COGNITION COCKPIT
Validation Kit

a look at Cognition's validation method for the Cockpit Platform

COGNITION

Cherie Young, Validation Consultant

Introduction

Validation is required, as regulated by FDA, to ensure that a company's product development software/system will meet its intended purpose. The software/system must show that it will function in a reliable, consistent manner and is in compliance with regulatory and business requirements. Additionally, once the software/system has been accepted and released for use, there is a need to maintain compliance and fitness throughout its operational life. Unfortunately, information on how to develop a validation plan and the activities expected as part of a validation effort are limited and subject to misinterpretation.

It is essential for the regulated company to have a clear and well-defined policy to ensure compliance and fitness for intended use of software used in the product development process. A validation framework should be included in this policy. Regulatory audits require a validation plan, validation report, and verifiable user/system requirements. The validation report, often the first document examined during a regulatory inspection, should demonstrate satisfactory completion of an agreed set of verification/test activities. The software/system is considered acceptable for release only after it has satisfied its verification efforts. Supplier assessments also need to be documented. Depending on the risk and complexity of the software, an audit of the supplier's development process may be necessary.

Cooperation is required between FDA, regulated companies, and external suppliers. Cognition is aware of the need for this regulatory compliance, and as a supplier, we play an important support role in achieving and maintaining system compliance and fitness for intended use as defined by our customers. Cognition Cockpit's Validation Kit provides a guide to assist medical device companies with their formal validation process. Designed to give an organization a baseline of Cockpit in its out-of-the-box state, the Validation Kit provides a framework to achieve FDA compliance, resulting in a comprehensive validation plan. Well-structured and modular by design, the Validation Kit provides for robustness, efficiency, and maintainability.

What is the Problem?

Documentation for validation can be confusing and limited, and as a result, there can be fear and concern over pending FDA audits and compliance concerns.

- What should the validation plan look like?
- What functionality should be validated?
- What determines compliance? Are there any gaps?
- How should test cases be designed to ensure all intended use cases are included?
- How is risk assessed?

Validation efforts are significant in terms of both time and cost.

- Who are the appropriate resources, and what is their availability?
- What is the validation process' impact on the current schedule?
- How long will the validation process take?
- How much is it going to cost?

Management of a validation process becomes critical.

What is the Solution?

Cockpit's Validation Kit can be a powerful aid to the software validation process. The Validation Kit documents evidence to show the system is performing as specified, thus meeting all its functional requirements as well as regulatory requirements. This provides confidence that the system is fit for its intended use.

Cockpit is determined as a GAMP Category 3[1], as defined in the book GAMP 5 - A Risk-Based Approach to Compliant GxP Computerized Systems. A thorough risk assessment has identified Cockpit's critical system impact on data integrity as low. Therefore, it is sufficient to provide traceability only between requirements and testing. Being a Category 3 allows the Validation Kit to have a simple approach consisting of one level of specification and verification in a single assessment.

System	Is there a potential for risk to product safety? (harm)	Is there a potential for risk to product quality? (performance)	Is there a potential for risk to record integrity?	Is there a potential for risk to the ability to demonstrate compliance?
Basic Functionality - Risks or hazards associated with the inherent functionality of the system.	No	No	Yes, R1	No
Defects - Risks associated with a defect present in the requirements, design, or code of a system.	No	No	No	No
Foreseeable Use Errors - Risks associated with unintentional use errors or when the user intentionally does something we recommend against.	No	No	Yes, R2	No
System Issues - Risks associated with potential hardware or other environment considerations.	No	No	No	No

Table 1: Risk Assessment

ID	Description	Severity	Control	Residual Risk
R1	Data history during design phase could be lost.	Low	• All reviewed and approved documents of record (whether stored in a corporate document control system or Cockpit itself) provide access to approved content. • System backups provide data/record redundancy.	Low: Backups can be restored and design data retrieved.
R2	Record loss due to user error or system failure.	Low	• User training conducted to ensure proper use of the system. • System Permissions and roles limit user operations. • Project and object versions and audit trails provide transaction history and recovery. • Quality recorded output includes a change history and is reviewed and approved as part of the document management process limiting the risk of inadvertent changes. • System backups provide data/record redundancy.	The system Admin can use the audit trail to identify who deleted a document and take corrective action. Backups can be restored and design data retrieved.

