From Code to Compliance: Navigating the SDLC with AI in Open-Source Clinical Applications

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Agenda

Validation Requirements & Challenges in Pharma

GAMP 5 Meets Modern Development

AI-Enhanced Software Development Lifecycle (SDLC)

Real-World Implementation

Future of Clinical Reporting

Validation is critical in a regulated environment

Why?

Subpart B—Electronic Records

§ 11.10 Controls for closed systems.

Persons who use closed systems to create, modify, maintain, or transmit electronic records shall employ procedures and controls designed to ensure the authenticity, integrity, and, when appropriate, the confidentiality of electronic records, and to ensure that the signer cannot readily repudiate the signed record as not genuine. Such procedures and controls shall include the following:

(a) Validation of systems to ensure accuracy, reliability, consistent intended performance, and the ability to discern invalid or altered records.

What?

Intended use

+

Requirements

+

Testing

Documentation

Validation:

Why

What

How

Challenges in clinical software validation

Traditional Validation Overhead

- Long time-intensive processes
- High documentation burden
- Waterfall bottlenecks
- Risk-averse culture

Open-Source Adoption Barriers

- Regulatory uncertainty
- Package validation complexity
- Lack of standards
- Skills gap

How can tech-enabled pharma companies leverage open-source innovation while maintaining regulatory compliance and competitive speed?

FDA points to medical device validation

GUIDANCE DOCUMENT

General Principles of Software Validation

Guidance for Industry and FDA Staff

JANUARY 2002

Download the Final Guidance Document

Final

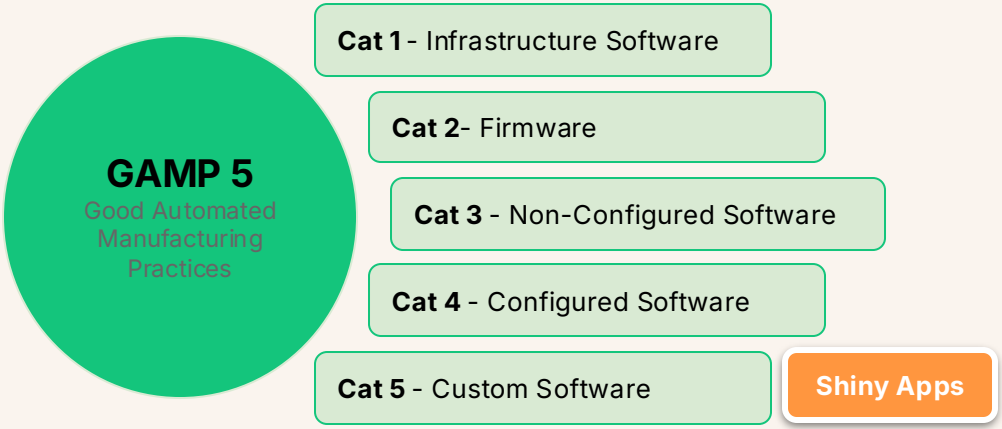
Docket Number: FDA-1997-D-0029

Issued by: Center for Devices and Radiological Health
Center for Biologics Evaluation and Research

This guidance outlines general validation principles that the Food and Drug Administration (FDA) considers to be applicable to the validation of medical device software or the validation of software used to design, develop, or manufacture medical devices. This final guidance document, Version 2.0, supersedes the draft document, General Principles of Software Validation, Version 1.1, dated June 9, 1997.

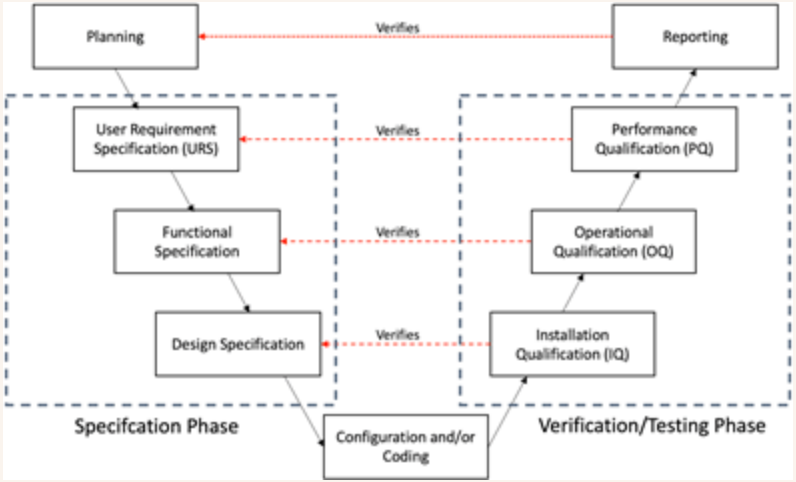
GAMP 5 provides another validation framework for GxP systems

