**Software Validation Form**

|  |  |
| --- | --- |
| TITLE: |  |
| AUTHORING GROUP: |  |
| DATE: |  |
| SUPERSEDE PROTOCOL NO.: |  |

**TABLE OF CONTENT**

|  |  |  |  |
| --- | --- | --- | --- |
| **Sr. No.** | **Contents** | | **Page No.** |
|  | **Information about the Software** | |  |
|  | **Intended Use and Use Context** | |  |
|  | **Quality Relevance** | |  |
|  | 3.1 | Criterion |  |
| **4.** | **General Assessment** | |  |
|  | 4.1 | Software Category |  |
| 4.2 | Risk Assessment |  |
| 4.3 | Critically and Review Schedule |  |
| **5.** | **Validation Plan** | |  |
|  | 5.1 | Participants |  |
| 5.2 | Test Environment |  |
| 5.3 | Testing Procedure |  |
| **6.** | **Validation Report and Requirements** | |  |
|  | 6.1 | Acceptance Criteria |  |
| 6.2 | Validation of Usage Requirements |  |
| 6.3 | Validation of Technical Requirements |  |
| 6.4 | Summary of Validation |  |
| 6.5 | Conclusion |  |
| **7.** | **Proof of Validation** | |  |
| **8.** | **Approval and Release** | |  |
| **9.** | **History** | |  |
| **10.** | **Annex: Additional Information for Critically Classification** | |  |

# <GMP Software> - Software Validation Form

## 1. Information about the Software

|  |  |
| --- | --- |
| QMS ID | <ID> |
| Name | <GMP Software Pvt.Ltd> |
| Version | <x.x.x> |
| Location | <url> |
| Processes | <processes in which this tool is used> |

**2. Intended Use and Use Context**

Describe intended use and usage context (e.g. automation, testing, control, altering). Include technical and usage requirements that the system shall fulfill.

**3.** **Quality Relevance**

Rate these aspects with yes (y) or no (n). If any of these aspects are rated as yes, the system is quality relevant and should be validated.

| **Criterion** | **Y/N** |
| --- | --- |
| Is the system used in one or more processes that steer the QMS? |  |
| Could the conformity of the organization’s medical devices be affected if the system does not work according to its specifications? |  |
| Could risks arise for patients, users, third parties or the organization if the system does not work according to its specifications? |  |
| Does the software generate or manage data / records that are relevant to the QMS or medical device approval by authorities? |  |
| Is the software used to generate electronic signatures on documents or records required by the QMS and/or state authorities? |  |

1. **General Assessment** 
   1. **Software Category**

* Infrastructure software (e.g. operating systems, databases, office applications, antivirus, network management software) (GAMP category 1)
* Non-configurable software (GAMP category 3)
* Configurable software (GAMP category 4)
* Custom (self-developed) software (GAMP category 5)

**4.2 Risk Assessment**

**List of Risks:**

* <list of risks>

**List of Risk Mitigation Measures (if necessary):**

* <list possible risk mitigation measures>

**4.3 Critically and Review Schedule**

*Refer to section 10 for descriptions of the criticality classifications. If a software is not highly critical and widely adopted / commonly used, it can be continuously re-validated during use.*

* **Low** (review upon major changes)
* **Moderate** (review every year)
* **High** (review every 6 months)

1. **Validation Plan** 
   1. **Participants**

| Role | Name | Task(s) |
| --- | --- | --- |

* 1. **Test Environment**
* Software tool accessed with <Windows 10 20H2 on Google Chrome 88.0.4324.150>
* Reference User Manual
  1. **Testing Procedure**
* Run software system on sample data

1. **Validation Report and Requirements**

**6.1 Acceptance Criteria**

The software is approved for use if it is validated successfully and works as expected.

**6.2 Validation of Usage Requirements**

| ID | Expected | Result | Pass? |
| --- | --- | --- | --- |
| U1 | e.g. “A radiologist can log in with their email and password.” | “Login with correct email and password grants access to the annotation tool.” | yes |
|  |  |  |  |

**6.3 Validation of Technical Requirements**

| ID | Expected | Result | Pass? |
| --- | --- | --- | --- |
| T1 | e.g. “Execute correctly in the specified runtime (Google Chrome).” | “The application runs correctly in Google Chrome.” | yes |
|  |  |  |  |

**6.4 Summary of Validation**

| Type | Total | Pass | Fail |
| --- | --- | --- | --- |
| Usage Requirements | 1 | 1 | 0 |
| Technical Requirements | 1 | 1 | 0 |

**6.5 Conclusion**

Approving the software for use is recommended due to the acceptance criteria being fulfilled completely.

1. **Proof of Validation**

You can optionally insert screenshots for proof of validation. Strictly speaking, this is not a hard requirement by the standards but it’s nice to show when you’re being audited.

U1 <insert screen short>

T1 <insert screen short>

1. **Approval and Release**

| Date of Approval | Name of Approver |
| --- | --- |
| <date> | <name> |

1. History

| Date | Name | Activity |
| --- | --- | --- |
|  |  | <Initial Approval> |

9. **Annex: Additional Information for Critically Classification**

**GAMP Implications**

* GAMP 5 always leads to “high” software critically
* GAMP 4 always leads to a “high” or “moderate” software criticality, depending on further risk assessment in step 4.2
* GAMP 1 and 3 typically leads to a “low” or “moderate” software criticality, depending on further risk assessment in step 4.2

**Criticality High**

* A software failure can lead to physical harm requiring medical intervention
* Software controls parameters or data that are essential during product release
* Software manages data relevant for clinical evaluation or product approval
* Software manages data from which conclusions about incident messages or recall actions are drawn

**Criticality Moderate**

* A software failure can lead to physical damage requiring medical intervention
* Software administers documents whose loss endangers the certification
* Software controls intermediate results in the product realization, which are revealed in later steps by other processes

**Criticality Low**

* Software manages documents that play a role in the QM system, and whose loss would lead to an audit variance