



STANDARD OPERATING PROCEDURE

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1 Objective

The purpose of this procedure is to outline the Software Development Life Cycle (SDLC) to be followed for software engineering projects. This procedure briefly outlines the Agile and Waterfall Frameworks, along with their respective phases and deliverables. The applicability of deliverables may be Expected (must do) or Conditional (if applicable) according to the type of project being carried out. The scope of the project may be defined by various projects parameters; such as whether the project is a configuration or customization of Commercial Off-the-Shelf (COTS) software products, Software-as-a-Service (SaaS) initiative, or new application development.

2 Scope

SDLC is a framework for initiating, planning, developing, releasing, operating, and archiving and retiring of information systems or applications. It outlines the activities that must be performed with associated deliverables to deliver software of high quality that is also compliant when developing, maintaining, replacing, altering or enhancing specific software for a given software engineering project.

The structure of this procedure details two supported Frameworks under SDLC; the Agile Framework and the Waterfall Framework. The Frameworks specify the deliverables under each phase based on the Entry Criteria, Tasks to be performed, Verification to be executed and Exit Criteria/Deliverable expectations. The outputs of the SDLC are project deliverables, often electronic reports containing signatures or project data captured in the tools utilized. Per Johnson and Johnson JJT-TS Quality Manual, each Operating Company shall abide by their local procedures for creating, updating, reviewing, approving, developing and conducting training, releasing, performing periodic reviews, and retiring these deliverables which are considered Quality System Documents (QSD).

2.1 Out of Scope

The following are not required to use this procedure:

- Medical Device Software (MDS) – Software that is intended for use as a medical device.

- Infrastructure and tools that support infrastructure (Use SDLC Infrastructure SOP-5981 for this type of project).
- Automated manufacturing and laboratory equipment and instrumentation.
- Proof Of Concept (POC) – Designed purely to verify the functionality of a single or a set of concepts to create a new application or to be unified into existing applications but not released into production.

Note: As we continue to evolve with technology, the reliance on Proof of Concepts (POCs) are becoming more and more important in proving out that an idea or concept has the potential for real-world applications. With respect to POCs, they are only to be used or tested in non-production environments. In the event, the need arises to move a POC or code to a production environment then the full SDLC process must be followed. Furthermore, POCs should not use J&J production data and should make sure that the appropriate security protections are applied.

If the intent is to make the POC production ready, then it is highly recommended that the required SDLC documentation be created along the way in an effort to save time prior to a release.

3 Definitions

It is assumed the audiences of this SOP have an understanding of basic IT terms and acronyms and hence are not required to be defined in this section.

3.1 Terms and Acronyms

- **Application Security Assessment** – Two-part assessment tool which is completed by the IT project team in order to understand the risk and potential security control gaps in projects, perform risk assessment and define security requirements. The assessment:
 - i. Provides a heat map of control strength vs. a risk-based target level in order to enable the IT teams to build-in an adequate level of security protection consistent with the Information Asset Protection Policies (IAPP).
 - ii. Allows the receiving support team to ensure that the appropriate security controls have been built into software relative to the risk to the business.

iii. Meet J&J policy requirements for application security.

- **Approved Supplier List (ASL)** – The sub-set of Suppliers approved to provide GxP products and services for JJT. This list is based on an assessment or audit of the applicable components of the supplier's quality management system supporting provisioning of GxP JJT products and services. The approval is based on the supplier qualification criteria and process described in this SOP. The ASL is a living document maintained by JJTQ&C Supplier Quality Management and will be updated based on the process defined in this SOP.
- **B2B** – Business to Business
- **Business Impact Assessment (BIA)** – Describes the business use and various business risks of a business application as well as the requested Disaster Recovery parameters: Recovery Time Objective (RTO) and Recovery Point Objective (RPO), and/or the option to not have Disaster Recovery and accept that risk.
- **Business Partner Risk Assessment (BPRA)** – Used to assess the risk of 3rd parties who gather administer or host J&J data or software, or with whom there are open B2B connections to the J&J environment. The assessment looks at the vendor's overall security posture, policies and procedures, training program, infrastructure controls, etc.
- **Business Process Analysis (BPA)** – Process maps, process modeling, and other documentation associated with the analysis of current business processes and the identification of improvements to reduce wasteful steps and identify process improvements.
- **Business Simulation Testing (BST)** – Mimics real-life business scenarios to ensure the solution delivered solves the business need it was intended to resolve.
- **Change Control** – Is a formal approved request or an order for the implementation of a change to the system which is usually submitted in a

Change Management System. For GxP projects, the use of an authorized Change Management System is mandatory.

- **Code Review Record** – Typically, code review focuses on ensuring that the code is in accordance with the technical design and that it follows applicable coding standards.
- **Coding Standards** – A set of guidelines for a specific programming language that recommend programming style, practices, and methods for each aspect of a program written in that language.
- **Commercial Off-the-Shelf (COTS)** – Packaged solutions which are procured and then adapted to satisfy business needs.
- **Compliance Analysis (CA)** – Identifies the compliance requirements for the software being delivered. The results of this analysis establish the following:
 - i. Descriptive data for entry into the Configuration Management Database (CMDB).
 - ii. Information to aid in determining detailed Compliance Requirements, which will be captured in the User Requirements or User Stories and information to aid in determining additional compliance deliverables, to be defined in the Compliance Plan.
 - iii. Application categorization, to assist in further project planning and input for identifying risks.
- **Compliance Plan (CP)** – Describes the activities that must be performed to provide evidence that the software has been developed and installed as per predefined specifications and operates as intended.
- **Compliance Summary Report (CSR)** – Summarizes the compliance deliverables, the activities performed, documents deviations from the Compliance Plan, and provides an executive summary of the validation activities carried out. For GxP applications, it also authorizes the implementation of the software in a production environment.

- **Conditional Documentation** – Project documentation that is needed for the specific project, such as user guides, checklists, job aids, Work Instructions (WIs), Standard Operating Procedures (SOPs), or other such documentation that is project specific. Conditional documentation should be identified and included in the Compliance Plan.
- **Continuous Process Improvement (CPI)** – Is an ongoing effort to improve products, services, or processes. These efforts can seek "incremental" improvement over time or "breakthrough" improvement all at once. Delivery (customer valued) processes are constantly evaluated and improved in the light of their efficiency, effectiveness and flexibility.
- **Critical Success Factors (CSFs)** – Critical factor or activity required for ensuring the success of the software engineering product.
- **CSV Risk Assessment Report** – The objective of the risk assessment is to assess GxP and business priority high/medium business requirements to determine the recommended testing based on risk. In addition, the risk assessment will be used to document multiple controls, as applicable.
- **Data Conversion/Migration Requirements Specification** – The requirements for transferring and/or translating data from one format and/or location to another by a set of customized, qualified, and validated programs or scripts.
- **Data Flow Map** – A visual representation of application components, users and the transmission, processing, and storage of data of different classifications (public, confidential, restricted, highly restricted) between those components.
- **Defect Form** – Highlights conditions when the system in test does not function as required. The purpose of a defect form is to state the problem as clearly as possible so that developers can replicate the defect easily and resolve it. Corrective actions that are to be taken to resolve the defect and close out are captured.

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- **Definition of Done (DoD)** – Refers to completion of all activities necessary to deliver usable software, with varying degrees of Done at project, release increment, and user story level. This is applicable for the Agile Framework only.
 - **Definition of Ready (DoR)** – Refers to completion of all activities necessary before starting development of user story. This is applicable for the Agile Framework only.
 - **Design Specifications** – Describes functional and technical design which developers can understand and construct the code as specified. Design specifications are used to design software features.
 - **Disaster Recovery Plan** – The documentation that formally describes the implementation and execution for a disaster recovery; which is the process of re-establishing an environment using alternate capacity in an alternate location.
 - **Entry-Task-Validation-Exit (ETVX)** – Model that views processes within the context of Input or Triggers, Tasks (also called procedures), Controls, Constraints and Outputs.
 - **Feature** – Is a unit of functionality (group of consumable user stories) of an application/software system that satisfies a requirement, represents a design decision, and provides a potential configuration option.
 - **Functional Requirement (FR)** – Requirements that describe the behavior of the solution and the information managed, allowing for developers to fully understand how the software must function and what attributes are needed to meet user requirements. In the case of a system or application, these are the features and functions of the system.
 - **GxP** – An abbreviation that refers to all relevant regulations, including but not limited to Good Laboratory Practice (GLP), current Good Manufacturing Practice (cGMP), Good Clinical Practice (GCP) and Good Distribution Practice

(GDP). GxP can refer to one specific set of practices or to any combination of regulations.