- Developed by the International Society for Pharmaceutical Engineering (ISPE)
- Risk-based framework for ensuring quality, integrity, and compliance
- Impact + complexity
  - Product quality (IP)
  - Patient safety
  - Clinical data integrity
- Categories are increasing in technical complexity



Emily Yates. "Code that Cures: Validating GxP-Compliant R Shiny Apps for Clinical Decisions." R/Pharma Virtual Conference 2024.

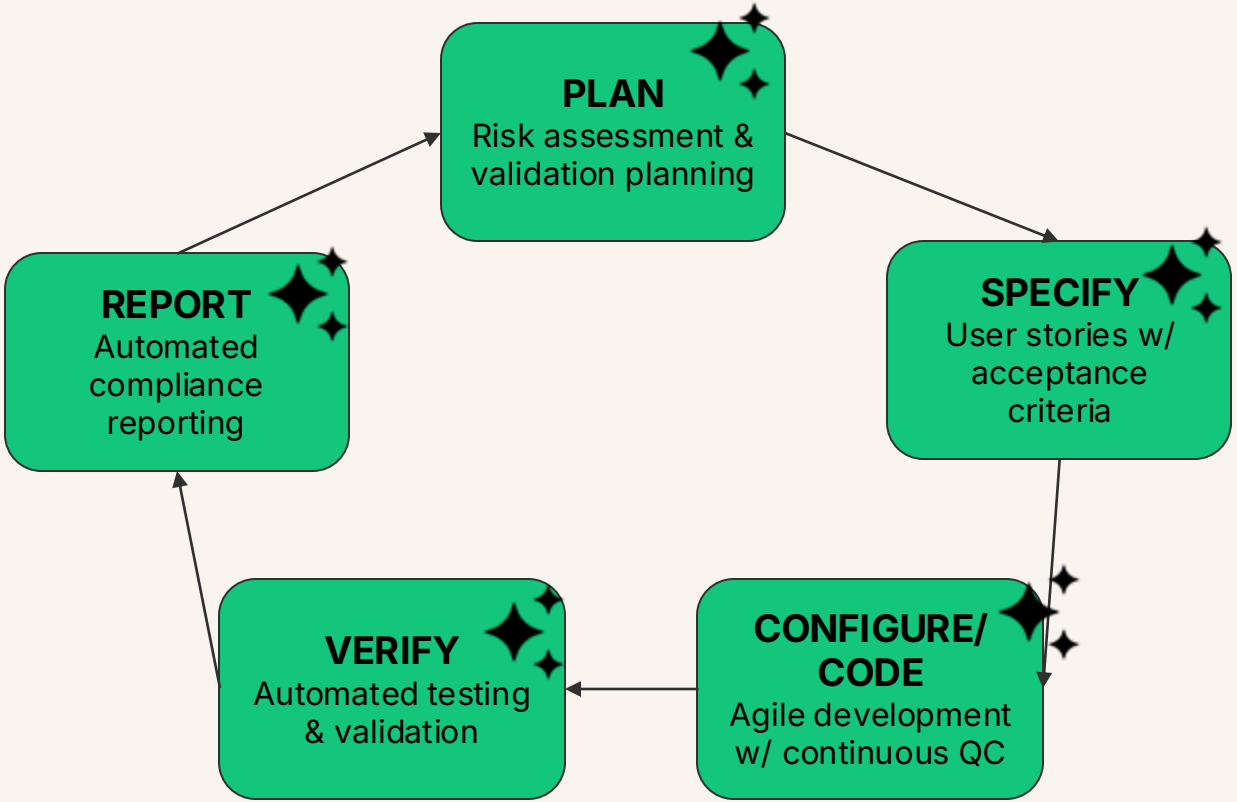
GAMP 5 compliant SDLC meets modern agile development



