questions (for GXP ASSESSMENT) | (√) The Answers |
|---|---|---|
| Q1 | Does the Computerized system impact the patient safety? | ☐Yes ☐No ☐ N/A |
| Q2 | Does the Computerized system functionality create any hazards to the environment including people working on the system such as process control systems? | ☐Yes ☐No ☐ N/A |
| Q3 | Is the system involved in capturing information that would alert the organization to take an action or support the execution of an action that impacts the product quality (e.g. product recall, adverse event reporting)? | ☐Yes ☐No ☐ N/A |
| Q4 | Does the system impact or store or retrieve data about the quality of the product? | ☐Yes ☐No ☐ N/A |
| Q5 | Does the system produce data which is used to accept or reject product? (e.g. Electronic Record System or critical process chart recorder)<br>Note: This data could be supporting data and need not be the only criteria for accepting or rejecting a product? | ☐Yes ☐No ☐ N/A |
| Q6 | Is the system a process control system (e.g. PLC, HMI) that may affect product quality and is there any independent verification of the control system performance in place? | ☐Yes ☐No ☐ N/A |
| Q7 | Is the computerized application/system the official auditable, archive or record of any regulated activity? | ☐Yes ☐No ☐ N/A |
| Q8 | Is the computerized system used to control and/or generate data and documentation to be included in a regulatory submission or otherwise submitted to the FDA, EMEA or other similar regulatory agencies? | ☐Yes ☐No ☐ N/A |
| Q9 | Is the computerized system used as part of the company's Quality System? | ☐Yes ☐No ☐ N/A |
| Q10 | Is the computerized system used to control Quality System documentation? | ☐Yes ☐No ☐ N/A |
| Q11 | Is the computerized system used to control Manufacturing documentation? | ☐Yes ☐No ☐ N/A |
| Q12 | Is the computerized system used to control Verification and Validation documentation or data? | ☐Yes ☐No ☐ N/A |
| Q13 | Is the computerized system used to control any packaging or labeling activities? | ☐Yes ☐No ☐ N/A |
| Q14 | Is computerized system used to track/perform maintenance and/or calibration of testing, laboratory, manufacturing or production equipment? | ☐Yes ☐No ☐ N/A |
| Q15 | Is the computerized system used to maintain purchasing, inventory, or distribution data for the company's products? | ☐Yes ☐No ☐ N/A |

| |
|---|
| **Note:** If answer is "Yes" to any one question, then system shall be categorized as "**GxP Applicable System**" ; else shall be categorized as "**GxP Not Applicable System**" |
| **Conclusion of Section-B :The system is:☐GxP Applicable System ☐GxP Not Applicable System** |
| **Note:** If the system is categorized as "**GxP Applicable System**", then answer the questions of **Section-C**. |

**[Appendix 2e-Template of GxP Assessment]**

**SECTION-C: ELECTRONIC RECORDS APPLICABILITY**

| Q. No. | Questions (for Electronic Records Applicability) | (√) The Answers |
|---|---|---|
| **Q1** | Does the system generate GxP applicable electronic records? | ☐Yes ☐No ☐ N/A |
| **Q2** | Does the GxP applicable electronic records stored on durable media? | ☐Yes ☐No ☐ N/A |
| **Note:** If Answer to both the questions of Section-C are Yes, then Electronic Records is "Applicable" else "Not Applicable" | | |
| **Conclusion of Section-C :Electronic Recordsis:☐Applicable ☐ Not Applicable** | | |

**SECTION-D: ELECTRONIC SIGNATURE APPLICABILITY**

| Q. No. | Questions (for Electronic Signature Applicability) | (√) The Answers |
|---|---|---|
| **Q1** | Does the system has provision to practice Electronic Signature in system? | ☐Yes ☐No ☐ N/A |
| **Q2** | Does the mechanism of Electronic Signature is enabled in the system? | ☐Yes ☐No ☐ N/A |
| **Note:** If Answer to both the questions of Section-D are Yes, then Electronic Signature is "Applicable" else "Not Applicable" | | |
| **Conclusion of Section-D :Electronic Signatureis:☐ Applicable ☐Not Applicable** | | |

**SECTION-E: SYSTEM NATURE (OPEN/ CLOSE)**

**Close System**: An environment in which system access is controlled by persons who are responsible for the content of electronic records that are on the system
**Open System**: An environment in which system access is not controlled by persons who are responsible for the content of electronic records that are on the system

| Q. No. | Questions (for System Nature) | (√) The Answers |
|---|---|---|
| **Q1** | Does the system is Close System? | ☐Yes ☐No ☐ N/A |
| **Q2** | Does the system is Open System? | ☐Yes ☐No ☐ N/A |
| **Conclusion of Section-E :System is:☐Close System ☐Open System** | | |

