BASE life science whitepaper

The Veeva Value Journey: Keeping efficient operations and lifecycle management in sight from day one

As Veeva Systems has established Veeva Vaults across the pharma value chain, BASE life science has developed a structured approach of how to efficiently onboard a company's document and data management system for the Quality, Regulatory and Clinical areas. Here, the focus is on operational activities and is fully aligned with the Veeva Vault Cloud architecture and ready-to-use standard functionality embedded throughout their platform. This robust and operational approach takes the Veeva Vault customer through all the system lifecycle phases by aligning project preparations, implementation, and migration activities to reach an efficient system end state with agile and compliant operations. We call it the "Veeva Value Journey".

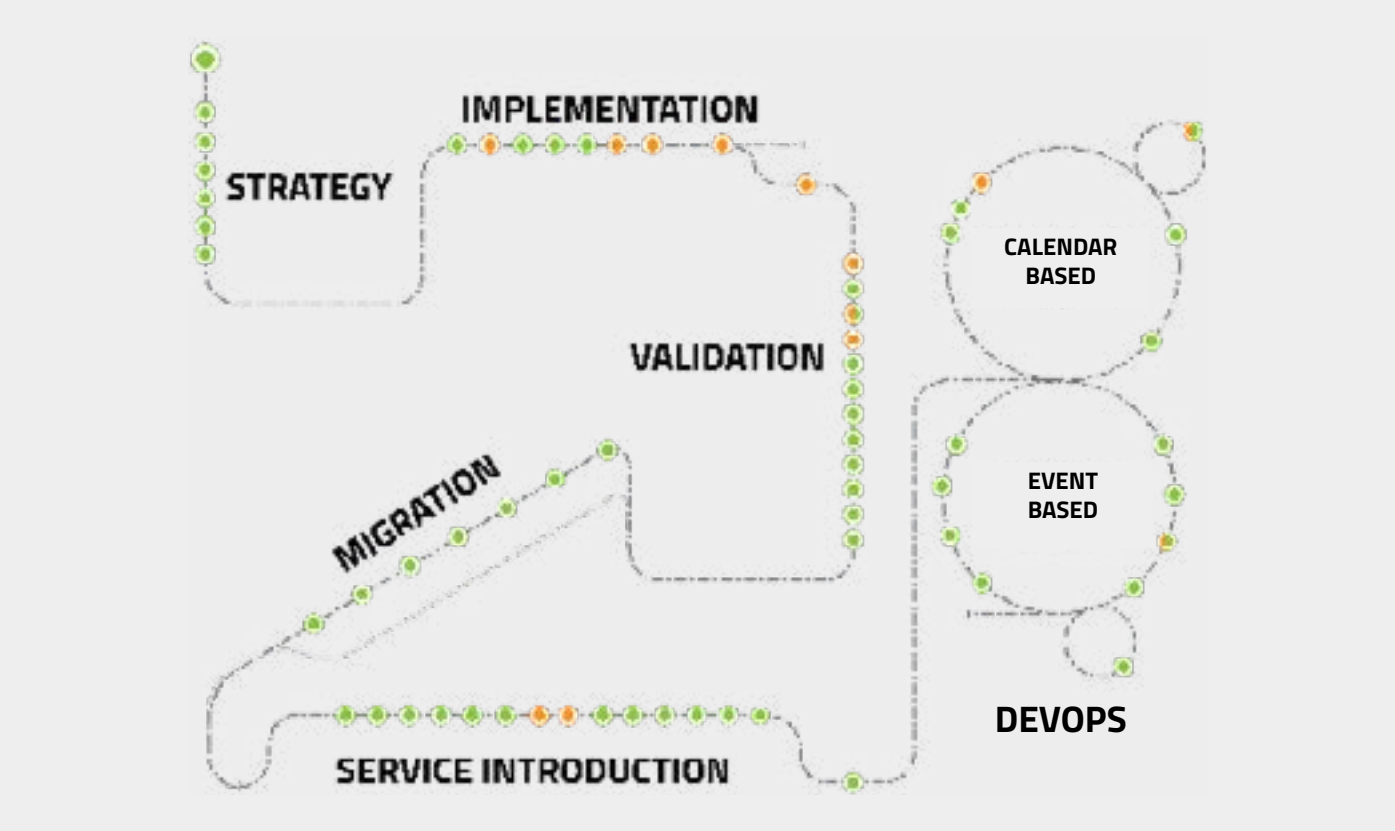
Replacing either a mature corporate document management system or introducing one for the first time is not a simple exercise. Existing systems typically have years of use and consequently contain a high number of documents and data, combined with multiple generations of indexing standards and resulting in related need for data cleaning. In the latter scenario, formalisation of processes across the (global) company is necessary, challenging the decisions made when company processes were based on e.g. paper/Excel, shared drives and SharePoint.

