Validation Release Certification

This document confirms and attests that the 24R2 release of **Veeva SiteVault** on August 9, 2024, has been successfully validated by Veeva Systems as part of the *Veeva Digital Trials Platform*[1].

Approvals

Doc ID:	QV-40359		
Name	Title	Signature	Date
Business Approval			
George Essilfie	Director, Product Operations	*Approval by Electronic Signature in EDMS Vault*	
Validation Approval			
Harneet Kaur	CSV Program Manager, Clinical Systems	*Approval by Electronic Signature in EDMS Vault*	
Quality Approval			
Melissa Woodruff	Senior Quality Operations Program Manager	*Approval by Electronic Signature in EDMS Vault*	

The validation package is published to Veeva Compliance Docs. In the case of an audit or inspection, the validation package can be made available to SiteVault customers by contacting SiteVault Support. The validation package includes the following documents:

Deliverable	Description
System Overview	Overview of the system and the validation boundaries
Validation Project Plan	The plan of activities, deliverables, and resources
Qualification Protocol	Overview of the testing environment, strategy, assumptions, and test design
Requirements & Specifications[2]	System requirements and specifications
Installation Qualification Testing[2]	Qualification of the test team, devices used, test environment, and configurations required for the system to perform its intended use
Operational Qualification Testing	Testing and verification of the functional requirements
Performance Qualification Testing	Testing and verification of business processes and performing its intended use within a normal operating environment
Requirements Traceability Matrices	Traceability of system requirements to test cases
System Release Memo[3]	Early summary of validation results to support customer pre-release testing
Validation Summary Report	Summary of all the validation activities performed and confirmation the system is fit for use

System validation will be maintained through the use of approved standard operating procedures. All future modifications to the core functionality will be addressed through change control procedures. Veeva has validated the technical controls of SiteVault in alignment with industry recognized frameworks including:

- ISPE GAMP 5 A Risk-Based Approach to Compliant GxP Computerized Systems
- PIC/S Good Practices for Computerized Systems in Regulated “GXP” Environments
- FDA General Principles of Software Validation

[1] Veeva Digital Trials Platform encompasses systems and functionality that connects study sponsors, research sites, and study participants.

[2] Specifications and Installation Qualification Testing are only available during audit of Veeva, or in the case of Health Authority Inspection/Audit review with Veeva personnel supporting.

[3] Only applicable for SiteVault Enterprise customers.

Signature page for SiteVault 24R2 Validation Release Certification (v1.0)

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