General Instructions:

* This template can be used as the Validation / Assurance (V/AP) template. Margins, Headers, text and page formatting are pre-filled for consistency in format. DO NOT MODIFY STYLES.
* Blue text is sample text. Select the appropriate value or remove.
* Delete or replace all red text in final version. All text must be black in the final version.
* Black text is required and must be addressed in the template.

# PURPOSE

Provide a brief and general statement defining the purpose of the Validation / Assurance Plan, such as a new system implementation, major upgrade, etc.

This Validation / Assurance Plan (V/AP) describes the overall software assurance and testing activities for the <Computer System Name>, overall classified as a GAMP5 <Category 3 - COTS, Category 4 – Configured, Category 5 – Custom> application. Specifically, this V/AP defines the approach for documenting the evidence to demonstrate that this computer system has been installed accurately, operates reliably and is functioning per intended use and <System Requirements Specification>.

Compliance Group procedure XXXXXXX, *Computer Software Assurance*, is the guiding procedure for the creation and execution of the Validation / Assurance Plan.

This V/AP will:

* Define the software assurance strategy to be adopted
* Describe the organization and responsibilities
* Describe the assurance testing process
* Describe the structure of the software assurance documentation
* Define the required software assurance documentation deliverables

# SCOPE AND OVERVIEW

In this section provide the assurance scope. Include major system components or modules if data migration is involved and any planned exclusions.

## In-scope

In-scope will ensure the system is adequately documented, installed as specified and operating as intended. Specifically, this will include:

* Development of system requirements specifications per procedure XXXXXXX
* Development of system build specifications per XXXXXX
* Installation verification (IQ) of the Quality (QA) environment for the database and application
* Functional verification (OQ) of the user application
* Data migration from the legacy system
* Installation verification (IQ) of the Production (PROD) environment
* Performance testing (PQ) of the Production (PROD) environment

## Out-of-scope

The following activities are considered out-of-scope for this software assurance effort.

* Infrastructure qualification
* Systems which provide data to this system
* Network qualification

## System Overview

Provide a high-level overview of the system, including its intended use. Include general information about the basic system functionality, utilization, system name, location, major components, and software categorization. This is basic orienting information to better understand what business processes and records the system manages.

### Description of System

Intelex is an enterprise, configurable documentation lifecycle tool. It is intended to be used as the repository for controlled documents, part drawing, Nonconformances and CAPAs. Intelex features fully configurable review and approval workflows. It further allows content to be segregated into vaults with unique permissions to protect sensitive data.

### System Diagram

A picture is worth 1000 words. Provide something like workflow drawings (simplified) or a records hierarchy with relationships. This is intended to help an auditor or user understand what this system does. If a System Description is created, reference it here rather than repeat the image.

### Component Identification

This provides a list of major aspects of the system: workflows, modules, database, application, etc.

1. Component Identification

| **Module Name** | **Description** | **Comments** |
| --- | --- | --- |
| Oracle R12 | Base system name | Used for authentication and base functions |
| EBS |  |  |

## System Categorization

1. Component Identification

| **Component Name** | **Categorization** | **Purpose** |
| --- | --- | --- |
| Oracle Database | Category 3 | Oracle databases utilized to store configuration settings, system settings and data. |
| Oracle software | Category 4 | Configurable software used to create functional workflows |
| Crystal Report | Category 5 | Custom reports designed to meet business requirements |
|  |  |  |

## Background

Provide any needed background (corporate strategies, previous studies). Refer to the user requirements if needed. For system previously validated:

The <Computer System Name> was assessed as a GxP system per procedure XXXX-SOP*, XXXXX* <with / without> electronic records and <with / without> electronic signatures. The results of this assessment can be found in the *Compliance Assessment*, XXXXXX.

# ROLES AND RESPONSIBILITIES

The responsibilities listed are the primary responsibilities for the identified roles. This is not intended to be an all-inclusive list, limiting any resource from supporting the validation initiative, as needed. Additional resources or designees may be assigned, as needed.

The BPO, SO, Validation and Quality roles are required. Other roles are optional and may be added as needed.

