::: fme
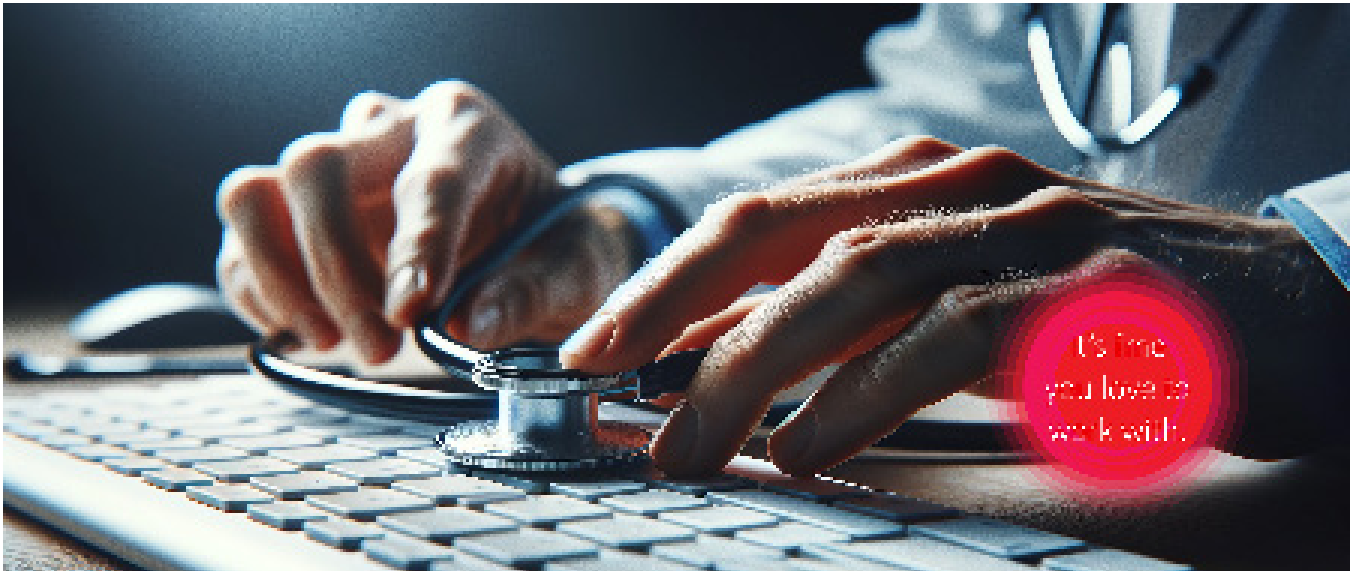
HealthCheckAssist - Vault RIM

Introduction

HealthCheckAssist from fme is a pioneering service solution designed to enhance the efficiency and effectiveness of Regulatory Information Management (RIM) solutions, such as Veeva Vault RIM. It aims to address organizations' complexities and challenges in managing regulatory information through a comprehensive suite of services that optimize solution performance, improve data and document quality, ensure compliance with industry standards, and take advantage of existing and new feature functionality. Much time and money went into implementing the RIM solution, and fme is ready to help make the most of those investments.

Challenge

Organizations face numerous challenges in managing regulatory information, including data fragmentation, adherence to standards, and inefficient processes. Added pressures from compliance risks and the need for continuous solution improvement continually push the organization to stay current with the regulations and the software capabilities. The complexity of regulatory environments and the high volume of data and documents make it difficult for companies to maintain operational efficiency and ensure compliance with global regulatory needs. The RIM solution must also evolve to comply with new regulatory requirements from multiple Health Authorities worldwide.

An increasing list of features and functionality allows Vault RIM to help organizations keep up with new regulations. Veeva introduces three product releases per year where the RIM Vault is enhanced with new features that

are automatically turned on and configurable. The volume of changes can be significant, and some organizations fall behind in implementing the configurable features. What can inhibit adopting the new functionality is that many configurable features are not immediately beneficial but are utilized to build a foundation for future innovations that provide additional efficiencies.

Features and functionality will lead to efficiency, but an overly complex security scheme can stunt the utilization of the solution. A properly configured and maintained RIM solution should allow all its users to find the information necessary to complete current Regulatory tasks easily. Often, during solution implementations, an organization will try to configure a security scheme far too granular, complex, and not conducive to efficient collaboration. The overly complex security will cause frustration and loss of user adoption of the solution. A complex security scheme will also cause burdensome administrative overhead and limit the available scope of change requests from the user community.

Solution

HealthCheckAssist is a targeted service solution to successfully navigate these challenges by conducting thorough assessments of the Veeva Vault RIM solution. Through stakeholder and user interviews, feature utilization reviews, data and document organization assessments, security reviews, and training and documentation evaluations, HealthCheckAssist identifies areas for improvement and optimization. The fme Team will utilize our proprietary dqMan application to interface with the Vault RIM solution.

Our Offering

Our comprehensive service includes:

- **Stakeholder and User Interviews:** Engage with key stakeholders to understand the goals and objectives behind the Veeva Vault RIM implementation. Gather feedback directly from users regarding their experiences, challenges, and expectations from the Vault RIM system.

- **Feature Utilization Review:** Review RIM data such as Events, Regulatory Objectives, Activities, eCTD submissions, registration tracking, HA interactions and commitment tracking to ensure they are leveraged to their full potential.

- **Data and Document Organization Assessment:** Review the structure of regulatory data within Vault RIM. Check for consistency, accuracy, and completeness of data entries.

- **Security Review:** Verify that the solution meets the highest data security and privacy standards while remaining collaborative and maintainable.

- **Training and Documentation Review:** Examine the training materials, user guides, and documentation provided to the end-users. Ensure they are up-to-date and align with the current system configuration and processes.

Following the assessment, we provide a detailed Health Check Report outlining the current solution status and a strategic improvement plan to address identified issues.

Benefits

HealthCheckAssist delivers significant benefits, including:

✓ **Optimized Solution Performance**
Streamlined processes and improved solution utilization lead to enhanced efficiency and help drive user adoption.

✓ **Improved Data and Document Quality**
High-quality, well-organized data and documents reduce verification efforts and compliance risks.

✓ **Strategic Improvement Planning**
Customized recommendations for solution enhancements to support long-term operational excellence and user adoption.

✓ **Minimized User Involvement**
Our business process outsourcing model reduces the burden on end-users, allowing them to focus on core activities.

✓ **Compliance Assurance**
Ensures your RIM solution adheres to all relevant regulatory standards, minimizing compliance risks.

With HealthCheckAssist, fme will be your partner, offering a path to enhanced efficiency, compliance, and solution value. We assist in navigating the complexities of regulatory information management and help you align your solution use with your vision of success.

dqMan®

Added Bonus - Veeva Vault Edition of dqMan

As an additional bonus, will also include a single user annual license for dqMan as part of the engagement.

dqMan is a professional administration tool designed to boost productivity and maximize your efficiency as a Veeva Vault expert. Carefully crafted on the robust dqMan platform this tool reveals the true power of the VQL (Vault Query Language) and MDL (Metadata Definition Language). It provides users with exclusive capabilities and a broad feature set while enhancing user accessibility and streamlining operations alongside the comprehensive functionalities offered by Veeva Vault Admin. Seamlessly installable on any Windows machine, our enterprise-grade software solution boasts an intuitive user interface, delivering a great user experience.

Say goodbye to manual, time-consuming tasks and focus on what truly matters — managing your Veeva Vault applications efficiently.