Contents

1. Purpose

This Work Instruction (WKI) specifies the minimum testing required to demonstrate that application software meets requirements and intended use.

It defines the process for identifying testing approaches, authoring and executing a test script, gathering and labeling objective evidence, and addressing deviations encountered during testing.

The Software Testing process correlates with multiple global IS processes e.g., *Software Development Life Cycle (SDLC),* ISSOP_SDM_001; *Project Management,* ISSOP_PMA_001; *Scrum Software Development Lifecycle,* ISSOP_SDM_002; *Change Management*, ISSOP_CMA_001. These procedures govern the listed processes; follow the directives described in the respective procedure and test software commensurate with the system risk.

2. Scope

This Work Instruction applies to testing all application software customized, configured, created, or implemented by Global IS.

This WKI applies to all staff, service, location, contractor / consultant, and / or third parties providing services to Stryker Information Services (IS) on Stryker-managed systems or services.

3. Definitions

Term/Acronym	Definition
Actual Result	Testing outcome. The system output, return, or data generation created to meet test criteria.
Core Functionality	System functionality required by the business.
Deviation	Any test when the Actual Results do not match Expected Results. Test Script Errors and Tester Errors are not considered deviations, unless the discrepancy indicates an issue.
Environment – Development	An environment where prototyping or programming takes place prior to testing in a controlled environment. (GAMP 5)
Environment – Testing / QA	An environment where formal testing is performed. (GAMP 5)
Environment - Production	Operational environment where the system is in its target environment. (GAMP 5)
Expected Result	Anticipated testing outcome. The system output, return, or data generation created to meet the criteria of a test.
Formal Testing	Testing conducted in accordance with test plans and procedures that have been reviewed and approved by a customer, user, or designated level of management. (IEEE) This evidence shall include executed test scripts, objective evidence, and documentation of deviation when actual results did not meet expected results.

Term/Acronym	Definition
GxP	Summarizes all good practice quality guidelines. 'G' stands for 'Good' and 'P' for 'Practice.' The x in the middle provides an abbreviation for a specific area of application, Manufacturing, Laboratory, Documentation or Distribution, Engineering, Clinical, Automated Manufacturing, etc. (CQM-02)
Informal Testing	Any testing that is not formal. No formal documented evidence is required for informal testing; however, it should include bug/deviation logs and may include test scripts.
Objective Evidence	Documented data that can be independently proven true that is collected to support the truthfulness or veracity of an item, process, system, or product and was obtained through direct observation, measurement, test, or analysis. (CQM-02)
Resolution	Actions taken to address a deviation. Resolution can involve multiple approaches: software repair to meet requirements, requirement updates to match software functionality, procedural updates to the business process, or software deferment to a future release.
Software	All or part of the programs, procedures, rules, and associated documentation of an information processing system. Note 1 to entry: Software is an intellectual creation that is independent of the medium on which it is recorded. (ISO/IEC 2382-1, definition 10.01.08)
Testing (Automated) Tools	A special software (separate from the software being tested) to control the execution of tests and the comparison of actual outcomes with predicted outcomes. Test automation can automate some repetitive but necessary tasks in a formalized testing process already in place, or perform additional testing that would be difficult to do manually. Not all testing tools automate software testing – some provide only a paperless test environment for manual test execution.
Test	An activity in which a system or component is executed under specified conditions, the results are observed or recorded and an evaluation is made of some aspect of the system or component. (IEEE)
Test Case	Documentation specifying inputs, predicted results, and a set of execution conditions for a test item. (IEEE)
Tester Error	Minor issue encountered in the testing results that is not the result of an incorrect test script or system error. This may include but not be limited to: • Missing / incorrect objective evidence. • Test results not fully completed. • Test step not accurately followed. Note all tester errors in the test script. No Deviation Log entry is required.