1. Roles and Responsibilities

| **Role** | **Name** | **Responsibilities** |
| --- | --- | --- |
| Business Process Owner (BPO) | Name | * This column may be deleted unless there are unique responsibilities outside or different from XXXX-SOP, XXXXX. If deleted, resize the table to 100%. |
| Quality Assurance (QA) | Name |  |
| Subject Matter Expert (SME) | Names |  |
| System Owner (SO) | Name |  |
| Validation | Name |  |

# TERMS, ACRONYMS and DEFINITIONS

Include any definitions, abbreviations or acronyms used by the system. It is not necessary to include any terms defined in the IT procedures. These should be unique to the computer system, and not commonly recognized. If no definitions are required, write “Not applicable.”

## ANDA – Abbreviated New Drug Application

## EBR – Electronic Batch Record

# Environments

Define the computer system’s landscape.

The computer system’s changes progress through a series of environments during the development and validation processes. The following environments are used to deploy: Development, Integration, Quality, Training and Production. Specific development, training and validation activities occur in each environment as defined in the table below. A “Sandbox” environment is leveraged to work out the feasibility of software solutions to business needs.

1. Environments

| **Environment** | **Activities** | **Comments** |
| --- | --- | --- |
| Development | Supports the creation and integration of new and revised functionality. | This is not a controlled environment. Once changes are made here and developer tested for proper functionality, changes are moved to Quality for formal testing activities.  This system does not have a Quality environment. After developer testing is complete, DEV will be locked from further changes, managed as a Quality environment for testing purposes, and upon successful completion, demoted back to a Development environment. |
| Quality | Support validation testing activities such as executing Installation Qualification (IQ), Operational Qualification (OQ)  Equivalent to the Production environment in terms of configuration and functionality  Representative data is sufficient to support the use of the environment for qualification testing  This environment is required to be qualified and is placed under change control after go-live. | Configuration is <moved / keyed / installed> to the Quality environment after the design is accepted by stakeholders and the governing Change Control is approved for QA.  Configuration changes may be made to the QA environment, provided an impact on requirements and testing has been evaluated.  Code shall be setup/migrated using appropriate test cases. QA is a controlled environment and objective evidence of configuration shall be captured by means of formal test cases, forms and/or defect resolution, following a risk-based approach. |
| Production | The Production (PROD) environment is the end-user application, released for business use upon completion of all activities defined in this plan.  This environment is required to be qualified and is placed under change control after go-live. | Configuration changes are <moved / keyed / installed> to Production environment after all test cases executed in the Quality environment are passed and closed.  No configuration changes are made to the Production environment, except for those configurations that are environment specific, unless an assessment of requirements and testing has been completed and stakeholders have approved the change.  PROD is a controlled environment and risk-based objective evidence of changes related to the Release shall be captured by means of formal test cases, forms and/or deviation resolutions. |

# ASSURANCE STRATEGY

The activities defined in this V/AP are intended to provide the objective evidence necessary to ensure that the <Computer System Name> is correctly installed in the QA and PROD environments and meets its intended use. Testing approaches are determined by procedure XXXXX-SOP, *Computer Software Assurance* and XXXXX-SOP, *Computer Software Assurance Risk Assessment / Test Assurance*. The sequence of qualification activities is defined below.

## Installation in Quality (QA) Environment

This text may be revised as appropriate. Merge the IQ and OQ sections together if an IOQ is planned. The same rule applies to Appendices.

Installation Qualification (IQ) of the Quality (QA) environment shall be conducted to ensure the Quality environment is installed and configured per the design specifications for the system. The Installation Qualification tests that shall be performed are defined in the Appendix A of this V/AP.

## Operation in Quality (QA) Environment

This text may be revised as appropriate. Merge the IQ and OQ sections together if an IOQ is planned. The same rule applies to Appendices.

Once the installation of the Quality (QA) environment has been successfully verified and test cases approved, the Operation Qualification (OQ) may commence. The Operation Qualification tests that shall be performed are defined in the Appendix B of this V/AP.