With the arrival of Veeva Vault, a mature software as a service (SaaS) offering, swift implementation of pre-configured and qualified software is now possible. This allows companies to focus on the significant challenges of business alignment, as Veeva's design is based on industry best practice processes. Veeva has significant market traction across the pharma industry with currently around 650 Veeva Vault customers. A prerequisite for the customer's successful adoption of Veeva SaaS is that Veeva Vault is implemented as designed, allowing focus on predictable post go-live operations in which daily business work is delivered and optimisation benefits realised. Therefore, the traditional approach of specifying needs based on current company processes must be turned upside down, i.e. for a successful implementation of mature SaaS the following rules of engagement should be adhered to:

- Adopt Veeva Vault functionality as designed and adapt company processes to the system. Current business processes will need to be updated anyway, so why not challenge company's non-industry best practice.
- Focus all project preparations, internal alignments, execution and migration activities, and decisions on post go-live efficiency, both regarding business use and system operations.
- Should adoption of Veeva Vault as designed be challenged, a business case for the deviation should be generated and executive management approval given before execution.

In the following sections, the phases of the Veeva Value Journey will be explained. Selected Journey "stations" will be detailed along the way. Before diving in to the individual phases, an overview of the full Veeva Value Journey is presented on the beginning of the following page.

OVERVIEW / the full Veeva Value Journey



STRATEGY / ensuring company fit to SaaS and future operations

The Veeva Journey approach is operational in its simplicity. Let the tactics of implementation and operations setup be governed by the overall company Sourcing and Management strategy for buying standard 3rd party services and focus on the main business of the company: to develop, produce, and deliver drugs to patients. The same tactics can be applied for IT. Customers choose standard SaaS platforms to have continuously updated, compliant and industry-compatible solutions, bringing IT directly to the business and minimising unnecessary responsibility of operations. The specific IT tactics to that should be considered include:

- Selecting a system that allows for fast realisation of industry best practices by establishing who provides the best business case for the full "all-inclusive" GxP-grade operations. This point is important, as it eases the customers' own development burden and shifts attention from "staying in compliance and providing technical IT support" to business process support.
- Execute the IT strategy by developing best practice Guiding Principles that accelerate meaningful business requirements suitable for SaaS solutions. This enables a focus on business process fit, rather than on details that are already incorporated in an industry best practice solution such as Veeva Vault Suites.
- GxP Cloud solutions are not "discount" IT, but an opportunity to buy a full-stack GxP-compliant service without having to staff experts and take technical risk on board. To compare Total Cost of Ownership (TCO), all services must be included on both sides of the comparison, in order to correctly assess their value. For example, services for full backup-restore, continuous technology stack updates, application development, etc., are all part of the contracted Veeva Vault delivery. To compare apples to apples, all services must be included in any comparison between alternative customer scenarios, on-premise or via hosted operations etc., even though e.g. backup-restore is typically not part of on-premise services on legacy systems.