Table 2: Risk Control

Cockpit's user/system requirements focus on all key aspects of Cockpit usage and are driven by the customer's process needs. Requirements are written by Cognition Cockpit Engineers to ensure all core functional areas of Cockpit have been fully tested. Cockpit provides complete traceability from the user requirements, to the system requirements, to the tests. Each system requirement is

1 "If the product is purchased off-the-shelf and does not require configuration to support business processes, or where the default configuration is used by the regulated company, supplier involvement with the regulated company is, typically, limited to the provision of documentation, training, support, and maintenance. The product should be developed and maintained by the supplier in accordance with good practices."

fully testable, fully defined, and well organized. These requirements are then submitted to regression/acceptance tests, ensuring that existing core functionality has been retained. The Validation Kit also states any constraints and defines appropriate regulatory requirements, such as 21 CFR Parts 11 and 820, where applicable. Companies who use the Validation Kit save significant time since the need for developing user and system requirements is practically eliminated. Additionally, the Validation Kit is provided directly from Cognition Corporation in correlation with each new release of Cockpit, so new features are validated. Unused Cockpit features do not require validation by the business.

The Cockpit Validation Kit's testing approach simulates actual use with a practical approach in mind. Each test case typically consists of a single test. They are designed using a step-by-step systematic approach to provide appropriate and adequate testing, without redundancy, and to ensure database integrity. Procedures are well documented, and instructions for running test cases are clear and concise. The Validation Kit's test documents may be used as part of the customer's verification/validation documentation. As testing is a major time consuming exercise, the Validation Kit offers the greatest opportunity for efficiency by covering close to 100% of the intended use functions.

Cognition's development of the Validation Kit has taken into account not only the needs of customers, but also existing Cognition internal validation guidelines, including product quality requirements written for FDA, specifically 21 CFR Part 11. The Validation Kit test cases, where suitable, provide the traceability to the 21 CFR Part 11 matching regulatory requirement.

Validation Kit Coverage

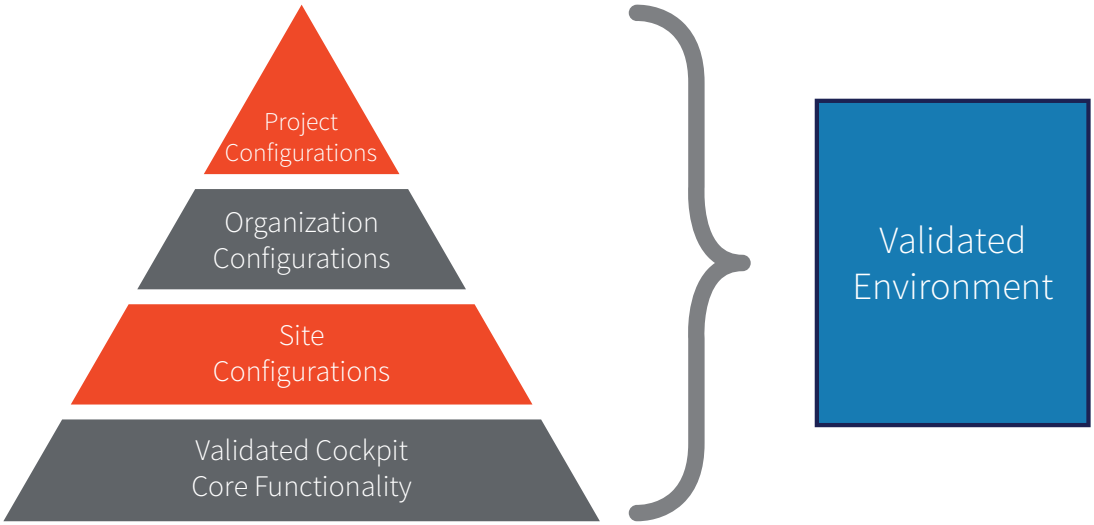
This Validation Kit is designed to give an organization an environment for validating Cockpit in their product development process for their intended use. The validation effort can be significant and quite costly; this Validation Kit will help reduce the resources required for a company to validate Cockpit.