## QA Environment Release

To release QA approve an initial version of the Validation / Assurance Report (V/AR).. In lieu of an initial report for QA, a test case may be used to verify everything committed to be completed prior to advancing to PROD is complete. This text may be revised as appropriate

Upon completion of the IQ and OQ in the Quality (QA) environment and approvals of OQ test cases, a release test case will be executed to inventory the completed deliverables, with testing reports, against the requirements defined in the Validation / Assurance Plan (V/AP) for the QA environment, including the outcome of the Installation and Operation testing and approved documentation. As this test case summarizes all activities in the QA environment, it is considered equivalent to a written report.

## Installation in Production Environment

This text may be revised as appropriate.

IQ of the Production environment shall be conducted to ensure the Production environment is installed and configured per the design specifications for the system and that the Production environment is equivalent to the qualified Quality environment. The Production Installation Qualification tests that shall be performed are defined in the Appendix C of this VQP.

## Performance in Production Environment

This text may be revised as appropriate. Consider stress or performance testing as a PQ, as needed.

Upon successful completion of the IQs in the Production environment, PQ testing may commence. The Performance Qualification tests that will be executed are defined in the associated Change Control or Validation / Assurance Plan (V/AP). <Given that the OQ testing includes end-to-end business scenarios, traditional PQ user testing may not be performed. Testing in Production may be limited to the system response times to perform system performance baselines on common user activities. /The Performance Qualification tests that shall be performed are defined in the Appendix D of this V/AP.>

## Validation / Assurance Report (V/AR)

This text may be revised as appropriate.

Upon successful approval of all documentation and completion of all testing, a Validation / Assurance Report (V/AR) shall be issued to summarize the close of the V/AP. Approval of the report shall provide authorization to close the Validation / Assurance Plan (V/AP).

# ASSURANCE ACTIVITIES AND DELIVEARABLES

The following table is instructional and includes considerations for cloud versus on premise systems.

1. Cloud versus On Premise Considerations

| **Deliverable** | **On-premise** | **Cloud** | **Comments** |
| --- | --- | --- | --- |
| ***Validation Documentation*** | | | |
| User Requirements   * Include ERES | Yes | Yes | Include data integrity, ERES requirements |
| Supplier Audit | Yes | Yes | On-premise - reduce testing burden  Cloud - critical deliverable |
| Service Level Agreement (SLA) | No | Yes | Include availability and quality metrics requirements |
| GCompliance Applicability | Yes | Yes | Document required for both |
| Validation Plan | Yes | Yes | Cloud - define each company’s responsibilities |
| Functional Requirements   * Include ERES | Yes | No | Cloud - supplier needs to provide and maintain |
| Configuration / Design Specification | Yes | No | Cloud - supplier needs to provide and maintain and must be aligned to client’s unique details (not a generic spec) |
| Risk Assessment | Yes | No | Cloud - supplier should work with client to determine critical and high risk functionality and maintain the risk assessment |
| Development   * Code reviews * Unit testing * UAT testing | Yes | No | Cloud - supplier performed. Process reviewed in Supplier Audit. Deliverables for client not required. |
| Minimum Environments | DEV  QA/TEST  PROD | PROD | Cloud - supplier may use a refresh of lower environments for client, but not required to maintain multiple environments. Client needs to verify their instance is segregated physically or logically from other clients. |
| Installation Qualification | Yes | No | Cloud - performed by vendor |
| Operation / Functional Qualification | Yes | No | Cloud - performed by Vendor |
| End-user/PQ Acceptance Testing | Sometimes | Yes | Cloud – critical testing activity to ensure the provided solution meets client business needs and compliance requirements. |
| Testing Defects | Yes | Yes | Cloud – for PROD environment only. |
| Traceability Matrix | Yes | No | Cloud – maintained by vendor |
| Validation Report | Yes | Yes | Cloud – outlines what is managed and maintained by vendor per SLA |
| ***Procedures*** | | | |
| Access & Security | Yes | Yes | Required for both, but confirm who creates accounts |
| Archival/Retrieval | Yes | No | If applicable |
| Backup / Restore | Yes | No | Cloud – must provide backup plan and restore evidence |
| Business Continuity/Disaster Recovery | Yes | No | Cloud – provide plan approach |
| Change Management/Control | Yes | Yes | Cloud – high-level for system change history, ensure changes are approved by the client, change schedule and priorities are driven client, acceptance criteria defined by client |
| Document Control | Yes | Yes | Shared responsibility based on ownership of deliverables |
| Operation Support Manual | Yes | No | Cloud – vendor-defined process |
| Periodic Review | Yes | No | On-premise - follows company cycle and process |
| NCR / CAPA | Yes | No | Cloud – support investigations and corrections (if applicable) |
| Problem Supporting | Yes | No | Cloud – provide a means of reporting issues |