- **Hypercare Transition Plan** – The document that identifies the roles, responsibilities, readiness, timelines, and acceptance criteria to transition operational support from the sending organization to a receiving organization(s). This Transition plan will be used as a formal agreement to align the sending and receiving organizations functions during transition and provides a formal documented signoff by the leaders of these respective organization(s). This includes the Service Level Agreement (SLA) that has to be followed by the Operations team.
- **IAPP** – Information Asset Protection Policy
- **ISM** – Integrated Service Management
- **Key Performance Indicators (KPIs)** – Business metrics used to evaluate the success of an organization or of a particular activity in which it engages.
- **Knowledge Management Repository (KMR)** – Confluence-based space containing key SDLC Process information, Process Assets, and references
- **Minimum Viable Product (MVP)** – A release of a software system that has just those core features that allows the product to be deployed, and no more. It is a strategy targeted at avoiding building products that customers do not want, that seeks to maximize the information learned about the customer per dollar spent.
- **Non-Functional Requirement (NFR)** – Requirements that define the qualities of the solution or the environmental conditions under which the solution will remain effective. This often refers to characteristics of capacity, such as response time, security, availability, etc.
- **Operations Run Book (ORB)** – Is a set of defined procedures developed by the administrator or IT professional for maintaining the everyday routine, as well as the exceptional operations of the computer system or network. The ORB should contain all the information a staff would need to perform daily

operations as information on dealing with any problems that arise during usage from the operational system or network.

- **Product Backlog** – The Product Backlog is a prioritized list of everything that might be included in a product. Product Backlog items can be anything from features, user stories, bugs, technical work, knowledge acquisition (e.g. spikes), documentation, to other artifacts. This also includes regulatory, internal controls, and security requirements as prioritized by the Business Asset Owner (BAO). This is applicable for the Agile Framework only.
- **Project Case** – Captures the reasoning for initiating a project or task, usually citing benefits; such as the reduction of costs, early market entry, or process improvement.
- **Product Increment** – The increment (or Potentially Shippable Increment (PSI)) is the sum of all the Product Backlog items completed during a sprint and all previous sprints. At the end of the sprint, the increment must be done according to the Scrum Team's criteria called Definition of Done (DoD). The increment must be in a useable condition regardless of whether a Business Asset Owner (BAO) decides to actually release it.
- **Rapid Requirements Development Services (rRDS)** – A requirements development methodology for the definition and documentation of requirements (business, user, and functional).
- **Release Plan** – This plan includes how and when project releases will be delivered.
- **Requirements Specification** – Is a comprehensive description of the intended purpose and environment for software under development. It fully describes what the software will do and how it will be expected to perform.
- **Retirement Plan** – The Retirement Plan describes the approach for retiring the application (decommissioning of the system) and specifies any additional deliverables to be produced. The Retirement Plan identifies the components of the computerized system to be decommissioned (for example, data, software,

hardware, documentation, procedures, etc.) and how each component will be disposed of (for example, archived, migrated, deleted, repurposed), and the responsibilities and timelines for the decommissioning process.

- **Retirement Report** – A required deliverable that documents and summarizes the results of the retirement activities as described in the Retirement Plan including deviations from the Retirement Plan.
- **SDLC Project Deliverables** – The outputs of the SDLC process, usually electronic reports containing signatures, or the project contents captured in approved tools or templates.
- **Software as a Service (SaaS)**¹ – The capability provided to the consumer is to use the provider's applications running on a cloud infrastructure. The applications are accessible from various client devices through either a thin client interface, such as a web browser (e.g., web-based email), or a program interface. The consumer does not manage or control the underlying cloud infrastructure including network, servers, operating systems, storage, or even individual application capabilities, with the possible exception of limited user specific application configuration settings. The customer licenses the use of SaaS vendor's application service, built on the vendor's environment, on a subscription basis. A standard service is provided for all customers; limited customization possible in some cases.

Examples: Salesforce.com, Tableau, Cisco WebEx, Microsoft Office 365, SharePoint, JIRA, etc.

- **Software Development Life Cycle (SDLC)** – Describes the process for initiating, planning, creating, testing, deploying, operating, and retiring software.
- **Sprint Backlog** – Used to identify the scope of work in a sprint, including the user stories to be developed and their associated tasks, success criteria, and release information.

¹ Definition per the National Institute of Standards and Technology (NIST).

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- **Sprint Planning** – Scrum event where the team determines the product backlog items they will work on during the sprint and discusses their initial plan for completing those product backlog items.
 - **Sprint Retrospective** – Is an opportunity for the Scrum Team to inspect itself at the end of iteration (sprint) and create a plan for improvements to be enacted during the next sprint. During the retrospective, the team reflects on what happened in the iteration and identifies action for improvements going forward.
 - **System Testing (ST)** – The testing conducted on a complete, integrated system to evaluate the system's compliance with its specified requirements. System testing falls within the scope of black-box testing, and as such, should require no knowledge of the inner design of the code or logic. System Testing encompasses pre-UAT testing, such as regression, functional testing, integration testing, load testing, and stress testing.
 - **Test Protocol** – This document describes the overall test strategy and test approach for a project. The document's main purpose is to:
 - i. Identify the system under test.
 - ii. Specify test levels and test strategy (pre-UAT, UAT) for the system under test.
 - iii. Define a test approach for each test level, its entry and exit criteria, test types and techniques to be used.
 - iv. Identifies timelines, time dependencies and test resource roles and responsibilities needed to execute the test strategy.
 - v. Testing to provide objective evidence that the software can be used in its operating environment for its intended purpose. Testing is documented in such a manner as to allow independent verification of the day-to-day use of the software, based on new or existing end-user procedures.
 - **Test Report** – Final report that summarizes the outcome of Test Protocol execution.

- **Test Scripts** – A set of instructions that will be performed on the system under test to validate that the system functions as expected. There are various types of tests to verify the application software; including but not limited to unit test, user acceptance test, functional test, integration test, stress test and performance test. The means for executing these test scripts are varied.
- **Traceability Matrix (TM)** – Captures approved requirements and their traceability delivered at the conclusion of the life cycle. The Traceability Matrix links the user and functional requirements, to their corresponding design/configuration specifications, test scripts and production release. System Test Scripts are linked to the functional and technical requirements and UAT scripts are linked to the user requirements identified within the test scripts.
- **User Acceptance Testing (UAT)** – The last phase of the software testing process where actual software users test the software to make sure it can handle required tasks in real-world scenarios, according to specifications. Any end-to-end testing or regression is included.
- **User Story** – Small, self-contained unit of development work designed to accomplish a specific goal within a product. A user story is usually written from the user's perspective.
- **Validation Deliverable** – Documentation which serves as objective evidence that the application performs as intended, is in compliance with regulatory requirements and J&J CSV procedures. SDLC deliverables that are considered validation documentation are listed in the CSV SOPs and includes, but not limited to deliverables resulting from using the SDLC, Standard Operating Procedures, Work Instructions, etc.
- **Vendor Assessment** – A formal assessment of the Vendor and their total quality management system to ensure their policy, procedures and practices are robust enough be compliant with J&J regulatory and other standards.

3.2 Role Descriptions

The SDLC is role based, not resource based; offering the agility needed to address business needs and changes in direction. This means that on a given project:

- one person can have multiple roles;
- multiple people can have the same role; and
- one person can play the same role on multiple teams.
- Key roles (**IQ (GxP), SQA (non-GxP), ISRM, RIM, and Regulatory Affairs**) that are reserved **cannot** be performed by other members of the project team.

NOTE: For additional Role Definitions, please refer to the SDLC KMR.