The Validation Kit includes verification of the core functions in Cockpit as well as regulatory requirements. As the Validation Kit evolves, more verification of Cockpit functions are added, which follow the same standard approach used in the current version.

The Validation Kit was designed to help validate Cockpit software for use in a "design controlled" environment as part of a product development process. In addition, Cockpit software undergoes rigorous internal testing as part of Cognition's corporate Quality Assurance process.

Any formal validation of Cockpit must take into account the company's environment, users, processes, IT constraints, and any configurations or changes made to the software. This Validation Kit is a starting point to guide a design controlled environment in its formal validation process. Its modular design makes it easy to add business requirements and tests for any configurations. Site, organization, and project configurations verification tests are easily added, resulting in a complete and final validation report. The result is a validated design controlled environment.

Cognition can provide assistance by including validation of customer configurations, or the customer can use the Validation Kit out-of-the-box and add validation activity for their configurations. The Validation Kit belongs to the customer and can be modified as required.



Not all possible use cases or implementations of Cockpit are covered in the Validation Kit. Instead, the Validation Kit is designed to provide a baseline validation for Cockpit in its out-of-the-box state. Any changes or configurations an organization makes to Cockpit in the design controlled environment can be documented and tested using the framework set up within the Validation Kit. Cognition provides validation of the core Cockpit functions giving a solid foundation upon which to add customer specific validation needs.

Organization of the Validation Kit is as follows:

Functional Area	Description
Voice Management	Stakeholder needs, voice of customer, and functions typically used in the early stages of the product development process up to the creation of formal requirements.
Requirements Management	Creating, importing, and general work with requirements. This includes tables, layouts, allocation, flowdown, traces, and functions typically used in the core area of requirements definition, management, and trace.
Test Management	Assigning tests, milestones, V&V plan, and setup/execution steps. Linking tests to requirements and reporting on test status.
Risk Management	Working with Hazard Analysis, Failure Mode and Effects Analysis (FMEA), Fault Tree Analysis (FTA), linking risk information to requirements, and reporting on risks.
Common Capabilities Management	A general area holding many of the common functions used throughout the Cockpit UI.
Electronic Records & Signatures	21 CFR Part 11 compliance including the use of audit trails.
User & Group Management	Creating and managing Cockpit users and user groups.
System Management	Users help functionality.
Workflow Management	Using the workflow functions of Cockpit to control access, updates, privileges, check-points, approvals, baselines, and change management.
Business Management	An area for capturing your specific business and organizational requirements for use in your Cockpit process.
Meeting & Collaboration Management	Working with Cockpit's meeting manager, meeting minutes, action items, and reminders.
Project Management	Importing, exporting, copying, and creating derivatives of projects.
Change Management	Change requests and the workflow process, auditing trails, and traceability.
Defect Management	Tracking issues with requirements, risks, and tests.
Attachment Management	Uploading and controlling various external documents (e.g., PDF, DOCX, XLS, Visio).
Group Management	Generally used to organize a Bill of Materials structure.
Configuration Management	Creating commonly used configuration types.
Initiative Management	Helps to close gaps in requirements.
Document Review Management	Collaborative techniques used to help with tracking documents as they move through a review cycle prior to final approval.

