Business Use

Policy Owner: CF - Information Technology (IT)	Approval date: Oct 31, 2017
Approver: Javier Polit	Scope: Global
Contact: Eugene Kholodenko	Effective date: October 1, 2019

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 with Business Impact Assessment of medium or high risk, 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, NonRegulated, 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. Please refer to the IT Service Validation and Testing standard for the detailed requirements and controls supporting this policy.

4.0 Definitions

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]

5.0 References

- Validation SOP QAS-S-04 LINK
- Standard for Service Validation and Testing LINK
- IT Discipline: A&I Testing LINK

6.0 Document Review & Revision History

Version	Date	Editor	Comments
1.1	*August 27 2019`*	*Armando Salas – IT Service Validation & Testing Governance leader*	*Removal of controls specified section to make the document high level. Reducing the scope of applications to those that have a business impact assessment (BIA) of medium or high risk.*