Term/Acronym	Definition
Test Script Error	Minor issue encountered with the test script that has no impact on the intent of the test when changed. This may include but not be limited to: • Missing step to close an error message. • Typographical error verified with the requirements document. Note all test script errors in the test script. No Deviation Log entry is required.
Testing Strategy	Document that describes the testing approach. It includes testing objective, types of testing, resources required, and testing environment. See ISSOP_SDM_001.T05.
Testing Summary	A document describing the conduct and results of the testing carried out for a system or system component. (IEEE)
Test Script (TS)	A series of one or more test steps used to produce evidence confirming one or more requirements. See ISSOP_SDM_001.T07.
Test Step	A step-by-step description of the action to be performed by testers along with the expected results. (GAMP 5)

4. Roles and Responsibilities

Role	Responsibilities
Independent Reviewer	Responsible for providing a review and approval on executed test scripts. The Tester and Independent Reviewer shall be different people. Responsible for ensuring that test deviations are logged.
IS Software Development Lead (DL)	Responsible for software development.
Tester	Responsible for executing test scripts following step-by-step instructions. Responsible for promptly reporting any test deviations to the Test Lead. Responsible for completing all required training *prior* to executing test scripts. This may include application, procedure, and testing tool training. Note: Prior to executing any test scripts, *all* testers shall have documented training in this procedure.

Role	Responsibilities
Test Lead	Responsible for coordinating the testing event, and all related deliverables. Responsible for authoring the Testing Strategy, Deviation Log, and the Testing Summary. Responsible for resolving all deviations documented in the Deviation Log. Resolution encompasses procedural and system solutions.

5. Instructions

5.1 General Requirements

5.1.1 Refer to ISGUD_QMS_001, Good Documentation Practices, for documentation / records guidance.

5.1.2 All GxP deliverables must be approved using a 21CFR Part 11-compliant E-signature tool or with wet signatures (physical by pen).

5.1.3 All data created to test the system shall be placed in the QA or Test environments, not the system Production environment. When unique circumstances warrant test data to be populated or migrated into the Production environment, special precautions are required:

- Provisions shall be taken to ensure that no user can and will actually use the test data for production purposes.
- Purge or disable all test data immediately after the controlled testing is complete to prevent access during production.
- Verify that the purging or disabling step was properly conducted.
- Verify that any special access granted for testing is disabled.

5.1.4 Any use of a testing tool must be assessed on a per event basis and agreed in advance with ISRC as part of developing the Testing Strategy.

5.1.4.1 Tools used for GxP/SOX systems may require qualification based on the intended use and risk assessment.

5.1.4.2 Testing tools that are not 21CFR Part 11 compliant, and cannot export test scripts in a form that meets approved IS requirements / procedures, may not be used as the official regulatory record.

5.1.4.3 Test management tools may be used, as testing management tools only, provided the testing efforts can be exported and meet the listed requirements in Attachment 3.

5.2 Test Strategy and Test Script Creation

Completed by Test Lead (TL) / Development Lead (DL)

5.2.1 An approved Test Strategy must be in place prior to Formal Testing activities. Refer to Attachments 1 - 2 for the required testing per application type.

5.2.2 Test scripts must meet the following requirements:

5.2.2.1 Each test script shall have a unique, sequential version.

5.2.2.2 Each test script and test step shall be uniquely identifiable.

5.2.2.3 Test scripts shall be traceable to requirements.

5.2.2.4 Each executed test script shall produce either:

- Evidence that actual results meet expected results with traceability to the test script.
- A deviation record, i.e., when actual results do not meet expected results.

5.2.2.5 The person who executed the test script shall be recorded.

5.2.2.6 Execute test scripts in non-production instances whenever possible. When not possible, quarantine any test data from potential production use.

5.2.3 Documents a summary of what the test will demonstrate.

5.2.4 Documents any pre-execution / set-up instructions.

5.2.5 Documents traceability to requirements, if not completed by some other method, e.g., *Traceability Matrix*, ISSOP_SDM_001.T04.

5.2.6 Documents the expected results for each test step.

5.2.7 Includes instructions for collecting objective evidence in test steps. Note: objective evidence may *not* be required at every test step.

5.2.7.1 Systems with regulatory or financial impact, e.g., GxP, SOX, etc., shall have at a minimum objective evidence for all core functionality and requirements that satisfy a regulation.