**[Appendix 2e-Template of GxP Assessment]**

## SECTION-F: COMPUTERIZED SYSTEM (SOFTWARE) CATEGORIZATION AS PER GAMP5

| Q. No. | Questions (for Software Categorization) | (√) The Answers |
|---|---|---|
| Q1 | Are the software functions as operating software used to manage the operating environment of the computerized system?<br>Example: Operating system, Data base etc. | ☐Yes ☐No<br>☐ N/A |
| Q2 | Are the software functions as utility software used to manage the utility function of the computerized system?<br>Example: Anti-virus, Remote access, Printer, Backup solution etc., | ☐Yes ☐No<br>☐ N/A |
| Q3 | Is the computerized system having software, only it is used to perform basic tasks, such as recognizing input from the keyboard, sending output to the display screen, keeping track of files and directories on the disk, and controlling peripheral devices such as disk drives, printers, office tools? | ☐Yes ☐No<br>☐ N/A |
| Q4 | Is the computerized system application software, cannot be configured to suit the business process but runtime parameters can be entered / stored?<br>Example: Setting of the defined recipe, creation of users etc. | ☐Yes ☐No<br>☐ N/A |
| Q5 | Is the computerized system application software, often very complex that can be configured by the user to meet the specific needs of the user's business process, but not possible to alter the source code?<br>Example: LIMS, Data Acquisition, SCADA systems, SAP etc. | ☐Yes ☐No<br>☐ N/A |
| Q6 | Is the computerized system application software custom designed and coded to suit the business process? | ☐Yes ☐No<br>☐ N/A |

**Note:** GAMP 5 categorization of Software with computerized system shall be considered as below:
1: If answer is **Yes** to anyone of the question among Q1 to Q3, but answer is **No or N/A** to all other Questions, then **Category 1 (Infrastructure Software)**.

2: If answer is **Yes** to only question, Q4, but answer is **No or N/A** to all other questions, then **Category 3 (Non configured Products)**.

3: If answer is **Yes** to only question, Q5, but answer is **No or N/A**to all other questions, then **Category 4 (Configured Products)**.

4: If answer is **Yes** to only question, Q6, then **Category 5 (Custom Applications)**.

**Conclusion of Section-F**

The Software system is categorized as: ☐**Category 1**☐ **Category 3** ☐ **Category 4** ☐ **Category 5**

**SECTION-G: Hardware Category**

**Category 1: Standard Hardware Component**

Standard hardware components should be documented including manufacturer or supplier details and version numbers. IQ should verify installation and connection of components. The model, version number and where available, serial number of pre-assembled hardware should be recorded.

**Category 2: Custom built (Bespoke) Hardware Components**

In addition to hardware category 1 requirements, bespoke items of hardware should have a design specification and be subjected to acceptance testing. A supplier audit should be performed for bespoke hardware development. Assembled systems using bespoke hardware from different sources require verification confirming compatibility of interconnected hardware components. Any hardware configuration should be identified in the design documentation and verified in the IQ.

**Conclusion of Section-G:**

**System is:** ☐ **Category 1: Standard Hardware Component**

☐ **Category 2: Custom built (Bespoke) Hardware Components :**

**[Appendix 2e-Template of GxP Assessment]**

## 8.0 OVERALL ASSESSMENT CONCLUSION:

The above Impact Assessment carried out for system in scope and conclusions are as below:

| Section | Title | Outcome |
|---|---|---|
| B | GXP ASSESSMENT | ☐GxP Applicable System<br>☐GxP Not Applicable System |
| C | ELECTRONIC RECORDS APPLICABILITY | ☐Applicable ☐Not Applicable |
| D | ELECTRONIC SIGNATURE APPLICABILITY | ☐Applicable ☐ Not Applicable |
| E | SYSTEM NATURE (OPEN / CLOSE) | ☐Close System<br>☐Open System |
| F | COMPUTERIZED SYSTEM (SOFTWARE) CATEGORIZATION AS PER GAMP5 | ☐Category 1 ☐Category 3<br>☐Category 4 ☐Category 5 |
| G | HARDWARE CATEGORIZATION | ☐Category 1 ☐Category 2 |