**Periodic Validation Review Report**

***[System Name]***



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**V.1.0**

**16 August 2017**

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# Introduction

## Purpose

The purpose of this Periodic Validation Review Report is to document the assessment of the [name] system’s state of validation, i.e., compliance with regulations, fitness for intended use, and in conformance with company policies and procedures.

## Scope

### System Description

Describe the system that is covered within this Periodic Validation Review Report. Include a brief description of the business processes within which the system is used.

### Periodic Validation Review Scope

Describe the scope of the system features (e.g., all features, only validated features, only some modules) covered within this Periodic Validation Review Report.

Identify the time frame covered within this Periodic Validation Review Report, e.g, from the time of initial validation on dd-mmm-yyyy through dd-mmm-yyyy, from the date of the last Periodic Validation Review in month/year until today.

## Definitions, Acronyms, and Abbreviations

| **Term** | **Definition** |
| --- | --- |
| FRS | Function Requirements Specification |
| SOP | Standard Operating Procedure |
| URS | User Requirements Specification |
| PVR | Periodic Validation Review |
| etc. |  |

## References

Identify references to any published work used to prepare this Periodic Validation Review and any documents referenced within this Periodic Validation Review.

# Periodic Validation Review Summary

## Summary of Gaps

The following table summarizes the gaps identified during the periodic validation review of [system name]. Additional details regarding each gap can be found in the Periodic Validation Review Details section of this document

| **Gap Summary** | | |
| --- | --- | --- |
| **Gap ID** | **Gap Title** | **Gap Description** |
| Unique ID | Brief title for gap | Write a short description of the gap that is described in more details in the “PVR Details” section of this document.  *For example,*   * The audit trail functionality of System X does not meet current regulations defined in … * The current use of System X for electronically signing SOPs is beyond the scope of validated system functionality * The performance of System X has degraded to a level where users have stopped using system.to… |
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## Closure of Gaps

Describe the method for tracking the closure of the gaps identified in the section above. For example:

The CAPA process, as defined in SOP QMS-x-xx Corrective and Preventive Actions, will be used to document the approach, timeline, and responsibility for closing each gap and for tracking each gap until closed.

# Periodic Validation Review Details

## Regulatory Expectations

List the regulations that apply to the regulated activities supported by the system. Identify the date of the last revision to each regulation.

| **Applicable Regulations** | | | |
| --- | --- | --- | --- |
| **Agency** | **Regulation** | **Regulation Name** | **Effective Date** |
| FDA | 21 CFR 11 | Electronic Records; Electronic Signatures | 20-AUG-1997 |
|  |  |  |  |
|  |  |  |  |

List any additions or changes made to these regulations during the PVR time frame and applying to the activities supported by the system. For each change, assess whether or not the system complies with the new or revised regulatory requirements.

| **Regulation Review** | | |
| --- | --- | --- |
| **Regulation** | **New or Changed Requirement** | **Compliance Assessment** |
|  |  |  |
|  |  |  |
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List any regulatory guidance documents that apply to the activities supported by the system. Identify the date of the last revision to each regulatory guidance document.

| **Applicable Regulatory Guidance** | | |
| --- | --- | --- |
| **Agency** | **Regulatory Guidance Name** | **Effective Date** |
| FDA | Q7 Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients | September, 2016 |
|  |  |  |
|  |  |  |

List any additions or changes in these guidelines made during the PVR time frame and applying to the activities supported by the system. Assess whether or not the system conforms to the new or revised regulatory guidelines.

| **Regulatory Guidance Review** | | |
| --- | --- | --- |
| **Regulatory Guidance** | **New or Changed Guideline** | **Conformance Assessment** |
|  |  |  |
|  |  |  |
|  |  |  |

If any gaps are identified in this section, record the gap(s) in the PVR Summary section of the report. If no gaps are identified, state a conclusion that the system continues to meet regulatory expectations.

## Intended Use

Identify the User Requirements Specification(s) that identify the intended use of the system for performing regulated activities. Identify the approval date of the latest version of each User Requirements Specification (URS).

| **User Requirement Summary** | | |
| --- | --- | --- |
| **URS ID** | **URS Document Name** | **Approval Date** |
| URS-System X-v1 | User Requirements for System X | 03-MAR-2014 |
| URS-System X-Reports-v1 | User Requirements for Crystal Reports for System X | 31-AUG-2014 |
|  |  |  |

List the SOPs that describe how users perform the regulated activities supported by the system. Identify the effective date of the latest version of each SOP.

| **Applicable SOPs** | |
| --- | --- |
| **Procedure ID & Name** | **Effective Date** |
| SOP-901 Authoring Documents in System X | 01-MAY-2014 |
| SOP-900 Signing Documents Electronically in System X | 04-JUL-2015 |
|  |  |
|  |  |

Assess the URS(s) and SOPs to determine whether the User Requirements cover all current, regulated uses of the system. Record any current, regulated uses not described within the User Requirements.

| **Review of Current Use** | |
| --- | --- |
| **#** | **Current Use Not Within URS** |
| 1 | System X is being used to electronically sign GxP documents; however, use of electronic signatures was not part of the system’s documented user requirements and has not been validated. |
|  |  |
|  |  |

If any gaps are identified in this section, record the gap(s) in the PVR Summary section of the report. If no gaps are identified, state a conclusion that the system continues to be used as intended and validated for regulated activities.

