

**Policy Owner:** CF - Information Technology (IT)**Approval date:** Oct 31, 2017**Approver:** Javier Polit**Scope:** Global**Contact:** Eugene Kholodenko**Effective date:** March 1, 2018

IT Service Validation and Testing

1.0 Intent

This is a policy to ensure new computerized systems or changes to existing computerized systems meet user, customer, regulatory and technical quality expectations, and to verify that IT operations can to support the new computerized system or changes to the existing system. This is a policy to ensure that changes to computerized systems are validated and tested through established standards and processes so that changes do what they are supposed to do (fit for purpose), are available and are useful as seen by users (fit for use).

2.0 Scope

This policy applies to organizations, individuals, including third party partners, who deploy, manage, or support P&G IT applications, data, platforms, software, networks and information systems. This applies to changes, including the establishment of new computerized systems, and changes caused by Projects, Releases, Hardware, and Technical Upgrades.

Note: Review the Validation QAS-S-04 (see References) for information and guidance for Regulated, Non-Regulated, and those computer systems controlling product quality.

3.0 Policy Requirements

Conduct validation and testing to prove the computerized system is operating as configured and that it meets business, regulatory, and technical requirements. Generate objective evidence that computerized system is qualified and approved prior to installation or move to production.

3.1 General Requirements

- i. New systems must be tested in an integrated way before being installed in the production environment, including application software packages, system software, hardware, communications services and environmental facilities.
- ii. Service Validation and Testing must be fully integrated in the lifecycle of computerized systems, specifically at the establishment (placed into production) and update or modification (any changes) of computerized systems.
- iii. P&G and partner personnel responsible for service validation and testing roles must be adequately trained in testing standards. All training must be documented.

3.2 Requirements Management

- i. Business, User and Stakeholders, Solution and Transition Requirements must be detailed and documented to build or modify, and test the computerized system.
- ii. New systems and changes to existing systems must be tested in accordance with predefined requirements and documented test plans.
- iii. Test scripts must be cross-referenced to the requirements. Test scripts must be updated when the linked requirement changes.



- iv. Testing must be designed to provide documented evidence of business, regulatory, and technical requirements meet their success criteria.

3.3 Test Management

- i. Changes must be tested per the P&G Testing Standard.
- ii. Testing affecting Regulated Systems or those controlling product quality must follow the requirements detailed in QAS-S-04.
- iii. Approved test management tools must be used.

3.4 Test Planning and Preparation

- i. The test scope, effort, sequencing, and test data/environment must fit the level of identified risk of the corresponding change.
- ii. Test plans must include security checks to ensure Confidentiality, Data Integrity and Availability.
- iii. Test success criteria must be established to assess whether test results are sufficient to move to the next testing stage or move to Production.
- iv. Test strategies and test plans must be approved to ensure all activities are complete and correct. This includes quality checks on the test scripts, test models or simulations to be used.

3.5 Test Execution and Defect Management

- i. Planned test cases must be executed to determine the change meets the desired success criteria.
- ii. Test results must be documented with objective evidence where indicated.
- iii. Test results must meet the agreed test success criteria to move to the next test phase, project phase or to move to production.
- iv. Defects must be identified, documented and mitigated.

4.0 Definitions

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| Computerized System | Includes hardware, software, peripheral devices, personnel, and documentation (FDA Glossary, 1995) that support a business process. |
| Validation (Regulated) | Establishing documented evidence, which provides a high degree of assurance that a specific process will consistently produce a product meeting its pre-determined specifications and quality characteristics. (US FDA definition, 1987) |
| Testing | The process consisting of all lifecycle activities, both static and dynamic, concerned with planning, preparation and evaluation of software products and related work products to determine that they satisfy specified requirements, to demonstrate that they are fit for purpose and to detect defects. [ISTQB V2.1 Glossary of Terms] |

4.0 References

- Validation SOP QAS-S-04 [LINK](#) and [LINK](#)
- Standard for Requirements Management [LINK](#)
- Standard for Test Management [LINK](#)
- Standard for Test Preparation [LINK](#)
- Standard for Test Execution [LINK](#)
- Standard for Test Library Maintenance [LINK](#)
- IT Discipline: A&I Testing [LINK](#)