IMPLEMENTATION / securing business preparations and impact transparency

The Veeva Vault implementation approach is highly structured, with customer tasks and responsibilities clearly communicated in the contract. Typically, customers will make use of an implementation partner to breach the SaaS experience gap, and it is important that this partner has expert knowledge of the Veeva architecture, data models, implementation approach and release cycle management. Examples of partner activities in this phase are:

- Mapping the "as is" process, document and data pre-Veeva Vault implementation, thereby setting the scene for SaaS adoption as well as rules of engagement in the project and impacted management teams.
- Ensuring a solid customer understanding of the sequence and operational expectations of the Veeva Vault implementation approach, including data structure and possible access set-up.
- Assisting and sparring with the customer during and after Veeva Vault implementation workshops, relating Veeva Vault questions to the customer's context, providing options to close workshop actions (RAID's) and ensuring that the ever-present need for standard adoption is promoted.
- Making sure that the validation plan and later operations will be aligned with the workshop outcome.
- Assisting the customer in updates and/or generation of work procedures and instructions matching customer ambitions for organisational change and input from Veeva Vault configuration workshops.
- Supplementing Veeva's "train-the-trainer" materials with customer-specific sandbox examples for practical exercises to support R&U training of instructions. As for all other change initiatives, follow-up training and end user support should be planned and budgeted. Otherwise, compliant use and thereby value realisation will dwindle over time, even for state-of-the-art software like Veeva Vault.
- All these activities will ensure a targeted standard and orchestrated implementation of Veeva Vaults, safeguarding a swift and structured transition to system operations.

VALIDATION / agile approach for platform and applications lifecycle

System validation can have the reputation of being time-consuming and lowering project and operations flexibility. Nevertheless, it is required to ensure the industry's unfailing focus on patient safety and product quality. However, the validation effort should be based on the right reasons and knowledge of the context:

- An informed risk-based approach, incorporating expert knowledge of regulatory requirements and Veeva Vault's qualification documentation, including processes for development and release. In this mature field of project activities, the customer may focus on cost reduction and operations efficiency to enable the business case and harvest desired business benefits.

About BASE life science

BASE life science is a fast-growing consultancy focused on the life science industry. Established in 2007 and based in Copenhagen, Denmark, BASE targets a local as well as a global customer base. Since its inception, BASE life science has focused on helping life science companies create real business value from digital platforms and data within its area of expertise: Commercial Excellence and Clinical, Regulatory Affairs, and Quality & Compliance. The company serves customers globally from its Denmark and Switzerland offices, employing more than 50 consultants.

- The risk assessment and validation strategy are paramount for effective and agile implementation of Veeva Vault, referencing the comprehensive pre-qualification done by Veeva during all their 3-times-yearly releases. Create a Validation Plan with SaaS focus, explaining how to trace customer requirements to Veeva Vault qualification documentation and single out selected customer validation activities. A prerequisite for this risk-based approach is a successful vendor audit (to date all are) and an alignment/on-boarding of the customer QA department.
- The validation execution and reporting that comes downstream of a focused validation strategy and delivery list enables a swift system validation that is fully aligned with Veeva Vault standard deliveries and set to continue in the operations phase. For example, adopting the Veeva Vault UAT as part of the PQ scope helps to reduce oveall customer validation activities.

MIGRATION / bringing clarity to metadata transformations enabling informed business decisions

If system validation can generate discussions such as "....is this really necessary....", then—if not risk-based and informed—migration can confuse or even worse, alienate, business users from their data and documents. Typically, a gap between the technical subject matter experts (SME) and the business users exists when it comes to clarifications of current data and document structures saturated with e.g. clinical or regulatory domain knowledge and regulations. To an architect or database administrator it not always clear why "historic" data objects are related as they are. An example could of this could be inserting links (to other logical objects) into free text fields to act as a workaround in order to relate important data despite old and over-mature system limitations. In other words, what may seem "illogical" to architects is simply the business doing their best to make ends meet with the system they have been allotted.

Data migration transparency, data quality control, and work process insights have taken massive steps forward with the arrival of new technologies such as assisted machine learning (ML) and Natural Language Processing (NLP), sometimes both or separately referred to as Artificial Intelligence (AI). When these technologies are brought into coordinated application with "older" technologies, such as Optical Character Recognition (OCR), they result in cleaned and aligned document metadata, with reduced duplicates and wrongly indexed documents, thereby resulting in the following two main benefits for the future operational phase:

- Reduced number of incidents due to "missing" documents and challenges related to work completeness
- Increased trust in the repository content, resulting in more compliant use throughout document lifecycles.