- **Business Asset Owner (BAO) (also known as Product Owner (PO)/Business Application Owner)** – A business representative that owns the application software and drives product vision, roadmap, and owns the product backlog.
- **Business Technology (BT) (also known as Business Unit Information Technology (BUIT))** – The organization responsible for ensuring the IT needs of the business units are addressed.
- **Independent Quality (IQ) (also known as Computer Systems Validation (CSV)/Technology Quality (TQ))** – The organization responsible for:
 - i. Ensures compliance with regulatory requirements (e.g., GxP, Part 11, Annex 11: Computerized Systems, etc.) and the Computerized System Validation QTS document throughout the application life cycle,
 - ii. Independent Quality (IQ) is the reviewer and approver of validation deliverables, including test scripts; and
 - iii. Ensures the GxP compliance requirements are implemented and verified through testing.
- **Information Security and Risk Management (ISRM)** – The organization responsible for:

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- i. Provides the security requirements, assessment requirements and tools, and subject-matter expertise consulting to design, build and operate secure application software consistent with the Information Asset Protection Policies (IAPP),
 - ii. Provides the assurance structure to ensure security and IT process controls are designed, built and continue to operate effectively in new and existing systems; and
 - iii. Responsible for the appropriate classification of Personal Identifiable Information (PII) used in the application.
 - **JJT Asset Owner (JJTAO) (also known as Service Owner (SO)/IT Application Owner)** – Responsible for the end-to-end delivery of the service (design, engineering, deployment, and operations), ensures quality and timely delivery of service to consumers, and determines functionality roadmap and milestones for the provided service.
 - **Privacy Representative** – Responsible for determining the privacy regulatory requirements to be built in the software, system, website or app and guiding the business to ensure that those requirements are properly implemented prior to go-live.
 - **Project Team** – Comprised of the IQ (GxP), BT and IT-AS (including SQA (non-GxP)) software engineering personnel that have been assigned to a software development and/or implementation project. Personnel may include Business Analysts, Project Managers, Testers, Developers, JJT Asset Owners, IQ (GxP), SQA (non-GxP), and other software engineering personnel needed to develop and implement software solutions.
 - **Records and Information Management (RIM)** – The organization responsible for all Records and Information Management matters. Records and Information Management refers to a set of activities required for systematically controlling the creation, distribution, use, maintenance, and disposition of recorded information maintained as evidence of business activities and transactions. The RIM SDLC Center of Expertise (CoE) serves as the signatory for RIM.
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- **Regulatory Affairs (RA)** – The organization that determines if an externally facing system is considered a medical device that will be used by patients, consumers, Health Care Providers, in order to document the respective conclusion in the Compliance Analysis (CA).
- **Scrum Team** – Comprised of the IQ (GxP), BT and IT-AS (including SQA (non-GxP)) software engineering personnel that have been assigned to a software development and/or implementation project. Personnel may include Business Analysts, Business Asset Owners, Testers, Scrum Masters, Developers, IQ (GxP), SQA (non-GxP), and other software engineering personnel needed to develop and implement software solutions.
- **Software Quality Assurance (SQA)** – An Independent organization that enables and helps teams to control and build in quality during the software development life cycle for non-GxP applications. The SQA team provides coaching and guidance to teams on best quality practices, while making sure that the delivered software, the related deliverables and applied processes do meet and comply with defined J&J quality standards and policies. Additionally, SQA puts focus on proactive quality assurance activities, risk based verification, data driven governance, metrics and continuous process improvements based on data and trend analysis.
- **Stage Gate Review Committee (SGRC)** – Operates within the Records and Information Management organization and provides additional support and guidance to strengthen existing data preservation safeguards across the J&J enterprise when decommissioning, migrating, archiving, consolidating, and/or upgrading systems containing data subject to record retention (including regulatory compliance) or legal hold preservation requirements. The committee consists of select members from J&J Technology, Records and Information Management, the Law Department, and outside counsel.
- **Technical Operations Owner (TOO) (also known as Operations Owner)** – Responsible for End to End Service Operations, running the technology environment, and meeting service level expectations.

4 References

The indication of TV references the TruVault Document Repository.

- **Doc ID:** – FRM-8621 **Title:** - CSV Risk Assessment
- **Doc ID:** – N/A **Title:** - S-15 Worldwide System and Application Lifecycle Security Policy (for IAPP)
- **Doc ID:** – POL-1769 **Title:** - Johnson & Johnson JJT-TS Quality Manual
- **Doc ID:** – SOP-1008 **Title:** - Disaster Recovery Planning and Management
- **Doc ID:** – SOP-5981 **Title:** - SDLC Infrastructure
- **Doc ID:** – SOP-8190 **Title:** - BIA Management Processes
- **Doc ID:** - SOP-8602 **Title:** - Computer System Validation Procedure for GxP Regulated Applications
- **Doc ID:** - SOP-8603 **Title:** - Risk Based Approach to Validation
- **Doc ID:** – SOP-8604 **Title:** - Agile CSV Procedure for GxP-Regulated Applications
- **Doc ID:** – SOP-8876 **Title:** – TECHNOLOGY QUALITY SUPPLIER QUALITY MANAGEMENT
- **Doc ID:** - TV-QTS-00018 **Title:** - Computerized System Validation

5 Activity Procedure Description

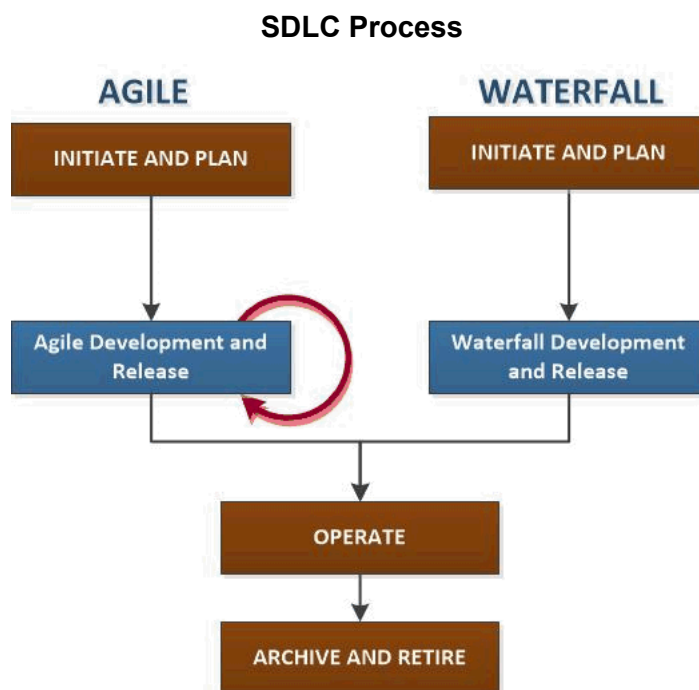
Activities, or tasks, have been included in the **Entry Task Validation eXit (ETVX)** table under the respective phases for Agile and Waterfall Frameworks.

Please consult your IQ (GxP) or SQA (non-GxP) representative to confirm which local tools should be utilized for your specific project.

6 Process Overview

This Standard Operating Procedure (SOP) describes Johnson & Johnson's Software Development Life Cycle (SDLC), including associated processes and requirements or activities and deliverables. The SDLC is intended to ensure that computerized systems are fit for intended use, meet business requirements and are compliant with applicable regulations and standards.

6.1 Process Diagram



7 General Guidance

The following is intended for all projects using the SDLC process.

- The Compliance Analysis (CA) helps to determine all applicable regulations for the application based on the intended use. This is done per application and will help to determine regulatory impact (e.g. whether an application is GxP or non-GxP). ***The Compliance Analysis at a minimum should be approved by the BAO, JJTAO, IQ, ISRM and RIM.***
- The Compliance Plan (CP) is used to dictate the SDLC deliverables required and the overall strategy for the project.
- For GxP projects, all validation deliverables require **a minimum of three approvers**: Business Asset Owner, JJT Asset Owner (IT Application Owner) and IQ. For all other SDLC deliverables, the Compliance Plan must be used to determine the approvers.

- Upon completion of the Compliance Analysis, ***non-GxP websites or low risk GxP websites classified as static content derived from product labeling*** are not required to follow the standard SDLC path. Please note that this track is to be used for websites only and should not be used for business applications with a web interface (where transactions, processing or analysis of information take place).
 - Mandatory SDLC deliverables will be limited to the Compliance Analysis and Business Impact Assessment.
 - Additional deliverables can be created as required by the project team in collaboration with the different compliance SMEs (e.g., TQ, ISRM, Privacy, Regulatory Affairs) as part of the Compliance Analysis evaluation.
 - In addition, the Business Asset Owner is responsible for ensuring that the appropriate Business Unit processes (e.g. copy approval, monitoring of adverse events/product quality complaints) are followed for these websites.
- For non-GxP projects, the Project/Scrum Team should work with their SQA (non-GxP) representative to determine the required approvers. In case an SQA representative is not engaged on the project, the Project/Scrum team is required to follow the minimum set of approvers as specified on the SDLC KMR.
- Additional approvers can be added to SDLC deliverables as deemed appropriate based on consultation with SQA (non-GxP) or IQ (GxP) representatives.
- All deliverables including validation deliverables **may be combined** when documented in a strategy defined by the Compliance Plan, Test Protocol or Change Control.
- The Compliance Summary Report is created in direct reference to the Compliance Plan before the application is released for use in the Production

Environment i.e. a Compliance Summary Report and Compliance Plan go hand in hand.

