

Title:

Software Development and Configuration

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1 PURPOSE

The purpose of this SOP is to outline the process for software development and configuration, ensuring quality, consistency, and security in the development and deployment of software products.

2 SCOPE

This SOP applies to all software development and configuration activities within the company, including the development, testing, deployment, and maintenance of software products.

3 REFERENCES

3.1 Internal References

- Document: QA-IR01 Internal References

3.2 External References

ISO 9001:2015 - Quality Management Systems – Requirements

- Chapter 8: Operation

ISO 27001:2022 - Information Security Management Systems – Requirements

- Chapter 8: Operation
- Chapter 10: Improvement

GAMP 5 - Good Automated Manufacturing Practice

- Chapter 4: Life Cycle Approach
- Chapter 5: Risk Management Approach

4 ABBREVIATIONS, TERMS & DEFINITIONS

Term	Definition
QA	Quality Assurance
URS	User Requirements Specification
FS	Functional Specification
DS	Design Specification
GxP	Good Practice (Quality Guidelines and Regulations)
RACI	Acronym for Responsible, Accountable, Consulted, and Informed
PM	Project Manager

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5 ROLES AND RESPONSIBILITIES

Role	Responsibilities
Project Manager (PM)	Oversees the software development process, supervises the execution of development models, conducts reviews and risk assessments, ensures adherence to coding guidelines, defines the 'definition of done', oversees deployment and release process, and continuous improvement. Represented by Project/Product Department.
Manager (Product)	The Product Manager is responsible for defining the product vision and planning the product roadmap.
Software Developer	Implements software requirements, works within development and testing environments, designs software architecture, manages source code, implements secure coding practices, fixes defects.
Quality Assurance Department	Reviews and approves test cases, identifies and tracks defects, reviews and approves traceability matrix and 'definition of done' report.
Security Department	Provides input for risk assessments, conducts security analyses, manages vulnerabilities.

6 PROCEDURE

6.1 Development Model

Role: Project Manager

The company adopts a flexible approach to software development, primarily utilizing the Agile Scrum methodology, which emphasizes iterative development, continuous integration, and regular communication. However, the Waterfall model may also be employed, contingent on the specific requirements and nature of the project. The Project Manager is tasked with supervising the execution of these development models.

6.2 Development and Test Environments

Role: Software Developer

The company maintains separate environments for development, testing, and production (for Cloud Solution only) to ensure code quality and prevent premature deployments. The Software Developer is responsible for working within these environments.

6.3 Product Planning

The Product Manager is responsible for defining the product vision and planning the product roadmap. This involves several key steps:

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- **Market Research:** The Product Manager conducts market research to understand customer needs, competitive landscape, and industry trends.
- **Customer Input:** The Product Manager actively seeks input from customers, especially for individual software solutions. This could be through direct communication, contracts, feedback forms, user forums, or customer advisory boards. The aim is to understand the specific needs and expectations of the customers, and to incorporate their feedback into the product planning process.
- **Product Features Definition:** Based on the market research and customer input, the Product Manager defines the features of the product. This includes the functionality, user interface, performance, security, and other aspects of the product.
- **Product Goals Setting:** The Product Manager sets the goals for the product, including the target market, expected sales, customer satisfaction, and other key performance indicators (KPIs).
- **Product Roadmap Planning:** The Product Manager plans the product roadmap, outlining the timeline for the development, testing, release, and post-release activities of the product.

The Product Manager ensures that the product planning process is customer-centric, data-driven, and aligned with the company's strategic objectives. The active involvement of customers in the planning process ensures that the product meets their specific needs and expectations.

6.4 Product Realization

Role: Project Manager, Software Developer

This involves acquiring requirements, managing changes, creating design documentation, and tracking development. The Project Manager is responsible for overseeing this process, while the Software Developer implements the requirements. The company uses a backlog system to manage Epics, Stories, Tasks, and Defects. This process should result in the creation of a User Requirements Specification (URS) document, a Functional Specification (FS) document, and a Design Specification (DS) document.

The comprehensive realization procedure should be delineated in a Validation Plan.

6.5 Change Management

Role: Project Manager

Change Management is an integral part of software development and configuration. It involves the systematic approach to proposing, evaluating, approving, and implementing changes to the software. This includes changes to software requirements, design, code, and testing procedures. The Project Manager and QA Manager are responsible for overseeing the change management process, while the Software Developer is responsible for implementing approved changes. Changes will be documented and tracked to ensure traceability. This process should result in the creation of a Change Management Log.

