



## **General Service Description**

This Service Description Document gives a high-level description of the Veeva SiteVault Free software application available from Veeva Systems.

### ***SiteVault Free***

Veeva SiteVault Free is a software application that is built upon the Veeva Vault platform. Signing up for SiteVault Free provides the customer access to the application on a Veeva managed infrastructure. Each SiteVault Free contains functionality to streamline their site regulatory processes. The SiteVault Free application has been designed with regulated system compliance in mind and includes functionality and controls in accordance with industry guidance.

There is no limit to the number of users at a customer site that can use the SiteVault Free application or the volume of documents or data that can be put in a customer vault. The maximum size of an individual file that can be uploaded to SiteVault Free is 4GB. Data and documents in SiteVault Free are subject to a time-based retention limit as specified in Veeva Terms of Service per study, beginning from the date on which the study record was created. When a study has reached this milestone, Customers are responsible to extract any data and documents for the study that need to be retained. Veeva will provide application functionality and support to the customer for this extraction activity.

### ***SiteVault Free Validation***

Following a risk-based approach, Veeva will validate high-risk features of each SiteVault Free release and the validation documentation will be made available to the customers. The overall testing and validation approach follow a modified GAMP-V model.

A Validation Project Plan outlines the Installation Qualification (IQ) and Operational Qualification (OQ). Veeva Product Quality develops an Infrastructure Specification (IS) and confirms Hardware and Software Installation through Installation Qualification. Subsequently, a Business Requirements Document (BRD) is developed and tested against in system functional testing through Operational Qualification.

Veeva Services leads the Performance Qualification (PQ) portion of the validation. The following documents are developed as part of the validation effort: Validation Plan, User Requirements Specification (URS), Configuration Specification (system generated excel export), UATPQ Test Plan, UATPQ Test Scripts, Requirements Trace Matrix (RTM), and Validation Summary Report (VSR).