- Project/Scrum Teams can use other templates approved through an enterprise approved Document Management System in consultation with SQA (non-GxP) and IQ (GxP) representatives.
- Any deliverable that contains the word “**approved**” in the exit criteria/deliverable will require formal review and approval (meaning signatures are required). For a particular **SDLC deliverable to be approved**, all the documents referenced in the entry criteria of the ETVX matrix must be completed and/or approved. For example, the Business Impact Assessment (BIA) and Compliance Analysis (CA) must be completed and approved prior to the approval/sign off the Compliance Plan (CP).
- When approving SDLC deliverables, the meaning of signature (e.g., Approval role) confirms that all content within the document is accurate and complete as per the approver’s functional area of subject matter expertise. To avoid a conflict of interest, and following appropriate segregation of duties, **a person cannot approve for multiple key roles within the same document**. The document’s author is not required to sign as the author role, only approvers need to sign. When using digital document systems, author’s name can be captured in metadata or explicitly. When using paper document systems, author’s name, if required by the document, must be captured explicitly.
- While using SDLC templates to create deliverables, it is acceptable to add sections, as appropriate, but removal of sections is not allowed. For sections that do not apply, please mark “N/A” (not applicable) and document the rationale.
- For SaaS projects, vendors should have roles equivalent to J&J roles (as defined in this document and SDLC KMR) in order to ensure quality deliverables are documented, reviewed and approved as appropriate. For further guidance, please consult your IQ (GxP) and SQA (non-GxP) representatives.

- Business Simulation Testing (BST) is highly recommended for all projects. It is not a replacement for formal testing.
- In Agile projects with four systems landscape (Development, Pre-Quality (Controlled Staging environment), Quality, and Production), Technical Acceptance Testing (equivalent to Unit Testing) will be performed in the Development environment, Feature Integration Testing (equivalent to System Test) can be performed in the Pre-Quality environment, and User Acceptance Testing (UAT) will be performed in the Quality environment.
- The Technical Operations Owner should be consulted to ensure that Non-functional requirements (NFR) captured are accurate, complete, and verify that the design caters to the finalized NFRs captured as user stories or in a requirements specification document.
- Data in validated tools with electronic signatures will not need separate approval signatures as in a manually compiled deliverable. Ex: Traceability Matrix report created out of a tool, Sprint Backlog, etc.

8 Software-as-a-Service (SaaS)

SaaS projects provide a different approach as the software is licensed or leased from a vendor but the data is usually owned by the enterprise. To protect Johnson & Johnson assets, data, and applications the below depicts the validation process for a SaaS project.

For SaaS projects:

- Vendors providing SaaS applications that are GxP must be assessed to verify that their processes are acceptable for use and can be leveraged as part of SDLC.
- A Business Partner Risk Assessment (BPRA) must be conducted for all Vendors providing SaaS applications. The BPRA is not linked to the Approved Supplier List (ASL).

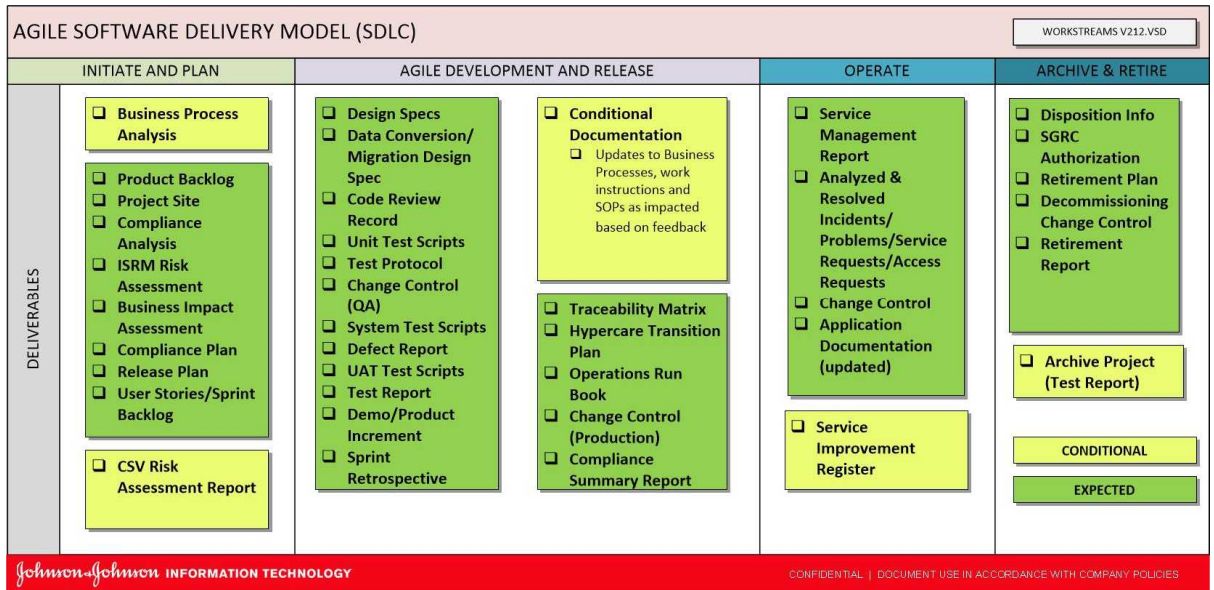
- In addition, the GxP Approved Supplier List (ASL) must be reviewed for the approved suppliers who are qualified to provide GxP SaaS service; all vendors must be qualified prior to their respective SaaS initial GxP use.
- SDLC tasks that utilize Vendor processes, Work Instructions, standards, templates, and tools must be clearly identified and approved in the Compliance Plan (CP).
- In some instances, both the vendor and project team are responsible for tasks in a specific SDLC Phase, such as Release Management. If this is the case, the expectation is that J&J SDLC process will be utilized for this portion of the project.
- There are SDLC tasks that must be executed using the tools and templates as identified by the SDLC in order to be in compliance with quality and regulatory oversight.
- A Business Continuity Plan at the Operating Company is required to address how data may be used or viewed when the SaaS application is retired, what happens if the vendor relationship is terminated, and a detailed plan on how the data will be migrated from the host system to the appropriate J&J platform.

This process identifies the J&J SDLC tasks that must be executed for SaaS projects in each phase for both the Waterfall and Agile Frameworks. For further guidance on GxP or non-GxP SaaS engagements, please contact your IQ or SQA representatives respectively.

9 Agile Framework

The Agile Framework is an approach for requirements and solutions to evolve through the collaborative effort of self-organizing cross-functional teams. It promotes adaptive planning, evolutionary development, early delivery, and continuous improvement, and it encourages rapid and flexible response to change.

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9.1 Initiate and Plan

The purpose of this phase is to elicit and analyze requirements, assess compliance applicability, assess risks of the business requirements, and prepare the Compliance Plan for the release. The key activity in this phase is to prepare the Product Backlog in consultation with Business Asset Owner, after which the Product Backlog is prioritized from a business perspective.

The Business Asset Owner is responsible to identify all regulatory requirements (e.g., GxP, privacy, SOX) in consultation with IQ, RIM and ISRM, and Privacy teams.

This phase also involves preparation to begin Agile Development which includes refining the Product Backlog, Release Planning, and Sprint Planning based on the Business Requirements. During Sprint Planning, identification and refining of User Stories are completed for the upcoming sprint.

In addition, controls are established in the form of Definition of Ready (DoR) and Definition of Done (DoD) as decided by the Scrum Team. The Business Asset Owner determines acceptance criteria for each release which includes the MVP and subsequent enhancements.

Please note:

- *The GxP Approved Supplier List (ASL) should be consulted for GxP applications as all vendors must be qualified prior to their initial GxP use.*
- *The Traceability Matrix must be initiated in this phase for Business Process and User Stories, Test Scripts and any other constructs as applicable.*

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- For Agile Teams, if a validated application is used to document and approve User Stories and Risk Assessment, it is not required to export and approve the Sprint Backlog separately.