5.2.7.2 Systems that do not have regulatory or financial impact shall have objective evidence for all core functionality.

5.2.8 Includes instructions for Data Migration Testing, when the system retrieves data from

an ancillary system or when data is migrated from a previous system. Includes objective evidence of this testing.

5.3 Test Script Execution

Completed by Tester:

5.3.1 Performs any pre-execution or setup steps.

5.3.2 Executes test steps in order, unless otherwise specified.

5.3.3 Verifies actual results as directed by the test step and indicates if the expected results have been satisfied.

5.3.4 Captures objective evidence as specified by the test step, and labels it with the following information:

5.3.4.1 Test script name and version,

5.3.4.2 Test step reference,

5.3.4.3 Page numbering (1 of x).

5.3.5 Resolves test script and tester errors by making the correction on the test script without opening a deviation. Explain the corrections with an account of why the correction was made, include reference-supporting documentation, as appropriate, initial, and date.

5.3.5.1 See Attachment 4 for testing tool guidance.

5.3.5.2 Resolves any test script or tester errors that prevents the test execution from proceeding with the TL or DL.

5.3.6 Records all test failures, i.e., the actual result differs from the expected result, in the *Deviation Record*, ISSOP_SDM_001.T08.

Deviation Record information:

5.3.6.1 A unique identifier.

5.3.6.2 The test script and test step where the deviation occurred.

5.3.6.3 A description of what occurred includes objective evidence as appropriate to describe the deviation.

5.3.7 After a deviation has been logged, continues test execution until the test script is complete, unless the deviation prevents continuation. If test execution is halted prior to completion, documents it on the test script, signs and dates the completed results. Consults with the TL or DL if unsure how to proceed.

5.3.8 Approves the test script(s) upon completion. If more than one tester, indicate the test cases each tester completed.

5.3.9 Provides the test script and all evidence / deviations to the Independent Reviewer for final review.

5.4 Deviation Resolution

Completed by Test Lead (TL) / Development Lead (DL)

5.4.1 Works with the project / testing team, as needed, to resolve deviations. Documents the resolution(s), including whether retesting is required.

5.4.2 If a configuration or code change is required, the DL works with the project / testing team as needed to evaluate the impact of the change, and determine what needs to be retested.

5.4.3 Retests deviations as necessary and documents the results.

5.5 Executed Test Scripts

5.5.1 An Independent Reviewer, other than the tester, reviews and approves the executed test script, objective evidence, and Deviation Log for completeness and accuracy.

5.6 Test Summary

5.6.1 A Test Summary is developed by the Test Lead / Development Lead and is approved to document the testing results which includes a summary of all deviations, notes resolution or mitigation, or refers to a deviation log, as appropriate.

6. References

- ISSOP_PMA_001 – Project Management
- ISSOP_SDM_001 – Software Development Life Cycle (SDLC)
- ISSOP_SDM_001.T04 – Traceability Matrix
- ISSOP_SDM_001.T05 – Testing Strategy
- ISSOP_SDM_001.T07 – Test Script
- ISSOP_SDM_001.T08 – Deviation Record
- ISSOP_SDM_002 – Scrum Software Development Lifecycle
- ISSOP_CMA_001 – Change Management
- ISGUD_QMS_001 – Good Documentation Practices
- CQM-02 – Stryker Corporation Quality and Regulatory Master Glossary
- GAMP 5 – Good Automated Manufacturing Practice (GAMP) – Technical subcommittee of the International Society for Pharmaceutical Engineering (ISPE) and a set of guidelines for manufacturing / automated systems
- IEEE – Institute of Electrical and Electronics Engineers

- ISO - International Organization for Standardization
- NIST – National Institutes of Standards and Technology