## System Issues

List all of the System Incidents reported for the system during the PVR time frame. Provide the incident date, a brief description, and the current status (e.g., open, closed).

| **Incident Summary** | | | |
| --- | --- | --- | --- |
| **Incident ID** | **Incident Date** | **Incident Description** | **Incident Status** |
| IT-00005 | 02-MAY-2014 | Error message when uploading a PDF | Resolved |
| IT-00018 | 03-MAY-2014 | User needed help re-entering reason for rejection | Resolved |
| IT-02246 | 11-AUG-2014 | User locked out after forgetting password | Resolved |
| IT-02518 | 14-AUG-2014 | User requested assistance in using rejection codes | Resolved |
| IT-02701 | 31-AUG-2014 | LA site reported extreme system slowness | Open |
|  |  |  |  |
|  |  |  |  |

List all CAPAs recorded during the PVR time frame where the system was cited as the root cause of the issue. Provide the CAPA date, a brief description, and the current status (e.g., open, closed).

| **CAPA Summary** | | | |
| --- | --- | --- | --- |
| **CAPA ID** | **CAPA Date** | **CAPA Description** | **CAPA Status** |
| CP-14-026 | 09-SEP-2014 | Error in lab testing due to problem with SOP in System X | Closed |
| CP-16-229 | 02-FEB-2016 | Failed to identify quality issue due to improper use of rejection codes in System X | Ongoing Investigation |
|  |  |  |  |

### Technology Issues

Assess the Incidents and CAPAs listed above to identify any technical issues, e.g., performance, security, reliability, which are impacting the ability to use the system for regulated activities. Summarize the issue and describe the impact.

| **Review of Technical Issues** | | |
| --- | --- | --- |
| **#** | **Technology Issue** | **Impact** |
| 1 | System response times are very slow at the LA site | Users at the LA site are often resorting to the use of paper copies of documents which could be out of date. |
|  |  |  |
|  |  |  |

If any gaps are identified in this section, record the gap(s) in the PVR Summary section of the report. If no gaps are identified, state a conclusion that the system continues to function in a manner suitable for intended use in regulated activities.

### Training Issues

Assess the Incidents and CAPAs listed above to identify any training issues, e.g., frequent user errors, which are impacting the ability to use the system for regulated activities. Summarize the issue and describe the impact.

| **Review of Training Issues** | | |
| --- | --- | --- |
| **#** | **Training Issue** | **Impact** |
| 1 | Many users do not fully understand the functionality for rejection codes and are making errors. | QA management could miss a negative trend in product quality if the rejection coding is incorrect or inconsistent. |
|  |  |  |
|  |  |  |

If any gaps are identified in this section, record the gap(s) in the PVR Summary section of the report. If no gaps are identified, state a conclusion that the system users continue to be able to be able to operate the system for intended use in regulated activities.

## Change Management

List all of the changes made to the system during the PVR time frame. Provide the change ID, change date, and a brief description.

For each change:

1. Assess whether the change was tested prior to implementation to confirm required functionality and suitability for use. In the table, record “Yes” (tested adequately), “No” (not tested adequately), or “N/A” (change did not require testing).
2. Assess whether impacted system documentation, e.g., Requirements, Designs, Configuration Specifications, Trace Matrices, were updated to reflect the change. In the table, record “Yes” (updated correctly), “No” (not updated correctly), or “N/A” (change did not impact any system documentation).
3. Assess whether impacted SOPs and training materials were updated to reflect modifications to the system’s functionality, user interface, or reports. In the table, record “Yes” (updated correctly), “No” (not updated correctly), or “N/A” (change did not impact any SOPs or training materials).

| **Change Summary and Review** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Change ID** | **Change Date** | **Description** | **Tested** | **Documentation Updated** | **SOPs & Training Updated** |
| CR-X-001 | 01-JUL-2014 | Added memory to data server | Yes | Yes | N/A |
| CR-X-002 | 15-JUL-2014 | Added new code to rejection code list | Yes | Yes | Yes |
| CR-X-003 | 31-AUG-2014 | Implemented Crystal Reports for use with System X | Yes | Yes | Yes |
|  |  |  |  |  |  |

If any gaps are identified in this section, record the gap(s) in the PVR Summary section of the report. If no gaps are identified, state a conclusion that as changes were made to the system, appropriate testing was performed and the associated system documentation, SOPs, and training materials were updated.