## Applicability

The following is a list of required responses for applicability of validation deliverables.

### Yes – Indicates the deliverable is required; requirement may be satisfied by creation of a new document or revision of an existing

### No – Indicates the deliverable is not required; the comments column must provide the rationale for not including

### N/A – Indicate a deliverable is not applicable or will be satisfied by an alternate mechanism; use comments to provide any details or rationale

## Supplier Management

Describe the activities performed.

A Supplier Audit was performed. The outcome and conclusion of the evaluation has been documented as successful and is used as an input to the validation strategy. Any relevant information from the supplier explaining the design, installation, use or maintenance will be factored into the validation. Any known software issues have been evaluated and are accounted for in the validation approach.

1. Supplier Audit

| **Deliverable** | **Document No** | **Applicability** | **Procedure / Rationale** |
| --- | --- | --- | --- |
| Supplier Audit Report | XXXXXXXX | <Yes / No> | <Supplier Name> was found to satisfy the company Supplier Audit process.  **Procedure / Template:** XXXXXXXXXX |

## Compliance and Overall Risk Assessment

1. Compliance Assessment and Overall Risk Assessment

| **Deliverable** | **Document No** | **Applicability** | **Procedure / Rationale /Approval** |
| --- | --- | --- | --- |
| Compliance Assessment | XXXXXXXX | Yes | <Computer System Name> was determined to be a GxP system with Electronic Records and Electronic Signatures applicable.  **Procedure / Template:** XXXXXXXXX / XXXXXXX |
| Overall Risk Assessment (ORA) | XXXXXXX | Yes | <Computer System Name> was determined to be a <Low / Medium / High> risk system with based on patient safety, product quality and data integrity impact measured against overall.  **Procedure / Template:** XXXXXXXXX / XXXXXXX |

## Specification Documents

1. Specification Documents

| **Deliverable** | **Document No** | **Applicability** | **Procedure / Rationale /Approval** |
| --- | --- | --- | --- |
| System Requirements Specification (SRS) | XXXXXXX | <Yes / No> | The SRS defined both the business needs and expectations, along with the functional requirements defined in detail that will be used, configured or designed to satisfy those business needs and expectations for the <Computer System Name>.  **Procedure / Template:** XXXXXXX / XXXXXXX |
| Configuration / Design Specification (CS / DS) | XXXXXXX | <Yes / No> | The configuration specification document unique configuration parameters for the <Computer System Name>.  The design specification document custom coded functions of the <Computer System Name>.  **Procedure / Template:** XXXXXXX / XXXXXXX |
| Code Reviews | N/A | <Yes / No> | Custom code is reviewed for conformance to good coding practices and for the ability to meet the custom functions.  **Procedure / Template:** XXXXXXX / XXXXXXX |

## Functional Risk Assessment

1. Risk Assessment

| **Deliverable** | **Document No** | **Applicability** | **Procedure / Rationale /Approval** |
| --- | --- | --- | --- |
| Risk Assessment | XXXXXXXX | Yes | A Computer Software Assurance Risk Assessment is executed against the system’s functions. It examines a requirement’s potential to impact patient safety, product quality and data integrity. This is then compared to the function’s complexity (out-of-the-box, configured or custom) to determine the test assurance level.  **Procedure / Template:** XXXXXXX/ XXXXXXX |

## Testing Strategy

Define the test strategy and the extent of the qualification based on the Test Assurance level from the Risk Assessment. Include any Disaster Recovery or Business Continuity as needed.