No.	Applicability	Entry Criteria	Task/Validation	Template / Tool(s)	Exit Criteria / Deliverable	SaaS Applicability
1	Conditional (Supply chain projects with a budget of \$500,000 or higher)	Project Approval Vendor Assessment	Create Business Process Analysis (CPI)	Approved Tool Or Business Process Analysis Template	Approved Business Process Analysis	Use J&J SDLC
2	Expected	Approved Business Process Analysis (if applicable)	Create Product Backlog (rRDS if applicable)	Approved Tool	Product Backlog	Use J&J SDLC
3	Expected	Approved Business Process Analysis (if applicable) Product Backlog Project Case Newly Identified & Impacted System(s) & Application(s) Vendor Assessment (for SaaS)	Create Compliance Analysis	Approved Tool Or Compliance Analysis Template	Approved Compliance Analysis	Use J&J SDLC
4	Expected	Project Case Newly Identified & Impacted System(s) & Application(s)	Prepare Project Site	Approved Tool	Project Site	Use J&J SDLC
5	Expected	Product Backlog	Conduct ISRM Risk	Application Security	Data Flow Map	Use J&J SDLC

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No.	Applicability	Entry Criteria	Task/Validation	Template / Tool(s)	Exit Criteria / Deliverable	SaaS Applicability
			Assessment	Assessment Tool	Application Security Assessment	
6	Expected	Product Backlog Approved Compliance Analysis	Conduct Business Impact Assessment	Approved Tool	Approved Business Impact Assessment	Use J&J SDLC
7	Expected	Approved Compliance Analysis Product Backlog Approved Business Impact Assessment	Prepare Compliance Plan	Approved Tool Or Compliance Plan Template	Approved Compliance Plan	Use J&J SDLC
8	Expected	Approved Compliance Plan Product Backlog	Perform Release Planning	Approved Tool	Release Plan	Use J&J SDLC
9	Expected	Approved Compliance Plan Product Backlog	Refine User Stories (rRDS if applicable) (Can be approved at user story or feature level depending on project requirements)	Approved Tool	Approved User Stories or Feature Or Approved Sprint Backlog	Use J&J SDLC
10	Conditional (For GxP projects only)	Approved User Stories or Feature Or Approved Sprint Backlog Product Backlog	Conduct CSV Risk Assessment	Approved Tool Or CSV Risk Assessment Form	Approved CSV Risk Assessment Report	Use J&J SDLC

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No.	Applicability	Entry Criteria	Task/Validation	Template / Tool(s)	Exit Criteria / Deliverable	SaaS Applicability
		Approved Compliance Plan				

9.2 Agile Development and Release

The purpose of this phase is to implement User Stories that meet the DoD during a sprint. The sprint may result in a release. The Scrum Team is responsible to analyze, design, build and test each user story in the Sprint Backlog.

System Testing appropriate for the project (which includes functional, system, integration, performance, security, regression, data migration and data conversion, load testing, stress testing, business simulation, and installation quality testing as needed) and User Acceptance Testing (UAT) for User Stories executed in the Sprint Backlog is performed as needed. If there are any changes made to the user stories during the sprint then they must be added to the product backlog to assess for impact, prioritization, and test and must be traceable to the original user story. Please consult with IQ (GxP) or SQA (non-GxP) representative to align on the testing strategy prior to moving forward.

The product demo feedback is collected by the Scrum Team during a sprint. At the end of each sprint, a Sprint Retrospective may be performed to identify good practices and potential improvements. If the improvements result in new User Stories, they must be added to the Product Backlog and addressed in subsequent sprints.

It is imperative to have all identified deliverables per the Compliance Plan (CP) to be approved including Change Controls, Hypercare Transition Plan, Operations Run Book, etc. prior to a release. This is necessary to deliver an application with an operational capability that satisfies the Business Requirements. At the end of a release, a retrospective may be performed to identify good practices and potential improvements for the next release.

Please Note:

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- *The Hypercare Transition Plan should be drafted at the beginning of this phase with the involvement of the appropriate Operations Team.*
- *If Data Conversion/Migration is involved, the corresponding testing activities should be carried out.*

No.	Applicability	Entry Criteria	Task/ Validation	Template / Tool(s)	Exit Criteria / Deliverable	SaaS Applicability
1	Expected	Approved User Stories or Feature Or Approved Sprint Backlog Approved Business Process Analysis (if applicable)	Create Design Specification Create Data Conversion/Migration Design Specification (if data conversion/migration is involved)	Approved Tool Or Design Specification Template Data Conversion/Migration Design Specification Template	Approved Design Specification Approved Data Conversion/Migration Design Specification	Vendor Process acceptable (Integration Development must use J&J SDLC)
2	Expected	Approved User Stories or Feature Or Approved Sprint Backlog Coding Standards Approved Design Specification Approved Data Conversion/Migration Design Specification	Perform Coding/Development/Configuration Perform Code Review	Approved Tool Or Code Review Record Template	Development Assets (Code) Approved Code Review Record	Vendor Process acceptable (Integration Development must use J&J SDLC)
3	Expected	Approved User Stories or	Create and	Approved Tool	Unit Test Scripts	Vendor Process acceptable

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No.	Applicability	Entry Criteria	Task/ Validation	Template / Tool(s)	Exit Criteria / Deliverable	SaaS Applicability
		Feature Or Approved Sprint Backlog Development Assets (Code)	Execute Unit Test Scripts	Or Test Script Template		(Integration Development must use J&J SDLC)
4	Expected	Approved Compliance Plan Approved User Stories or Feature Or Approved Sprint Backlog	Create Test Protocol	Approved Tool Or Test Protocol Template	Approved Test Protocol	Vendor Process acceptable (Integration Development must use J&J SDLC)
5	Expected	Approved Design Specification Approved Data Conversion/Migration Design Specification Approved Test Protocol	Set up Test Environment/ Raise Change Control	Approved Tool	Approved Change Control	Vendor Process acceptable (Integration Development must use J&J SDLC)
6	Expected	Approved User Stories or Feature Or Approved Sprint Backlog Approved Test Protocol Approved Compliance Plan Unit Test Scripts	Create and Execute System Test Scripts Track System Test Defects	Approved Tool Or Test Script Template Defect Form	Approved System Test Scripts (pre and post approval required) Approved System Test Defects	Vendor Process acceptable (Integration Development must use J&J SDLC)
7	Expected	Approved User Stories or Feature	Create and Execute UAT Test Scripts	Approved Tool Or	Approved UAT Test Scripts (pre and post approval required)	Use J&J SDLC

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No.	Applicability	Entry Criteria	Task/ Validation	Template / Tool(s)	Exit Criteria / Deliverable	SaaS Applicability
		Or Approved Sprint Backlog Approved Test Protocol Approved Compliance Plan Approved System Test Scripts Approved System Test Defects	Track UAT Test Defects	Test Script Template Defect Form	Approved UAT Defects	
8	Expected	Approved System Test Scripts Approved System Test Defects Approved UAT Test Scripts Approved UAT Defects Approved Test Protocol Approved Compliance Plan	Create Test Report	Approved Tool Or Test Report Template	Approved Test Report	Use J&J SDLC
9	Expected	Approved User Stories or Feature Or Approved Sprint Backlog Development Assets (Code)	Perform Sprint Review/Demo	As applicable	Demo Feedback Product Increment	Vendor Process acceptable (Integration Development must use J&J SDLC)
10	Expected	Demo Feedback	Conduct Sprint Retrospective Meeting	Approved Tool	Sprint Retrospective	Vendor Process acceptable (Integration Development must use J&J SDLC)
11	Conditional	Approved Compliance Plan	Create Conditional	As applicable	Conditional Documentation	Use J&J SDLC

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No.	Applicability	Entry Criteria	Task/ Validation	Template / Tool(s)	Exit Criteria / Deliverable	SaaS Applicability
	(as per the Approved Compliance Plan)	Approved User Stories or Feature Or Approved Sprint Backlog	Documentatio n (User Manual, Standard Operating Procedure(s) (SOP), Work Instruction(s) (WI), Communicatio n Plan, etc.)			
12	Expected	Approved User Stories or Feature Or Approved Sprint Backlog Approved Design Specification Approved Data Conversion/Migration Design Specification Approved System Test Scripts Approved UAT Test Scripts	Create Traceability Matrix	Approved Tool Or Traceability Matrix Template	Approved Traceability Matrix	Use J&J SDLC
13	Conditional (DevOps team is not required to create a Hypercare Transition Plan but Production Readiness	Approved Test Report Approved Defect Report(s) Approved Compliance Plan	Perform Hypercare Transition Planning	Hypercare Transition Template	Approved Hypercare Transition Plan	Vendor Process acceptable (Integration Development must use J&J SDLC)

