# Introduction

## Overview

Veeva Vault is a Software as a Service (SaaS) content and data management platform and suite of applications developed by Veeva Systems. Vault is specifically designed for the life sciences industry, producing secure and compliant audit trails and electronic signatures in accordance with FDA’s 21 CFR Part 11 and Eudralex Annex 11 regulations.

Veeva delivers three (3) major releases per year and provides a Release Impact Assessment (RIA) for each major release to help customers evaluate the impact of the release on their application(s).

## Purpose

This document outlines the process that is followed in review of the Veeva Vault Risk Impact Assessment as it affects the <<customer name>> Vault applications. This document will demonstrate that the <<release number>> release has been evaluated for impact to all of <<customer’s>> Vault applications.

## Scope

Evaluation of the <<release number>> release features for the following Vault applications:

* Platform
* << Vault application>>
* << Vault application>>

# Approach

A risk-based approach was followed in evaluating the <<release number>> RIA and the new features available in the Vault. The following process was implemented:

1. Excel version of the <<release number>> Release Impact Assessment was obtained.
2. Features not applicable to the applications listed in the Scope section above were filtered out.
3. Remaining features were reviewed with a Veeva Vault Certified Administrator for impact to <<customer’s>> existing applications identified in the Scope section.

The result of this process yielded features grouped into the following categories:

|  |  |
| --- | --- |
| No impact | Does not affect <<customer>> configuration, and/or will not be adopted |
| No current change/impact | No immediate impact, but may assess for feature functionality and enhancement in the future |
| To be adopted | No immediate impact or change, to be evaluated for adoption on a schedule determined by <<customer>> |
| Will accept as auto-on with no further testing | <<customer>> will accept the feature and the validation documentation provided by Veeva without any additional testing |
| Will accept as auto-on with additional testing | <<customer>> will accept the feature and will perform additional validation testing in the pre-release Vault  |

# Results

Following the above approach, <<#>> features were evaluated for impacts and enhancements. The breakdown has been recorded in the <<customer’s Excel version of RIA>>.

# References

* <<RIA>
* <<customer’s Excel version of RIA>>
* <<applicable Veeva validation documentation (i.e. OQ test scripts)>>

# Approvals

Approval of this document and the associated <<customer’s Excel version of RIA>> demonstrates the evaluation of the release has been completed and the system is acceptable for upgrade.

Document Approvals will be administered in Vault. Signature renditions will be appended to this document.