6.6 Documentation

Role: Project Manager

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All stages of the software development and configuration process should be thoroughly documented. This includes, but is not limited to, requirements, design documents, test plans, test results, change management logs, risk assessments, and review reports. Key documents should be reviewed and approved by the relevant stakeholders before they are finalized. The Project Manager and QA Manager are responsible for ensuring that all documentation is complete, accurate, approved accordingly and stored in a secure and accessible location.

6.7 Architecture and Design Review

Role: Project Manager

The software architecture is designed to meet the requirements and is reviewed for efficiency, scalability, and robustness. The Software Developer designs the architecture, and the Project Manager conducts the review.

6.8 Risk Assessments

Role: Project Manager, Security Department

Risk assessments are conducted to identify, assess, and manage risks. This includes assessing GxP impact, security impact, and performance impact. Risk severity and probability scores are assigned, and risk handling strategies are identified. The Project Manager conducts the risk assessments, with input from the Software Developer and Security Team.

6.9 Source Code Management

Role: Software Developer

The company uses a version control system for source code management. Access control is enforced, code reviews are conducted, and coding guidelines are followed. The Software Developer is responsible for managing the source code, while the Project Manager ensures adherence to coding guidelines.

6.10 Secure Development Method

Role: Software Developer, Security Department

The company follows a secure development method, including static and dynamic security code analysis, third-party vulnerability scanning, and penetration testing. The Software Developer implements secure coding practices, while the Security Team conducts security analyses and manages vulnerabilities.

6.11 Test Management

Role: QA Department

The testing process should be documented in a Test Plan, which outlines the testing strategies for the system, including unit testing, integration testing, system testing, and

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acceptance testing. It should define the test objectives, test cases, test data, and expected results. Test Case are reviewed and approved by the Quality Assurance Team.

6.12 Defect Management and Emergency Procedures

Role: Software Developer, QA Department

Defects are tracked, prioritized, and managed throughout the software development lifecycle. The Software Developer is responsible for fixing defects, while the QA Team identifies and tracks them.

Emergency Procedures are plans for handling unexpected issues or failures during the software development and configuration process. This emergency procedure applies only in case of a system crashes, data loss, security breaches:

The process is as follows:

1. **Emergency Identification:** Team members identify potential emergencies and report them immediately to the Project Manager.
2. **Emergency Response:** The Project Manager together with the QA Manager and with input from the relevant team members, will determine the appropriate response based on the nature and severity of the emergency. This could include pausing the project, rolling back changes, or activating backup systems. The Project Manager will inform all Department Heads and will provide the relevant input and progress on the resolution.
3. **Emergency Resolution:** The team will work together to resolve the emergency. This could involve fixing bugs, restoring data, patching security vulnerabilities, or other actions depending on the situation.
4. **Post-Emergency Review:** After the emergency has been resolved, the team should conduct a review to determine the cause of the emergency, assess the effectiveness of the response, and identify any lessons learned. This review should be documented and used to improve future emergency procedures. The QA Manager oversee the execution of the lessons learned.

6.13 Traceability Matrix

Role: QA Department

A Traceability Matrix should be created to link user requirements, functional specifications, design specifications, and test cases to ensure all requirements have been addressed and tested.

The Quality Assurance team will review and approve the Traceability Matrix.

6.14 Product Deployment and Release

Role: Project Manager, Software Developer

Software products are deployed and released in a controlled manner, ensuring that all requirements are met, and all tests are passed. The Project Manager oversees the deployment and release process, while the Software Developer and QA Team ensure the

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product is ready for deployment. This process should result in the creation of a Validation Plan and a Validation Report.

6.15 System Operation and Maintenance

Documentation detailing the system's operation and maintenance procedures should be developed. These manuals will serve as guides for users and maintenance teams, ensuring the system is used correctly and maintained properly.

6.16 Retirement Plan

A Retirement Plan should be created to outline the approach for decommissioning the system at the end of its lifecycle, including data migration, system shutdown, and documentation archiving.

6.17 Continuous Improvement

Role: Project Manager

The company continuously improves its software development and configuration processes, incorporating feedback and lessons learned. The Project Manager oversees this process, with input from the Software Developer, QA Team, and Security Team.

5. ATTACHMENTS

ID	Name	Description
ATT01	Documentation Inventory	List of all documentation deliverables required for in-house developed software products, including requirements, design documents, test plans, test results, change management logs, risk assessments, and review reports.
ATT02	Documentation RACI	RACI matrix outlining the roles and responsibilities for creating, reviewing, approving, and maintaining documentation deliverables for in-house developed software products.
ATT03	Traceability Matrix Template	Template for maintaining a traceability matrix that links user requirements, functional specifications, design specifications, and test cases to ensure all requirements have been addressed and tested.

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