

Implementation and Optimization of Veeva Vault



Introduction

Veeva Vault has become one of the leading tools that life sciences teams are using to manage content and global product registration data. Vault offers capabilities on a single cloud-based platform that span the product development lifecycle. The Veeva Vault Suite includes a Clinical Suite, Quality Suite, RIM Suite, and the Commercial Cloud.

The regulatory lifecycle is complex and constantly changing. The need for teams to manage and access large volumes of information about development and commercial products increases the complexity. The information must be organized to support cross-functional access whenever and wherever it is needed. Large and small organizations have chosen Veeva Vault to address this need.

A well-planned global implementation of Vault, or any solution, can lead to significant efficiency gains. Yet, the technology is only an enabler of the larger business process. If the technology is not configured and implemented correctly to address the business needs, a system alone will not do anything but add to the complexity.

The other key component is an implementation that is informed by expertise and best practices. The combination of cutting-edge technology configured to enable proven work practices leads to success.

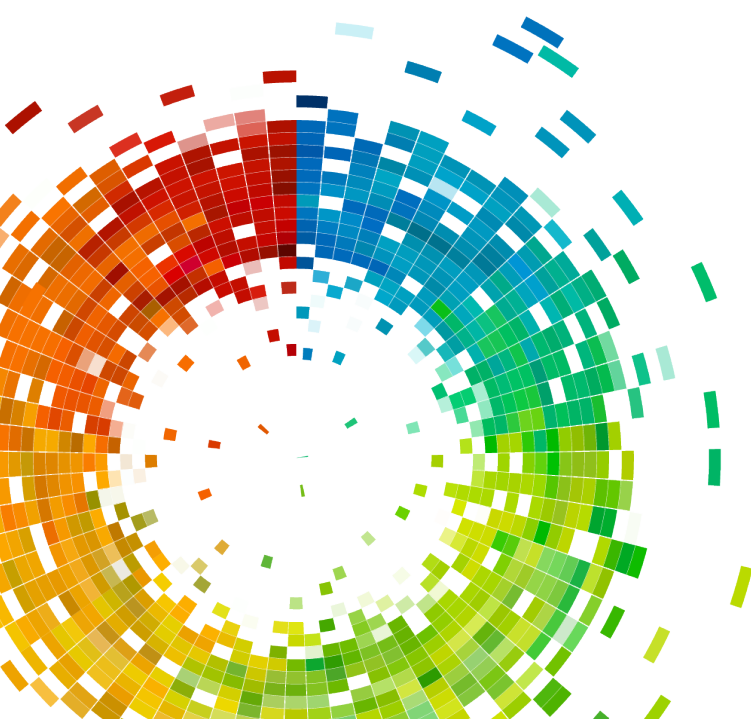
This paper will describe Red Nucleus R&D's proprietary approach to implementing and optimizing Veeva Vault. The approach is based on years of process, technology, and R&D expertise. The Red Nucleus R&D team continues to refine our practices and update our approach to address evolving requirements.

The Red Nucleus Methodology

The Red Nucleus methodology is centered on the premise that BUSINESS PROCESS is the foundation for system implementation, and it must serve as the core driver for all associated deliverables. Through our extensive experience with Veeva Vault, we have developed a proprietary toolkit that addresses the 5 key components of a Vault implementation:

- Business Process Requirements
- Data Governance
- Organization Change Management
- Configuration/Validation
- Migration/Ongoing Maintenance

The toolkit has evolved over time and has been formalized through numerous successful implementation projects. Each client organization has different needs and different current capabilities. We use the 5 components as a framework for discussions to develop a customized approach for each sponsor team. This approach combines proven strategies with customized tasks to ensure that the team gets the most from their technology investment.



Business Process Requirements

The Red Nucleus R&D team works closely with both business and IT leaders to develop a framework that ensures business processes are optimized and leveraged to drive system configurations that are tested and accepted for use.

The Red Nucleus R&D team drives best practice process development and optimization initiatives that serve as the foundation for system configuration and training. The processes help sponsor teams understand the technology context for their operations. The Red Nucleus team also provides the support for developing or updating SOPs based on the optimized processes and system needs.

Data Governance

The consistent use of solid data standards and practices is critical to success. We partner with sponsor teams to establish a security matrix with all the relevant tasks and roles identified in the business process. Detailed data and attribute definitions and descriptions support a comprehensive Master Data Governance Program that informs the implementation.

Organization Change Management

Change management, at its core, focuses on frequent and timely communication as well as end user training. The Red Nucleus R&D team develops a customized communication plan to promote education and awareness, improve stakeholder engagement, and provide functional briefings. The plan leverages existing communication channels as well as new mechanisms for sharing information.

Training programs are customized to meet the needs of the client organization. We offer train-the-trainer sessions, role-based training, e-learning modules, and other interactive means of educating stakeholders. Our substantial experience with Vault informs our training programs, ensuring that they are practical, useful, and relevant to the user community.