## Validation Documentation

Identify all of the validation deliverables listed in the Validation Plan and Validation Report for the last full validation of the system. For each deliverable, confirm that it is still available for presentation during an audit or inspection and note the location (e.g., building and room ID, system ID)

| **Full Validation Documentation Summary and Review** | | |
| --- | --- | --- |
| **Deliverable ID & Name** | **Available** | **Location** |
| PJ-0123 Validation Plan | Yes | RR-001 Box 17 |
| PJ-0123 Functional Requirements Specification | Yes | RR-001 Box 18 |
| PJ-0123 IQ-001 System X Server Installation | Yes | RR-001 Box 19 |
|  |  |  |

List all of the changes made to the system during the PVR time frame. Provide the change ID, change date. [NOTE: list can be copied from “Change Management” section above]

For each change:

1. List the validation deliverables required, per the associated Change Request or Validation Plan
2. Confirm that all deliverables are still available for presentation during an audit or inspection
3. Note the location of the deliverables (e.g., building and room ID, system ID)

| **Change Validation Documentation Summary and Review** | | | | |
| --- | --- | --- | --- | --- |
| **Change ID** | **Change Date** | **Deliverable List** | **Available** | **Location** |
| CR-X-001 | 01-JUL-2014 | Architecture Design, IQ | Yes | Site DMS |
| CR-X-002 | 15-JUL-2014 | FRS, Configuration Specification, OQ/PQ | Yes | Site DMS |
|  |  |  |  |  |

If any gaps are identified in this section, record the gap(s) in the PVR Summary section of the report. If no gaps are identified, state a conclusion that all system validation documentation has been retained and is available for audits and inspections.

## Validation Procedures

List all of the changes that have been made to the computer system validation process during the PVR time frame. For each computer system validation procedure and templates, provide the document ID, name, version number, change IDs, dates, and summary of changes

| **Validation Procedure Change Summary** | | | |
| --- | --- | --- | --- |
| **Doc ID & Name** | **Document Version & Date** | **Change ID** | **Change Summary** |
| SOP-100 Computer Validation | 1.0 01-JAN-2014 | CR-14920 | Original version of SOP |
| SOP-100 Computer Validation | 1.1 15-MAR-2015 | CR-15101 | Added requirement for System Owner approval of Testing Plans |
| SOP-100 Computer Validation | 2.0 05-JAN-2017 | CR-16811 | Complete rewrite of SOP to align with GAMP 5 methodology |
| SOP-101 Validation Testing Standards | 1.0 05-JAN-2017 | CR-16812 | Original version of SOP |
|  |  |  |  |

Assess the validation documentation listed above in the “Validation Documentation” section to identify any gaps between this documentation and the current version of the Validation Procedure(s) listed in the table above. Summarize any issues and describe the impact.

| **Validation Procedure Change Review** | | |
| --- | --- | --- |
| **ID** | **Procedure Change** | **Validation Impact** |
| 1 | Version 2.0 of SOP-100 requires a Risk Assessment for each system. | There is no Risk Assessment for System X because it was validated before v2 of SOP-100 went into effect. |
| 2 | SOP-101 requires negative testing and boundary testing for critical, custom-developed features. | Many critical, custom features of system X are missing negative testing and boundary testing because the system was validated before SOP-101 went into effect. |
|  |  |  |

If any gaps are identified in this section, record the gap(s) in the PVR Summary section of the report. If no gaps are identified, state a conclusion that the system continues to meet the organization’s current validation standards.

## Supporting Procedures

List the SOPs that support the regulatory compliance of the system, e.g., User Access Management, Audit Trail Review, Back-Ups. Identify the effective date of the latest version of each SOP.

For each procedure, assess a sampling of the output of each procedure to assess whether it is being followed. In the table, list the sample set (e.g., back-up dates, user access requests) and the conclusion regarding compliance with the SOP.

| **Supporting Procedure Summary and Review** | | | |
| --- | --- | --- | --- |
| **Procedure ID & Name** | **Version & Effective Date** | **Sample Set** | **Compliant** |
| SOP-200 User Access Management | 1.7 11-JUN-2014 | Requests 50, 100, 150, & 200 | Yes |
| SOP-210 System Back-Up | 1.1 12-MAY-2014 | Back-up logs for 15-JUN-2014, 15-DEC-2014, 15-JUN-2015, 15-DEC-2015, 15-JUN-2016 | Yes |
|  |  |  |  |
|  |  |  |  |

If any gaps are identified in this section, record the gap(s) in the PVR Summary section of the report. If no gaps are identified, state a conclusion that the system continues to be supported by the procedures required for regulatory compliance.

# Revision History

|  |  |  |  |
| --- | --- | --- | --- |
| **Document Version Number** | **Document Revision Date** | **Revisions Made By:** | **Revision Summary**  *(Reference section[s] changed)* |
| 1.0 |  |  | Original Version |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

# Approvals

Signature(s) below indicate agreement with the contents of this Periodic Validation Review Report as an accurate representation of the [name] system’s state of validation, i.e., compliance with regulations, fitness for intended use, and in conformance with company policies and procedures..

|  |  |  |  |
| --- | --- | --- | --- |
| Document Prepared by: | | | |
| Function | Name | Signature | Date |
|  |  |  |  |

Signatures below additionally signify approval of this Periodic Validation Review Report.

| Document Approvals: | | | |
| --- | --- | --- | --- |
| Function | Name | Signature | Date |
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