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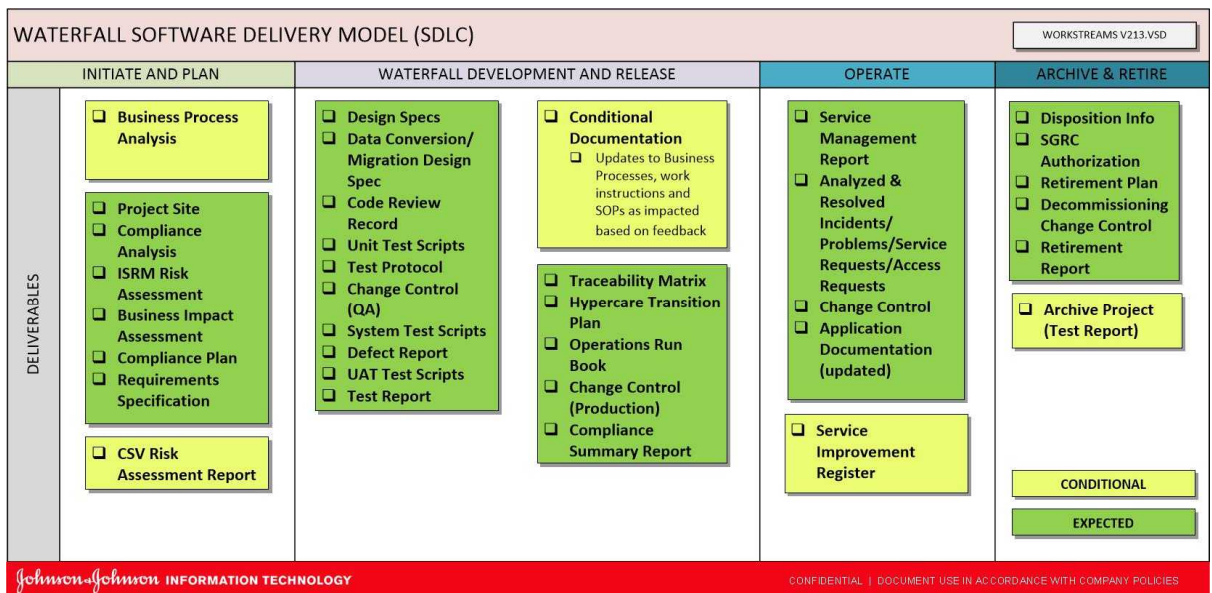
No.	Applicability	Entry Criteria	Task/ Validation	Template / Tool(s)	Exit Criteria / Deliverable	SaaS Applicability
	Checks must be documented and completed.)					
14	Expected	Approved Hypercare Transition Plan (if applicable) Approved User Stories or Feature Or Approved Sprint Backlog	Create/Update Operations Run Book (ORB)	Operation Run Book (ORB) Template	Approved Operations Run Book (ORB)	Vendor Process acceptable (Integration Development must use J&J SDLC)
15	Expected	Approved UAT Test Scripts Approved UAT Defects Approved Test Report Approved User Stories or Feature Or Approved Sprint Backlog Approved Compliance Plan	Prepare Production Environment/ Raise Change Control	Approved Tool	Approved Change Control	Vendor Process acceptable (Integration Development must use J&J SDLC)
16	Expected (must be approved before release for use)	Approved Compliance Plan Approved Test Protocol Approved Test Report Approved UAT Defects Developed Code/Configuration in Production	Create Compliance Summary Report	Approved Tool Or Compliance Summary Report Template	Approved Compliance Summary Report	Use J&J SDLC

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No.	Applicability	Entry Criteria	Task/ Validation	Template / Tool(s)	Exit Criteria / Deliverable	SaaS Applicability
		Loaded data in Production (if applicable)				

10 Waterfall Framework

The Waterfall Framework is a sequential design process, used in software development processes, in which progress is seen as flowing steadily downwards (like a waterfall) through the phases of conception, initiation, analysis, design, construction, testing, production/implementation, and maintenance. The following sections describe each of these phases in detail covering all the tasks and deliverables in order to deliver the required software and associated documentation.



10.1 Initiate and Plan

The purpose of this phase is to elicit and analyze requirements, assess compliance applicability, assess risks of the business requirements, and prepare the Compliance Plan for the release. The key activity in this phase is to prepare the requirements specification in consultation with the Business Asset Owner. The Business Asset Owner is responsible to identify all regulatory requirements (e.g., GxP, privacy, SOX) in consultation with IQ, RIM and ISRM, and Privacy teams. This phase also involves preparation to begin Waterfall Development which includes elaborating on the initial requirements.

Please note:

- *The GxP Approved Supplier List (ASL) should be consulted for GxP applications as all vendors must be qualified prior to their initial GxP use.*
- *The Traceability Matrix must be initiated in this phase for Business Process, User Requirements and any other constructs as applicable.*

No.	Applicability	Entry Criteria	Task/ Validation	Template/ Tool(s)	Exit Criteria/ Deliverable	SaaS Applicability
1	Conditional (Supply chain projects with a budget of \$500,000 or higher)	Project Approval Vendor Assessment	Create Business Process Analysis (CPI)	Approved Tool Or Business Process Analysis Template	Approved Business Process Analysis	Use J&J SDLC
2	Expected	Approved Business Process Analysis (if applicable) High Level Requirements	Create Compliance Analysis	Approved Tool Or	Approved Compliance Analysis	Use J&J SDLC

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No.	Applicability	Entry Criteria	Task/ Validation	Template/ Tool(s)	Exit Criteria/ Deliverable	SaaS Applicability
		Project Case Newly Identified & Impacted System(s) & Application(s) Vendor Assessment (for SaaS)		Compliance Analysis Template		
3	Expected	Project Case Newly Identified & Impacted System(s) & Application(s)	Prepare Project Site	Approved Tool	Project Site	Use J&J SDLC
4	Expected	High Level Requirements	Conduct ISRM Risk Assessment	Application Security Assessment Tool	Data Flow Map Application Security Assessment	Use J&J SDLC
5	Expected	High Level Requirements Approved Compliance Analysis	Conduct Business Impact Assessment	Approved Tool	Approved Business Impact Assessment	Use J&J SDLC
6	Expected	Approved Compliance Analysis High Level Requirements Approved Business Impact Assessment	Prepare Compliance Plan	Approved Tool Or Compliance Plan Template	Approved Compliance Plan	Use J&J SDLC
7	Expected	Approved Business Process Analysis High Level Requirements	Create Requirements Specification (rRDS) Create Data Conversion/Mi	Approved Tool Or Requirements Specification Template	Approved Requirements Specification Approved Data Conversion/Migration Requirements Specification	Use J&J SDLC

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No.	Applicability	Entry Criteria	Task/ Validation	Template/ Tool(s)	Exit Criteria/ Deliverable	SaaS Applicability
			gration Requirements Specification (if applicable)	Data Conversion/Mi gration Requirements Specification Template		
8	Conditional (For GxP projects only)	Approved Requirements Specification Approved Compliance Plan	Conduct CSV Risk Assessment	Approved Tool Or CSV Risk Assessment Form	Approved CSV Risk Assessment Report	Use J&J SDLC

10.2 Waterfall Development and Release

The purpose of this phase is to design, develop, test, and implement user requirements. The Functional and Non-functional Requirements (NFRs) are translated into design specifications (Architecture/Technical/Database Design Specifications as applicable) for the proposed solution. At this stage, alternatives are assessed, and architecture is based on the final selected solution.

System Testing appropriate for the project (which includes functional, system, integration, performance, security, regression, data migration and data conversion, load testing, stress testing, business simulation, and installation quality testing as needed) and User Acceptance Testing (UAT) for User Requirements is performed as needed. Please consult with an IQ (GxP) or SQA (non-GxP) representative to align on the testing strategy prior to moving forward.

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It is imperative to have all identified deliverables per the Compliance Plan (CP) to be approved (including Change Controls, Hypercare Transition Plan, Operations Run Book (ORB), etc.) prior to a release. This is necessary to deliver an application with an operational capability that satisfies the Business Requirements.