Configuration/Validation

Validation documentation can be difficult to develop and very time and resource intensive. The Red Nucleus R&D team delivers rigorous validation documentation as part of each Vault project. User requirements specification (URS), user acceptance testing (UAT), traceability matrix, and a complete validation plan are typically included in our approach. These documents often pose a challenge for sponsor teams because of the time and effort required to develop, review, and finalize. The devil is in the details – a detailed URS and UAT ensure that the system is configured to meet the business needs. We partner with the sponsor to facilitate the completion of these essential documents.

Migration/Ongoing Maintenance

Most sponsors already have some documents and data in legacy systems. The Red Nucleus R&D team maps document fields and values from the legacy system to Vault. Our experience includes significant migration testing and execution. The team is also versed in preserving the system and supporting processes and training post-go-live including triage, escalation, and sustainment of change controls and business help desk requests.



Core Program Deliverables

When a sponsor works with the Red Nucleus R&D team, they can expect the following high-quality deliverables:

- Business process with defined roles, responsibilities, and system touchpoints
- File guide (defines metadata standards and workflow requirements)
- Security matrix (Vault system permissions tied to the defined roles and responsibilities)
- User requirements specification, ensuring inclusion of all defined business requirements
- User acceptance testing (detailed scripts and execution)
- Migration management (strategy and oversight of mapping and testing)
- Training material (including process training, Vault video tutorials, e-learning, mobile quick reference, instructor-led training sessions)

Our Experience

The Red Nucleus R&D team consistently delivers successful Veeva Vault implementation and optimization projects. We form a unique partnership with clients and the Veeva Vault organization.

Red Nucleus's cross-functional expertise, process-driven approach, and proven methodology increase compliance, reduce costs, and enhance overall efficiency. We are not only consultants; we are customers of the same solutions. We understand the pain points and what is required for a successful Vault implementation.

Partnering for Success

As we initiate a Vault project, we work with both the client and Veeva to ensure a 3-way partnership. This defines all 3 organizations as team members. This common membership ensures that all participants are supporting the project goals to the fullest extent.

Following are brief case studies. The first describes a successful implementation project and the second details an optimization project in an existing Veeva Vault system.

A Global Vault Implementation

The Challenge

The global pharmaceutical company made the decision to implement Veeva's Submissions and Submissions Archive Vault.

The Red Nucleus R&D Approach

The Red Nucleus R&D team was retained to support the company with the end-to-end project. Our team was engaged well in advance of the Vault implementation. Red Nucleus R&D supported the program's overall project management office (including all global stakeholder management meetings). We worked closely with the global business team to define the business processes (including roles, responsibilities, access, and security controls). We also worked with the client's informatics team to ensure business requirements were appropriately translated to IT configurations. Our team supported the URS and UAT (development and execution). Through this process, we established a trusted partnership with the client and proceeded to support them in instructor-led training and ongoing system maintenance.

Solution

The Red Nucleus R&D team led a successful implementation of Submissions/Archive Vault for a global pharmaceutical company impacting ~1,700 users globally.

Optimizing Veeva's PromoMats Vault

The Challenge

A global pharmaceutical company needed to optimize Veeva's PromoMats Vault for use in the United States. The system had been previously implemented for global use; however, it was never configured appropriately for optimal use in the United States.

The Red Nucleus R&D Approach

Red Nucleus R&D served as the client's SME (understanding and guiding business needs of the commercial organization and translating them into system requirements). We worked closely with a cross-functional team to define the business processes and business requirements that served as the foundation for system configuration. Our team supported the US business team, working closely with the global business owner (not US based) to optimize the system accordingly. We also worked hand-in-hand with Veeva to ensure the business requirements were translated into system configurations. (Red Nucleus R&D took on this role so that the client could focus on their "day job" as the effort was significant and the client's team was short staffed.)

Solution

Our team led the optimization of PromoMats Vault for a global pharmaceutical company impacting ~50 users in the United States. We helped the team derive more value from their existing technology investment by optimizing processes and configurations to support their goals.

Conclusion

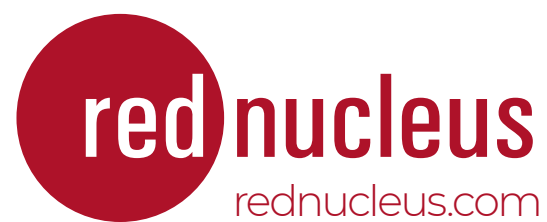
The Red Nucleus R&D team is proud of our extensive experience working with drug development and lifecycle application submissions, including global submissions. Our in-depth knowledge of relevant global guidelines and business processes allow us to identify technical requirements and better serve our clients with effective and efficient solutions.

We also have specialized experience implementing and optimizing Veeva Vault:

- **Veeva RIM Suite**
 - Vault Registrations
 - Vault Submissions
 - Vault Submission Publishing
 - Vault Submission Archive
- **Veeva Clinical Suite**
 - eTMF, CTMS
- **Veeva Quality Suite**
 - Vault QMS
 - Vault QualityDocs
- **Veeva Vault PromoMats**



**Red Nucleus
R&D is a White
Belt Certified
Veeva Vault
Implementation
Partner.**



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