Table 3: Core areas of Cockpit evaluated in Validation Kit

The Validation Kit follows these two standards:

AAMI TIR36-2007, Validation of Software for Regulated Processes

This applies to any software used to automate device design, testing, component acceptance, manufacturing, labeling, packaging, distribution, and complaint handling or to automate any other aspect of the quality system as defined by the Quality System Regulation (21 CFR 820). In addition, it applies to software used to create, modify, and maintain electronic records and to manage electronic signatures that are subject to the validation requirements (21 CFR Part 11). This TIR can also broadly apply wherever software automates processes regulated by the FDA. This TIR applies to software used in the production of a device and to software used in implementation of the device manufacturer's quality system. It does not apply to software used as a component, part, or accessory of a medical device or software that is itself a medical device.

The approach applied from the above standard is the validation of purchased software using a risk-based approach.

[AAMI]

GAMP 5 ®, A Risk-Based Approach to Compliant GxP Computerized Systems

GAMP guidance aims to achieve computerized systems that are fit for intended use and meet current regulatory requirements by building upon existing good practices in an efficient and effective manner. GAMP provides practical guidance that:

- Facilitates the interpretation of regulatory requirements
- Establishes a common language and technology
- Promotes a system life cycle approach based on good practice
- Clarifies roles and responsibilities

GAMP 5 ® is not a prescriptive method or a standard, but rather provides pragmatic guidance, approaches, and tools for the practitioner. When applied with expertise and good judgment, GAMP offers a robust, cost effective approach.

[GAMP]

Framework Prepares User Acceptance Tests

Although the ownership for the User Requirements Specifications belong to the business, leveraging Cockpit's user requirements from the Validation Kit provides the benefit of easily developing the framework for User Acceptance Tests (UAT). The Validation Kit's documentation of these requirements forms the basis for Cockpit acceptance testing. The Validation Kit's requirements and testing specifications offer an efficient way to develop UATs. The result is lean UATs, with an efficient, confident, validated environment without the burden of cost, resources, and time to the business.

Image 2: Phases of validation when using the Cockpit Validation Kit

Conclusion

Cockpit is an out-of-the-box, configurable software platform with low risk. Cognition Corporation conducts a thorough validation review of each Cockpit release. This validation effort includes all related requirements driving a Cockpit release. The Validation Kit provides a complete set of documentation in preparation for FDA audits:

Validation Kit Documents
Validation Plan with Risk Assessment
Validation Reports
User Requirements
System Requirements
Test Protocols with Results
IOQ Plan
IOQ Report
21 CFR Part 11 Gap Analysis

Table 4: Validation Kit Documents

Customers use the Validation Kit to support their ongoing validation efforts. Additional test cases required for specific configurations become simple once the framework has been provided. In addition, customers can use the Validation Kit's existing documentation when developing validation activities, such as UATs.

Customers can leverage Cognition's validation activities and documentation. This avoids duplication of effort. As a supplier of software for medical device product development, Cognition has a well-established, formal Quality Management System with significant test results available. The Validation Kit's testing strategy can be used as part of a customer's continuous validation effort, eliminating redundancy in testing.

Validation scope is determined by the extent of Cockpit's implementation as well as the extent of any customer specific configurations. Impact of the intended end use determines whether specific functions of Cockpit need additional validation. The Validation Kit supports ongoing future releases of Cockpit. It also supports continuous changes or additions to customer configurations.

Customers will see reductions in cost, time, and resources using the Cockpit Validation Kit. Cognition updates the Validation Kit constantly to support new Cockpit platform releases.

Resources

1. AAMI TIR36-2007, Validation of software for regulated processes
2. GAMP 5: A Risk Based Approach to Compliant GxP Computerized Systems
3. General Principles of Software Validation; Final Guidance for Industry and FDA Staff

For more information on the Validation Kit or the Cockpit Platform contact the Cognition Sales Team: sales@cognition.us

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24 Hartwell Avenue
Lexington, Massachusetts 02421
1-781-271-9300
www.cognition.us | sales@cognition.us