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How to Leverage Agile Methodology to Deliver GxP IT Validated Controls and Documentation?

Practioner's approach

Unmesh Chaudhari
Tata Consultancy Services

***Abstract* – This chapter discusses how Agile Model be leveraged without compromising its agility but at the same time, how to meet the regulatory compliance of GxP Validated process and formal documentation in Pharmaceutical and LiveScience IT projects.**

***Keywords*—21 CFR; GXP; Validattion and Verficiation Controls; Agile methodology; V-Model; GXP Documentation**

I. INTRODUCTION

Over the last few years, Agile Methodology implementations have been setting news trends of flexibility and business alignment. All leading industries intend to capitalize the full potential of Agile methodology including the Life science and pharmaceutical industry. The pharmaceutical industry, especially IT systems implemented in Regulatory, Safety and Clinical Trial functions have a unique requirement to comply with Title 21 the Code of Federal Regulations (21 CFR) and stringent GxP (good practice) validated controls.

This chapter will present the efficiency challenges typically encountered in Life science and Pharmaceutical IT projects while implementing GXP validated: (1) challenge to implement GxP Validation Controls using the Traditional Execution Model, (2) challenges to implement GxP Validation Controls using the Agile Execution Model. It presents the practitioner solution to implement GxP Validation Controls using Agile Model Adaptation

Note: This chapter does not detail the nuances of Agile Sprint process nor GxP Validation controls but focuses on an explicit use case about Agile adaptation to implement GxP Controls efficiently.

I.I PRAGMATIC CHALLENGES

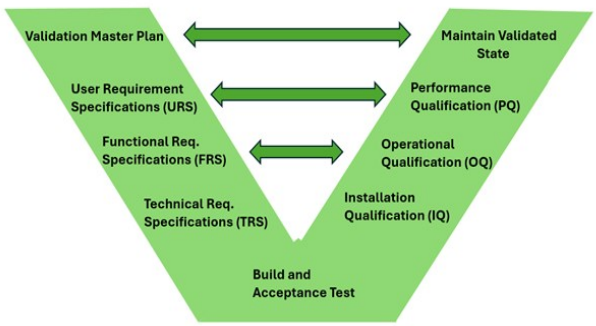

Figure 1: Traditional V-model of GxP Validation and Verification

A. Challenges to implement GxP Validation Controls using the Traditional Execution Model

Above figure 1 depicts how validated systems are typically implemented to comply the GxP Validation and Verification controls through the waterfall software development lifecycle phases

The validation controls for Installation Qualification (IQ), Operational Qualification (OQ) and Performance qualification traditionally are implemented in sequential manner. This may be less efficient in terms of cost, time sensitivity and perceived less flexible given the industry trends of Agile methodologies.

B. Challenges to implement GxP Validation Controls using the Agile Execution Model

- Most Viable Product (MVP) may get evolved over the sprints but getting it validated with GxP control documentation may impede the speed.
- Sponsors may perceive that agility of MVP and quality of GxP Validation controls may be competing and eventually compromise the cost and effort overrun.
- The morale of the Project team and the sponsors may adversely get impacted.

III. PRACTITIONER SOLUTION TO IMPLEMENT GXP VALIDATION CONTROLS USING AGILE MODEL ADAPTATION

The proposed solution is based on separating the focus on Agile development and V-Model Controls into a staggered but consecutive Sprints which should follow Implement, Validate and Deploy the MVP (n) iteratively.

The approach is based on the two key focus principles.
(1) Design, Build and Test MVP(n) functionally in Sprint(x)
(2) Verify/Validate MVP (x) and Design/Build/Test MVP(x+1) functionality in Sprint (x+1).
The Product Owner may choose to deploy one or multiple scrum teams collaborating but focusing individually on MVPs and Validation.

A. Solution Approch

The approach is detailed below.

(1) Sprint (x)

(1.a) Implement MVP(x): Design, Build and User Acceptance Controls in Sprint (x)

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(2) Sprint (x+1)

(2.a) Validate MVP(x): IQ, OQ, PQ controls

(2.b) Deploy MVP(x)

(2.c) Take up next MVP(x+1): Design, Build and User Acceptance Controls in Sprint (n)

(2.d) Repeat above approach during further Sprint iterations until Validating MVP(Final)

(3) Hardening or the final Sprint: reconciliation

(4) Validate Master Validation Plan

(5) Record the outcome as per GxP controls in the official system of records.