About the author

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SERVICE INTRODUCTION / preparing an efficient system lifecycle

It is a regulatory requirement that processes are in place to keep the validated state once the system is released for use. At the same time, the company also has a vested interest in ensuring that these processes are efficient and allow for flexibility. The latter to allow for changing regulatory requirements and end-user-focused optimisations.

When investing in Veeva Development Cloud (term for Clinical, Regulatory and Quality Suites), focus should be on "real world issues" in the system lifecycle. Here, ninety percent or more of all costs and time is spent. Therefore, focusing on fast and cost-efficient implementation projects will be worthless, if the lifecycle operations is not efficient and agile. Focus in preparation must be to adjust on-premise support processes to allow for full Cloud adoption and value utilisation, e.g. Veeva Vault's three-times-a-year release cycle must be accommodated in order to reap full benefits of easy-to-activate functionality and behind-the-scene tech-stack maintenance.

The following key areas must be observed during Veeva Vault onboarding, planned, and prepared for during the project implementation:

- Re-design and alignment of existing support processes to allow for Veeva Vault release cycle and ITSM setup. The latter usually takes significant time and coordination effort with local customer IT departments.
- Lifecycle governance ensuring business involvement when deciding to include new Veeva Vault functionality or needed company configuration. Veeva Vault development pace is impressive and to enable use of offered functionality, the customer needs to have swift decision processes close to the end user departments.
- Training and handover from project to both customer IT departments and end-user stakeholders. Typically, to empower specialists and business super users that are Veeva Vault certified when relevant.

Paving a highway before the traffic commences, ensuring that Veeva Vault is fit for the customer and vice versa.

DEVOPS / executing and adopting

The DEV: system development should adopt agile principles (e.g. SAFe) to the Veeva context. For example:

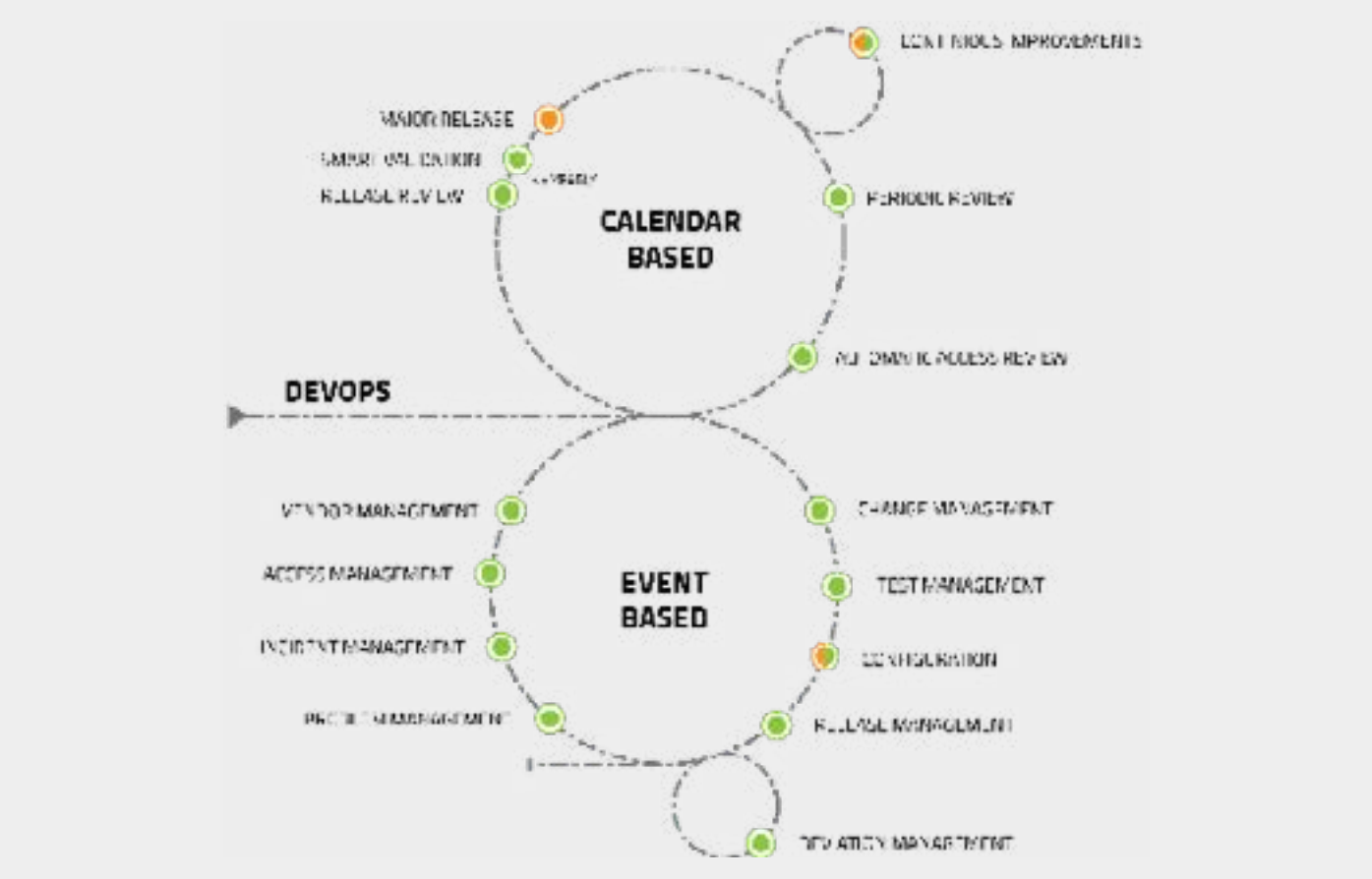
- Use changes, backlog and sprints during the system lifecycle development, incorporating Veeva Vault's predictable release cycle deliverables.
- Insist on configuration only, keeping maintenance light, e.g. no code review necessary and maximise reference to Veeva Vault's qualification package updated for each Release.
- Assess need and value of automatic testing. This is not only a matter of critical mass, but also of the maturity of the customers' IT processes and their approach to computer system qualification/validation.