2008: Waterfall

2022: Agile

Agile SDLC AI-native process transformation



Important agile principles:

Tooling flexibility

Proof of validation and adherence to the process can live in more modern tools, such as Jira, instead of documents

Automated testing

Unit/Integration/E2E tests are mentioned in the guidance to demonstrate a successful feature implementation, but doesn't need to be manual

Critical thinking

Shift away from yes/no questionnaires to make decisions and towards discussions with that consider the system in question and its impact

Risk-based validation scalability

We can scale up/down validation activities and process based on the system complexity, risk, and impact

Risk assessment is a key component of an agile SDLC

- Every system requirement becomes a user story that is assessed for risk by a cross-functional group

- We do this by quantifying:
  1. **GxP Relevance**: does the feature impact patient safety, investigational product quality, trial data integrity?
  2. **Severity of Impact**: how bad is it if the feature fails. Does it directly, indirectly, or *not* impact the above?
  3. **Probability of Occurrence**: how likely is it that the feature will fail?

     → Proxy for complexity/novelty: more complex/novel features are more likely to fail

  1. **Probability of Detection**: how likely is it that we can detect a failure before there is GxP impact?

- These values go into a formula to quantify risk which determines the required level of testing:
  a. Low = Unit
  b. Medium = Unit + Integration
  c. High = Unit + Integration + E2E

Risk assessment for SAE Summary Report Generator

Example

System Requirement	System must generate standardized SAE reports exportable to PDF/Excel, filtered by trial/site/date	
User Story	As a clinical data manager, I want to generate SAE reports so I can share them with the safety monitoring board	
Risk Assessment	**GxP Relevance**: **High** *Directly impacts patient safety*	**Severity of Impact**: **High** *Directly impacts trial data*
	Probability of Occurrence: **Low** *Low complexity output*	**Probability of Detection**: **Med** *Failures could be missed*

Phase	Traditional Waterfall	AI-Enhanced Agile
Plan	Manual documentation Static specifications 6-8 week cycles	AI-supported validation plans Human-in-the-loop feedback cycles 1-2 week cycles
Specify	Manual architecture review Sequential approval gates Weeks for feedback	AI-supported requirements Continuous compliance checks Real-time feedback
Configure and/or Code	Periodic code review Manual documentation Post-development testing	AI-supported code development & review Continuous AI code review Test-driven development
Verify	Manual test case writing Sequential test phases Batch fixes	AI-generated test cases Automated test execution Immediate fixes
Report	Manual validation packages Weeks for approval Infrequent releases	Auto-generated documentation Continuous deployment Daily releases possible

AI implementation roadmap

Phase I: Foundation

- GAMP-complianct agile SDLC & Validation SOPs/workflows
- AI tooling such as ChatGPT Enterprise w/ Model Context Protocol (MCP)
- Validated data pipelines & programming environments (SAS, Posit, etc.)

Phase I: Intelligence

- AI-assisted documentation & code (Custom GPTs & Copilot)
- Automated test generation
- Human-in-the-loop reviews with feedback cycle

Phase I: Integration

- Implement multi-agent systems
- Continuous compliance monitoring
- Full process automation

Phase I: Optimization

- Model performance tuning
- Regulatory submission readiness
- Exponential efficiency gains while maintaining quality

Future of clinical reporting with AI

AI-Enabled Analytics Beyond Traditional Reporting

Moving from static reports to intelligent, real-time decision support systems that adapt to user needs and provide predictive insights

Next-Gen Capabilities

- **Dynamic visualization:** AI supported data exploration & context-aware dashboards
- **Automated insights:** AI generated interpretation of clinical findings
- **Predictive analytics:** Ai models for patient outcomes & trial success
- **Natural language interfaces:** Query clinical data using plain English

Collaborative Decision Support

- **Multi-stakeholder platforms:** Clinicians, statisticians, & regulators
- **Real-time collaboration:** Shared validation & review workflows
- **Intelligent recommendations:** AI-suggested analysis approaches
- **Regulatory readiness:** Built-in submission preparation tools