



Validation Release Certification

This document confirms and attests that the 25R2 release of **Veeva SiteVault** on August 01, 2025, has been successfully validated by Veeva Systems.

Approvals

Doc ID:	QV-52259		
Name	Title	Signature	Date
Business Approval			
Cooper VanLare	VP Product, Site Solutions	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 [Veeva Site 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 & Specifications¹	System requirements and specifications
Installation Qualification Testing¹	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 Memo²	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, accessed via web or Veeva Vault Mobile³, 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 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.

² Only applicable for SiteVault Enterprise customers.

³ Veeva Vault Mobile functionality validated as part of the Veeva Vault Platform.

Signature page for SiteVault 25R2 Validation Release Certification (v1.0)

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Functional Approver	Cooper VanLare Approver 30-Jul-2025 23:58:59 GMT+0000
Functional Approver	Melissa Woodruff Approver 31-Jul-2025 02:20:12 GMT+0000
Functional Approver	Harneet Kaur Approver 01-Aug-2025 00:12:45 GMT+0000