Please Note:

- *The Hypercare Transition Plan should be drafted at the beginning of this phase with the involvement of the appropriate Operations Team.*
- *If Data Conversion/Migration is involved, the corresponding testing activities should be carried out.*

No.	Applicability	Entry Criteria	Task/ Validation	Template / Tool(s)	Exit Criteria / Deliverable	SaaS Applicability
1	Expected	Approved Requirements Specification Approved Business Process Analysis (if applicable)	Create Design Specification Create Data Conversion/Migration Design Specification (if data conversion/migration is involved)	Approved Tool Or Design Specification Template Data Conversion/Migration Design Specification Template	Approved Design Specification Approved Data Conversion/Migration Design Specification	Vendor Process acceptable (Integration Development must use J&J SDLC)
2	Expected	Approved Requirements Specification Approved Design Specification Approved Data Conversion/Migration Design Specification	Perform Coding/Development/Configuration Perform Code Review	Approved Tool Or Code Review Record Template	Development Assets (Code) Code Review Record	Vendor Process acceptable (Integration Development must use J&J SDLC)

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No.	Applicability	Entry Criteria	Task/ Validation	Template / Tool(s)	Exit Criteria / Deliverable	SaaS Applicability
		Coding Standards				
3	Expected	Approved Requirements Specification Development Assets (Code)	Create and Execute Unit Test Scripts	Approved Tool Or Test Script Template	Unit Test Scripts	Vendor Process acceptable (Integration Development must use J&J SDLC)
4	Expected	Approved Compliance Plan Approved Requirements Specification	Create Test Protocol	Approved Tool Or Test Protocol Template	Approved Test Protocol	Vendor Process acceptable (Integration Development must use J&J SDLC)
5	Expected	Approved Design Specification Approved Data Conversion/Migration Design Specification Approved Test Protocol	Set up Test Environment/ Raise Change Control	Approved Tool	Approved Change Control	Vendor Process acceptable (Integration Development must use J&J SDLC)
6	Expected	Approved Requirements Specification Approved Test Protocol Approved Compliance Plan Unit Test Scripts	Create and Execute System Test Scripts Track System Test Defects	Approved Tool Or Test Script Template Defect Form	Approved System Test Scripts (pre and post approval required) Approved System Test Defects	Vendor Process acceptable (Integration Development must use J&J SDLC)
7	Expected	Approved Requirements Specification Approved Test Protocol Approved Compliance Plan	Create and Execute UAT Test Scripts Track UAT Test Defects	Approved Tool Or Test Script Template	Approved UAT Test Scripts (pre and post approval required) Approved UAT Defects	Use J&J SDLC

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No.	Applicability	Entry Criteria	Task/ Validation	Template / Tool(s)	Exit Criteria / Deliverable	SaaS Applicability
		Approved System Test Scripts Approved System Test Defects		Defect Form		
8	Expected	Approved System Test Scripts Approved System Test Defects Approved UAT Test Scripts Approved UAT Defects Approved Test Protocol Approved Compliance Plan	Create Test Report	Approved Tool Or Test Report Template	Approved Test Report	Use J&J SDLC
9	Conditional (as per the Approved Compliance Plan)	Approved Compliance Plan Approved Requirements Specification	Create Conditional Documentation (User Manual, Standard Operating Procedure(s) (SOP), Work Instruction(s) (WI), Communication Plan, etc.)	As applicable	Conditional Documentation	Use J&J SDLC
10	Expected	Approved Requirements Specification Approved Design Specification Approved Data	Create Traceability Matrix	Approved Tool Or Traceability Matrix Template	Approved Traceability Matrix	Use J&J SDLC

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No.	Applicability	Entry Criteria	Task/ Validation	Template / Tool(s)	Exit Criteria / Deliverable	SaaS Applicability
		Conversion/Migration Design Specification Approved System Test Scripts Approved UAT Test Scripts				
11	Conditional (DevOps team is not required to create a Hypercare Transition Plan but Production Readiness Checks must be documented and completed.)	Approved Test Report Approved Defect Report(s) Approved Compliance Plan	Perform Hypercare Transition Planning	Hypercare Transition Template	Approved Hypercare Transition Plan	Vendor Process acceptable (Integration Development must use J&J SDLC)
12	Expected	Approved Hypercare Transition Plan (if applicable) Approved Requirements Specification	Create/Update Operations Run Book (ORB)	Operation Run Book (ORB) Template	Approved Operations Run Book (ORB)	Vendor Process acceptable (Integration Development must use J&J SDLC)
13	Expected	Approved UAT Test Scripts Approved UAT Defects Approved Test Report Approved Requirements Specification Approved Compliance Plan	Prepare Production Environment/ Raise Change Control	Approved Tool	Approved Change Control	Vendor Process acceptable (Integration Development must use J&J SDLC)

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No.	Applicability	Entry Criteria	Task/ Validation	Template / Tool(s)	Exit Criteria / Deliverable	SaaS Applicability
14	Expected (must be approved before release for use)	Approved Compliance Plan Approved Test Protocol Approved Test Report Developed Code/Configuration in Production Loaded data in Production (if applicable)	Create Compliance Summary Report	Approved Tool Or Compliance Summary Report Template	Approved Compliance Summary Report	Use J&J SDLC

11 Operate Phase – Agile and Waterfall Framework

The purpose of this phase is to ensure that the Application Services team and specifically the Operations staff are equipped with the information required to perform day-to-day operations and to respond to emergency situations or any event that effects the application or system. The same process is applicable for both the Waterfall and Agile Frameworks. All operational changes should be performed in accordance with the change control process defined for that specific system.

No.	Applicability	Entry Criteria	Task / Validation	Template / Tool(s)	Exit Criteria/ Deliverable	SaaS Applicability
1	Expected	Approved Hypercare Transition Plan (if applicable) Approved Operations Run Book (ORB)	Report Against Service Levels	Hypercare Transition Plan Template Operations Run Book Template	Service Management Report	Vendor process acceptable

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No.	Applicability	Entry Criteria	Task / Validation	Template / Tool(s)	Exit Criteria/ Deliverable	SaaS Applicability
2	Expected	Approved Operations Run Book (ORB) ISM SOP/WI	Manage Incidents	Approved Tool	Resolved Incidents Raised Problem Records (if applicable) Satisfaction Feedback	Vendor process acceptable
3	Expected	Raised Problem Records Approved Operations Run Book (ORB) ISM SOP/WI	Manage Problems	Approved Tool	Resolved Problems Workarounds and Known Errors Reports and Improvement Recommendations	Vendor process acceptable
4	Expected	Service Requests Approved Operations Run Book (ORB) ISM SOP/WI	Manage Service Requests	Approved Tool	Fulfilled Service Requests	Vendor process acceptable
5	Expected	Operational Alerts Approved Hypercare Transition Plan (if applicable) Approved Operations Run Book (ORB)	Manage Events	As applicable	Communicated and Escalated Events Event Logs Indication of completeness of support activities	Vendor process acceptable
6	Expected	Information Security Policies Approved Hypercare Transition Plan (if applicable) Authorized Requests	Access Management	Approved Tool	Provision of Access to IT Services Records & History of access granted / denied	Vendor process acceptable
7	Expected	Operational Changes (minor change/enhancements)	Raise Change Control	Approved Tool	Approved Change Control	Vendor process acceptable
8	Conditional	Service Reporting	Continual	As applicable	Service Improvement Register	Vendor process acceptable

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No.	Applicability	Entry Criteria	Task / Validation	Template / Tool(s)	Exit Criteria/ Deliverable	SaaS Applicability
		Proposed Problem Resolutions and Proactive Measures Service Management Knowledge Repository Achievements against metrics, KPIs and CSFs	Service Improvement			
9	Conditional	Approved Operations Run Book (ORB) Approved Hypercare Transition Plan (if applicable) Changing Business Needs	Update Service Levels	N/A Updating existing document	Approved Hypercare Transition Plan	Vendor process acceptable
10	Expected	Changes to an existing application/system	Maintain Application Documentation	Approved Tool	Approved Application Documentation	Use J&J SDLC

12 Archive and Retire Phase – Agile and Waterfall Frameworks

This phase addresses the process of retiring the system once it has been decided to decommission the system. For all production systems and non-production systems that contain unique records and information, a determination of record retention requirements and Legal Hold preservation obligations must be completed to determine the next step in the Decommissioning process. RIM must review and approve the Retirement Plan and Retirement Report.

The same process is applicable for both the Agile and Waterfall Frameworks.