7. Version History

Version	Date (dd-Mmm-yyyy)	Rationale and Description of Revision	Document Author
1.0	3-Nov-2017	Initial document release; changed document number to ISWKI_SDM_001 (formerly ISWKI_PMA_001). Other changes to note: • References for ISSOP_PMA_002 changed to ISSOP_SDM_001 (including reference changes for all associated templates) • References for ISSOP_PMA_005 changed to ISSOP_SDM_002 • Added Formal and Informal Testing to Definitions section • Reduced definitions and roles to those mentioned in WKI • Combined Test Strategy and Test Script Creation sections. Clarified Test Strategy requirements. • Removed references for ISSOP_PMA_002.T02, T03, and T12 • Removed Reference to ITSTAN-008 • Removed Attachment 1 – Testing Levels / Types • Clarified the definition and use of Automated Test Tools • Changed Design Lead to Development Lead to align with other SDM documents	Toni Slufik

8. Approvals

Author:

Typed/Printed Name	Signature	Date (dd-Mmm-yyyy)
Toni Slufik IS Governance and Performance Management Manager	DocuSigned by: Toni Slufik Signer Name: Toni Slufik Signing Reason: I approve this document Signing Time: 11/14/2017 2:17:08 PM EST E19D09B614E9449F90C35E49A3436FD9	14-Nov-2017 | 14:17:11 EST

Supervisor:

Typed/Printed Name	Signature	Date (dd-Mmm-yyyy)
Molly Nicolai IS Director, Governance & Process Management	DocuSigned by: Molly Nicolai Signer Name: Molly Nicolai Signing Reason: I approve this document Signing Time: 11/14/2017 12:30:16 PM EST BEAA803A734244BAA9A365539A304DB5	14-Nov-2017 | 12:30:18 EST

9. Attachment 1 - Application Software Types / Required Testing

Term/Acronym	Definition/Required Testing
Client COTS (Commercial-off-the-Shelf)	Acquired software installed and run locally on a user's machine, e.g., MS Word, Adobe Reader, etc. • No testing required.
Enterprise COTS	Acquired software installed on a server for enterprise use, e.g., SharePoint, Exchange, etc. • Formal testing required. • The rigor of testing should be sufficient to address the software criticality and complexity.
Configured Software	Acquired software set up to meet business requirements using means available within the system, as originally designed and supported by the vendor. • Formal testing shall be performed and Acceptance is required. • Testing is required to cover configured software or software components. • The rigor of testing shall be sufficient to address the software criticality and complexity.
Customized	Acquired software modified, i.e., changed, added to, or removed from, to behave differently than what is directly supported by the vendor. • Informal testing is recommended. • Formal testing shall be performed and Acceptance is required. • Testing is required to cover software or software components configured or customized. • The testing rigor shall be sufficient to address the software criticality and complexity.
Custom In-house	Software developed under Stryker's management; no vendor warrants or supports the software. • Informal testing is recommended. • Formal testing shall be performed and Acceptance is required. • The testing rigor shall be commensurate with the software criticality and complexity.

10. Attachment 2 – Test Requirement Matrix

	Informal	Formal	Acceptance
Client COTS	Not Applicable	Not Applicable	Not Applicable
Enterprise COTS	Not Applicable	Required	Not Applicable
Configured	Not Applicable	Required	Required
Customized	Recommended	Required	Required
Custom In-house	Recommended	Required	Required

11. Attachment 3 – Test Management Tools

Testing tools for GxP / SOX systems that are not 21CFR Part 11 compliant may be used, as testing management tools only, provided the testing efforts can be exported and meet the listed requirements:

- Any use of a testing tool must be assessed on a per event basis. The export package needs to be approved by ISRC prior to use. Examples include – Manually created Excel spread sheets, Microsoft Test Management Tool (MTM), and Open source testing tool - Selenium
- All testing exported from testing tool needs to be independent, and have no dependency on the tool.
- Test cases exported out of the test tool may have no links embedded to the testing application itself.
- Screenshots will be printed and attached to the test case exported as evidence and mapped to the test step.
- The Tester must sign-off all test cases and objective evidence independently of the testing tool on the day of execution, if the tool does not support capturing audit trail and signature functionality.
- A signature statement is required on the exported test script.
- The test script version number and revision history is required in the exported template.
- Any deviations captured in the tool must be mapped and approved in the Deviation Log, per the SDLC process.