

CASE STUDY

InformaticTech Improves the Report Management Process through Seamless Veeva Vault Implementation



Client Overview

The client has experienced a 200+ percent surge in its headcount. Currently, the business has more than 100 full users and two sites in San Diego and New York.

The Challenges

Focused on the development of therapies to treat chronic liver and intestinal diseases, the client's business wanted to implement marketing applications for managing two INDs (in-house); utilizing submissions outsourcing partner for NDA and MAA; and utilizing Veeva across a number of areas including Submissions, QualityDocs, PromoMats, MedComms, and CRM. These implementations, however, are complex and may cause business interruptions when done incorrectly. This is when they turned to InformaticTech for support.

The Solution





During the implementation, processes were being built in parallel to resolve the mismatch of initial configurations with existing business processes. As the timing of author training was critical to ensure successful transition, the InformaticTech team provided refresher training for "legacy" authors and new user training was completed during the first week. Follow-up training has been scheduled to ensure continuous learning.

Outcomes Delivered



The team created custom QA/QC workflow:

1. Select QA/QC group (one person from the group accepts or an individual of the QA/QC group)



2. Select the QA/QC Review Focus

-  Editorial
-  Internal Consistency (Content/Data)
-  External Consistency (Content/Data)
-  Data/Numbers Only

3. Select the QA/QC Review Type

-  Abbreviated (portion of the document)
-  Full (all of the document)

The team delivered significant elements for reporting and dashboard:

-  Reporting for initial IND or NDA/MAA
 - Report for each module
 - Easily configurable reports
 - Ability to export to Excel
 - Distribution to the team lead
-  Reporting for initial IND or NDA/MAA
 - Reports for submission
 - Submission log by application
 - Based on the binder metadata
 - Reports for correspondences
 - Correspondence log by application
 - Based on application + classification