No.	Applicability	Entry Criteria	Task/ Validation	Template/ Tool(s)	Exit Criteria/ Deliverable	SaaS Applicability
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No.	Applicability	Entry Criteria	Task/ Validation	Template/ Tool(s)	Exit Criteria/ Deliverable	SaaS Applicability
1	Expected	Decision to Decommission	Enter TIME (Tolerate, Invest, Migrate & Eliminate) Disposition and Rationalization Target Date	Approved Tool	TIME Disposition and Rationalization Target Date	Use J&J SDLC
2	Expected	TIME Disposition and Rationalization Target Date	Complete Stage Gate Review Committee (SGRC) Review	Standardized SGRC Communication	SGRC Authorization Communication including Legal Hold preservation obligations, retention and archive requirement	Use J&J SDLC
3	Expected	SGRC Authorization Communication	Develop Retirement Plan	Retirement Plan Template	Approved Retirement Plan	Use J&J SDLC
4	Conditional (This is a requirement if SGRC has determined archiving is required during SGRC review)	SGRC Authorization Communication	Execute an Archive project Verify data availability from the archived location	N/A	Approved Test Report(s) or equivalent from Archive Project	Use J&J SDLC
5	Expected	Approved Retirement Plan	Execute System Decommission	Approved Tool	Decommissioned System Approved Closed Decommissioning Change Control	Use J&J SDLC

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No.	Applicability	Entry Criteria	Task/ Validation	Template/ Tool(s)	Exit Criteria/ Deliverable	SaaS Applicability
6	Expected	Approved Retirement Plan Decommissioned system	Verify Decommission Results Create Retirement Report	Retirement Report Template	Approved Retirement Report	Use J&J SDLC

13 Document History

13.1 Superseded Document(s)

- **Doc ID:** – N/A **Title:** - N/A **Effective Date:** - N/A

13.2 Revision History

Version	DD-MM-YYYY	Author	Change Summary	Major/Minor Change
20.0	19-Feb-2021	Ozepher Lewis	Section 2.1 – Out of scope – additional guidance added for POC projects. Section 7 - General Guidance - added exception from standard SDLC path for non-GxP websites or GxP websites classified as static content derived from product labeling	Minor
19.0	08-Apr-2020	Ozepher Lewis	Section 2 – Out of Scope Software as a medical device changed to “Medical Device Software” Added Proof of Concept Section 3- Definitions Terms and Acronyms not used within the SOP was removed Role Definitions – Roles not being used within the SOP was removed TAO Role was removed Role Mapping done: Business Asset Owner mapped to Product Owner JJT Asset Owner mapped to Service Owner Technical Operations Owner mapped to Operations Owner IQ mapped to CSV/Technology Quality (TQ) Section 4 – References to POL-1769 and SOP-8604 added Section 6 – Updated Process Diagram Section 8 – General Guidance as a new section added Section 9 – Agile Framework updated Removed SQA Stage Gates	Major

Version	DD-MM-YYYY	Author	Change Summary	Major/Minor Change
			<p>Phases reduced to two – Initiate and Plan, Agile Development and Release</p> <p>Removed Business Impact Assessment as a Template</p> <p>Removed ISRM Risk Calculator as a template and as a deliverable</p> <p>Section 10 – Waterfall Framework updated</p> <p>Removed SQA Stage Gates</p> <p>Phases reduce to two – Initiate and Plan, Waterfall Development and Release</p> <p>Removed Business Impact Assessment as a Template</p> <p>ISRM Risk Calculator as a template and as a deliverable</p> <p>Section 12 – Entire Phase revised.</p> <p>RACIS removed from all sections</p>	
18.0	23-Jul-2019	Ozepher Lewis	<p>Section 3 – All definitions pertaining to Tools removed.</p> <p>Section 4 – Removed old references</p> <p>Section 8 and Section 9 – Both Frameworks have been made Tool Agnostic. All Tools names in the ETVX matrices replaced with “Approved Tool”.</p> <p>Section 8.5 and Section 9.3 – PO added as a signatory for Test Protocol</p>	Minor
17.0	16-Nov-2018	Ozepher Lewis	<p>Section 3.1 (Definitions) – Business Partner Risk Assessment (BPRA) was added to this section of the document.</p> <p>Section 3.2 (Role Descriptions) - added clarifying verbiage such as “also known as” to CSV, IT Application Owner, and PO roles.</p> <p>Section 7 (Software as a Service SaaS) - clarifying verbiage added to the first paragraph on Business Partner Risk Assessment (BPRA). Added that vendors have to be checked in the Approved Supplier List for qualification prior to use of any GxP applications.</p> <p>Section 8.1 - Added that vendors have to be checked in the Approved Supplier List for qualification prior to use of any GxP</p>	Minor

Version	DD-MM-YYYY	Author	Change Summary	Major/Minor Change
			<p>applications.</p> <p>Section 9.1 - Added that vendors have to be checked in the Approved Supplier List for qualification prior to use of any GxP applications.</p> <p>Section 8.5 PO added as a signatory to task 6 of the Test Phase for Final Test Report, Final Post-Execution UAT Scripts, Final Post-Execution System Test Scripts</p> <p>Section 9.3 (Design Spec and Data conversion/migration spec added which are similar to the Waterfall track). This is already what is being utilized by the SDLC practitioners in the field today.</p>	
16.0	27-Jun-2018	Deborah Lang	Updated the reference section of the SOP by replacing the old TruVault CSV procedure IDs (1. PROCEDURE FOR GXP-REGULATED APPLICATIONS, 2. Risk Based Approach to Validation, and 3. CSV Risk Assessment) with the new IDs from the EDMS migration.	Minor
15.0	31-May-2018	Deborah Lang	<p>Changed the verbiage “groom/grooming” to refine/refining” for the Agile Framework so it is aligned with industry best practices such as Scrum Alliance.</p> <p>Updated to version 4.0 of master template TMP-1779</p>	Minor
14.0	17-Oct-2017	Deborah Lang	Added language to clarify that tools cited in this document via the ETVX matrices are not all inclusive, however, represent enterprise-wide tools. Project Teams should reach out to their CSV representative or SQA analyst for guidance on what tools may be utilized locally.	Minor
13.0	24-Apr-2017	Deborah Lang	<p>Version 12.0 was never made public as a last-minute correction from ISRM on their new Risk Assessment deliverables and signatories was required. Version 13.0 contains all the changes made in 12.0.</p> <p>Changes:</p> <p>Waterfall: 8.1 Discovery & Initiate – broke out Risk Assessment task (Task 4) into 2 parts (Task 4a and Task 4b) to correct and clarify signatories on GxP and non-GxP Risk Assessment deliverables.</p> <p>Agile: 9.2 Discovery & Initiate - Broke</p>	Major

Version	DD-MM-YYYY	Author	Change Summary	Major/Minor Change
			out Risk Assessment task (Task 5) into 2 parts (Task 5a and Task 5b) to correct and clarify signatories on GxP and non-GxP Risk Assessment deliverables.	
12.0	19-Apr-2017	Deborah Lang	<p>General:</p> <ul style="list-style-type: none"> Corrected typos; verified ETVX matrix for consistent template names. Corrected and verified RACIs throughout the document Added new column in RACIs to include signatories. <p>Updated Section 2: Scope to clarify mobile applications is included.</p> <p>Changes to Section 3.1 Terms: and Acronyms:</p> <p>Changes to Section 3.2: Role Descriptions:</p> <p>Updated Framework Diagrams for both Agile and Waterfall.</p> <p>Changes to Section 8: Waterfall ETVX tables Section 8.1:</p> <p>Changes to Section 9: Agile ETVX tables</p> <p>Changes to Section 10: Operations: ETVX tables</p> <p>Changes to Section 11: Archive & Retirement ETVX tables</p>	Major
11.0	21-Nov-2016	Deborah Lang	<p>General :</p> <ul style="list-style-type: none"> SOP consolidated to include Waterfall and Agile Framework <p>Section 2 (Scope)</p> <p>Out of Scope:</p> <ul style="list-style-type: none"> Software as Medical Devices (SaMD) projects; and Infrastructure projects. <p>Section 3.1 (Terms and Acronyms)</p> <ul style="list-style-type: none"> Includes the definition of terms used across the document. No separate glossary document <p>Section 3.2: (Role Descriptions)</p>	Major

Version	DD-MM-YYYY	Author	Change Summary	Major/Minor Change
			<ul style="list-style-type: none"> Includes the description of each of the Roles played by an individual or a department in the SOP under Waterfall and Agile Framework across all the phases <p>Section 6.1 (Process Diagram)</p> <ul style="list-style-type: none"> Process diagram for Waterfall and Agile Framework included <p>Section 7 – SaaS</p> <ul style="list-style-type: none"> Overview on Software-as-a-Service projects. <p>Section 8 (Waterfall Framework)</p> <ul style="list-style-type: none"> Described in detail with an ETVX table and RACI matrix for all the 6 phases <p>Section 8 (Agile Framework)</p> <ul style="list-style-type: none"> Described in detail with an ETVX and RACI for all the 5 phases <p>Section 9 (Operate Phase – Agile and Waterfall Frameworks)</p> <ul style="list-style-type: none"> ETVX and RACI matrix created that is applicable for both Waterfall and Agile Frameworks <p>Section 10 (Archive and Retirement Phase – Waterfall and Agile Frameworks)</p> <ul style="list-style-type: none"> ETVX and RACI matrix created that is applicable to both Waterfall and Agile Frameworks 	

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