Minimally, qualification testing must be developed to ensure all requirements are covered. A review of requirements and the associated test case should be performed prior to entering the qualification phase to address any gaps before formal testing is initiated.

The IQ / IOQ / OQ OPQ / PQ test cases, including acceptance criteria will demonstrate that the software and its environment is installed and operating in compliance with requirements and the requirements documents and specifications.

1. Qualification Testing

| **Deliverable** | **Applicability** | **Procedure / Rationale** |
| --- | --- | --- |
| Protocol 1 | <Yes / No> | IQ testing in the Quality environment confirms the system is installed and configured per specifications.  **Procedure / Template:** XXXXX / XXXXXXX |
| Protocol 2 | <Yes/No> | IQ testing in the Quality environment confirms the system is installed and configured per specifications.  **Procedure / Template:** XXXXX / XXXXXXX |
| Quality Operation Test Cases | <Yes / No> | OQ testing in the Quality environment confirms functional behaviors operate as expected to satisfy the business needs.  **Procedure / Template:** XXXXX / XXXXXXX |
| Quality Operation Test Cases | <Yes / No> | OQ testing in the Quality environment confirms functional behaviors operate as expected to satisfy the business needs.  **Procedure / Template:** XXXXX / XXXXXXX |
| Production Installation Test Cases | <Yes / No> | IQ testing in the Production environment confirms the system is installed and configured per specifications.  **Procedure / Template:** XXXXX / XXXXXXX |
| Production Performance Test Cases | <Yes / No> | PQ testing in the Production environment confirms the system is performing as expected.  **Procedure / Template:** XXXXX / XXXXXXX |
| Deviation Reports | Yes | Any issues that occur during validation and qualification activities must be investigated and resolved.  **Procedure / Template:** XXXXXXX / XXXXXXX |

## Reports and System Documents

A Validation / Assurance Report will be created to describe the results of the validation activities, including deviations from the Validation / Assurance Plan and a decision if the system can be used for production purposes. The system may not be put in production service before the Validation / Assurance Report or an alternate release mechanism is approved.

1. Reports and System Documents

| **Deliverable** | **Document No** | **Applicability** | **Procedure / Rationale** |
| --- | --- | --- | --- |
| Traceability Matrix | XXXXXXX | Yes | The Traceability Matrix maps requirements to testing to demonstrate full coverage.  **Procedure / Template:** XXXXXX / XXXXXXX |
| Validation / Assurance Report (V/AR) | XXXXXXX | Yes | The Validation Report summarizes all the validation phases and deliverables. The initial version summarizes the IQ/OQ / IOQ testing conducted in the QA environment, verifies that all requirements have been met, and authorizes the move of <Computer System Name> from QA to the PROD environment. The last version serves as the final Validation Report (VR).  The V/AR also documents that any issues reported during execution, analysis and closure.  **Procedure / Template**: XXXXXXX / XXXXXXX |

## Clarifications

This section may be adapted as needed by the project. N/A if there are no exceptions and include this statement.

Clarifications are used to detail any testing that cannot be conducted in a qualified environment. This may be due to data integrity and impact on other records or risks associated with changing configuration/design and migrating the change to simulate a negative scenario.

1. Clarifications

| **Scenario** | **Requirement** | **Comments** |
| --- | --- | --- |
| Specifications (user, functional, configuration and design) may be in final draft form for testing execution | XXXXXXX | Low risk – Specifications will be minimally, final draft. Any changes prior to approval will be tested in the system. |
| PQ testing will not be performed in the PROD environment as doing so would create test data that cannot be removed or identified as test. | XXXXXXX | Low risk – Allowed when creation of records in the live environment could affect trending and reporting. |

## Procedures

Adapt to the project as needed.