The OPS: smooth and competent operations should be catered for, for example:

- Properly skilled supporters backed by Veeva support and Managed Services. The customer should ensure staff is trained and on-boarded on the Cloud, as legacy on-premise processes will drain the value of the Veeva Vault investment and slow future system development significantly. This cannot be emphasised enough, as experience shows this area of organisational change to be especially challenging. Corporate and global processes take time to change and patience must be maintained.
- Unlike most other document management systems, Veeva Vault development makes a continuous flow of improvements available. To be able to activate these updates, the customer should ensure an overview of own

needs and usage (e.g. ITSM-based trending) and look ahead (prioritised governance). Consequently, system operations will no longer be focused on large upgrade projects every 2-4 years, but on a constant change stream focusing on business needs.

- The Veeva Vault approach also makes it possible to optimise mandatory compliance work, e.g.:
  - Standardised and template-based three-times-a-year Release review Reports ensuring that Veeva Vault release content can be reviewed, and possible business impact assessed.
  - Setting up automated/assisted periodic reviews for system: audit, configuration, and user.



Summarising, the Veeva Value Journey illustrates how to adopt the Veeva Vault services from a system lifecycle perspective. Their implementation comes with a reduced technical risk of implementation compared to legacy on-premise systems. This allows customers to focus on efficient, agile, and compliant system operations from day-one by keeping in mind:

- **STRATEGY**, establishing software as a service-based business case and company change needs up front, ensuring a foundation for coordinated implementation and efficient future operations
- **IMPLEMENTATION**, securing necessary business preparations and transparent impact transparency, enabling onboarding and timely contributions from all involved company stakeholders
- **VALIDATION**, verifying that company quality system and operations are ready for the required agile approach for the future platform and applications lifecycle
- **MIGRATION**, utilising modern technologies to bring transparency to legacy data and documents, assisting business in taking informed decisions regarding metadata cleaning and transformations
- **SERVICE INTRODUCTION**, system lifecycle is a product of coordinated cross-company disciplines from day-1, all focused on establishing agile and efficient processes across the business areas that are served, IT, and Quality
- **DEVOPS**, here, the fruits of preparations and labour is harvested. Executing daily business support while having swift and agile processes to adopt changes needed for business efficiency and compliance

Contact us

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