B. Solution Approach Illustration

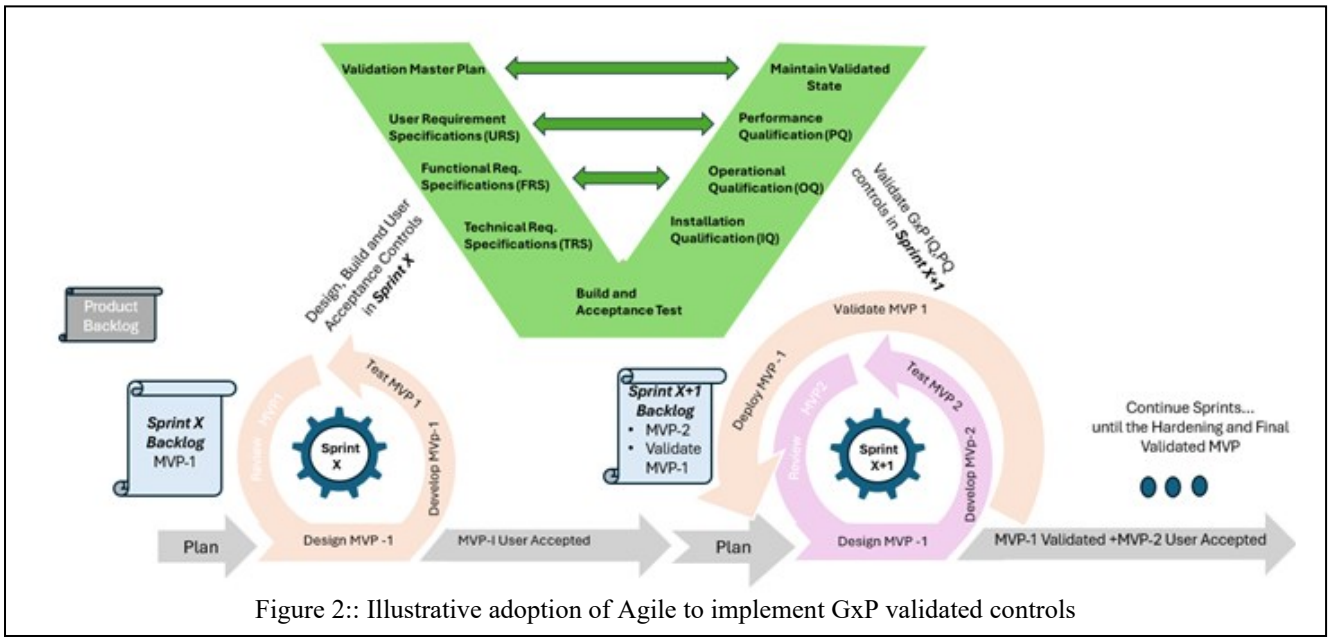

Figure 2:: Illustrative adoption of Agile to implement GxP validated controls

The following are the illustrative steps of Figure 2

(1) Develop Product Backlog including Functional Stories, Epics and Validation Plan

(2) In Sprint 1

(2.a) Plan the Sprint Backlog of MVP (1): Stories & Validation script preparations

(2.b) Execute:

- MVP (1): Develop and test
- MVP (1): Document URS, FRS and TRS
- MVP (1) User Demo and Acceptance

(3) In Sprint 2

(3.a) Plan

- Sprint Backlog about MVP (2) - Stories Validation script preparations

Validate and Deploy MVP (1)

(3.b) Execute:

- MVP (2): Develop and test.
- MVP (2): Document User Requirement Specifications (URS), Functional Requirement Specifications (FRS) and Technical Requirement Specifications (TRS)
- MVP (2) User Demo and Acceptance
- MVP (1): Validate IQ/PQ/OQ, Reflect in system of Records
- MVP (1): Deploy

(4) Iterate Sprints until the Hardening or Final sprint

(5) Reconcile in Hardening Sprint or Final Sprint

(5.a) Validate and complete IQ, OQ, PQ aligned to URS, FRS and TRS from the previous Sprint

(5.b) Verify the Master Validation Plan

(5.c) Validate Requirements Traceability Matrix

(5.d) Record the outcome as per GxP controls in the official system of records

IV. CONCLUSION

This chapter addresses the practical necessity for the pharmaceutical industry to implement GxP validated systems while leveraging Agile methodologies. It outlines common practitioner shortcomings observed in both traditional SDLC V-Model and ideal Agile methodologies. The chapter then presents a solution focused on separating the validation of GxP controls and distributing them over multiple sprints. While this solution mitigates the identified shortcomings, its application should be based on the project's duration and a cost-benefit risk assessment.