The following procedures that support the use and maintenance of the <Computer System Name> computerized system will be created (revised)

1. Procedures

| **Topic** | **Document No.** | **Impact** |
| --- | --- | --- |
| Access and Security |  | <Create / Revise / Exists / N/A> |
| Archival and Retrieval |  | <Create / Revise / Exists / N/A> |
| Business Continuity Plan |  | <Create / Revise / Exists / N/A> |
| Disaster Recovery Plan |  | <Create / Revise / Exists / N/A> |
| Change Management |  | <Create / Revise / Exists / N/A> |
| Document Control |  | <Create / Revise / Exists / N/A> |
| Help Desk / Incident Reporting |  | <Create / Revise / Exists / N/A> |
| Production Problems |  | <Create / Revise / Exists / N/A> |
| Retirement |  | <Create / Revise / Exists / N/A> |
| System Administration |  | <Create / Revise / Exists / N/A> |
| Training |  | <Create / Revise / Exists / N/A> |
| Business Process Standard Operating Procedure(s) |  | <Create / Revise / Exists / N/A> |

## Data Migration

Text may be removed if there is no data migration involved.

1. Data Migration

| **Deliverable** | **Document No** | **Applicability** | **Procedure / Rationale** |
| --- | --- | --- | --- |
| Data Migration Plan | XXXXXXXX | <Yes / No> | The Data Migration Plan details the data impacted, any cleansing or transforming activities, migration methods and sampling plans.  **Procedure / Template:** XXXXXXX / XXXXXXX |
| Data Migration Report | XXXXXXX | <Yes / No> | The Data Migration Report documents the results of the data migration, including testing and defects and includes release of data for production use.  **Procedure / Template:** XXXXXXX / XXXXXXX |

## Change Control

Changes to approved documents will be handled via a revision, amendment, or addendum to the original document.

Once the system has passed the Production Installation Qualification testing, the system is placed under change management and changes made to the code, configuration, or other system related items or functionality are managed by the change control process.

# DOCUMENT MANAGEMENT

All documents produced or updated as a result of this validation shall have a unique identity, be version controlled, and reviewed and approved by persons with proper knowledge prior to release for use, following document management practices.

# ACCEPTANCE CRITERIA

This Validation / Assurance Plan may be closed once the following conditions are satisfied.

* All document deliverables to specify the system’s intended use and function have been created and approved.
* Data has been successfully migrated to the system.
* All testing has been completed with ‘Passed’ or ‘Passed with Deviation’ results.
* All Deviation Reports have been investigated, resolved and closed.

# REFERENCES

## Internal References

XXXXXXXXX System Requirements Specification

## External References

Not applicable.

# Appendices

Adjust appendices as need, if for example, IOQ or OPQ testing is used.

## Appendix A Quality Installation Qualification (IQ)Test Cases

## Appendix B Quality Operation Qualification (OQ) Test Cases

## Appendix C Production Installation Qualification (IQ)Test Cases

## Appendix D Production Performance Qualification (PQ) Test Cases

1. QUALITY INSTALLATION QUALIFICATION (IQ) TEST CASES

| **No.** | **Test Case Name** | **Description** |
| --- | --- | --- |
| 1 | TC-Intelex-IQ-001 | Verifies the documents module is installed per the Configuration Specification. |
| 2 | TC-Intelex-IQ-002 |  |
|  |  |  |
|  |  |  |

1. QUALITY OPERATION QUALIFICATION (OQ) TEST CASES

| **No.** | **Test Case Name** | **Description** |
| --- | --- | --- |
| 1 | TC-Intelex-OQ-001 | Verifies the SOP route for approval workflow. |
| 2 | TC-Intelex-OQ-002 |  |
|  |  |  |
|  |  |  |

1. PRODUCTION INSTALLATION QUALIFICATION (IQ) TEST CASES

| **No.** | **Test Case Name** | **Description** |
| --- | --- | --- |
| 1 | TC-Intelex-PIQ-001 | Verifies the……. |
| 2 | TC-Intelex-PIQ-002 |  |
|  |  |  |
|  |  |  |

1. PRODUCTION PERFORMANCE QUALIFICATION (PQ) TEST CASES

| **No.** | **Test Case Name** | **Description** |
| --- | --- | --- |
| 1 | TC-Intelex-PQ-001 | Verifies the……. |
| 2 | TC-Intelex-PQ-002 |  |
|  |  |  |
|  |  |  |