

WHITE PAPER

How to accelerate your transformation to a unified platform

NNIT Veeva Powerhouse



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All the power in one life sciences compliance tool – NNIT Veeva Powerhouse

How do you improve both compliance and operational effectiveness of life sciences companies? In this white paper we've bundled content to answer exactly that. We will seek to illustrate how you can eliminate system, site, and country silos and streamline your end-to-end processes and data by utilizing a unified platform – more specifically: *Veeva Vault*.

What is it?

Veeva Vault is a cloud-based content management platform and suite of applications that reduce complexity and increase business agility in life sciences companies – and NNIT can help you facilitate the process from strategy and advisory to implementation and application support.

Traditionally, companies have had to deploy separate applications for content and associated data respectively. Veeva Vault is the only unified platform with the unique capability to manage both content and data across clinical, quality, regulatory affairs and soon safety.

This consolidation and simplification will improve both compliance and operational effectiveness of life sciences companies. Indeed, unified platforms like Veeva Vault mark the end of high cost maintenance.

NNIT: The experienced life sciences partner

But getting the full benefit of the Veeva platform requires proper and strategic planning, carefully executed implementation and due diligence in the continued operations and support.

The key differentiator in NNIT Veeva Powerhouse is NNIT. NNIT has chosen Veeva as our partner and invested a heavy amount of resources in building services, competences and references within the Veeva domain.

With our extensive experience working with clients in the life sciences industry, as well as our expertise with the Veeva platform, we strive to be your preferred partner with both the technology and business insight to help you maximize the benefits of Veeva for your life sciences organization.

Happy reading!

Improving pharma efficiency: From isolated applications to an integrated way of working

Sometimes, life in a life sciences company feels like juggling data and documents across a dozen different applications while trying to get a bit of work done. It's not just inefficient but can also be a compliance liability. See why replacing the silos with a unified platform should be a top priority.

Have you ever stopped to count the number of different applications and systems involved in getting your company's products from clinical trial to regulatory approval and product launch – not to mention doing variations? In the worst case, you'll run out of fingers on both hands before you stop counting.

There is the CTMS holding your patient information, budget and clinical data. And the myriad of documents stored in your EDMS and eTMF. The QMS that your Quality needs to make sure everything is up to code as well as the RIMS you need for regulatory registration and approval.

The list quickly grows. And while the individual applications may be robust and well suited for that specific task, they are often not designed to work together. That hurts your organization's efficiency, time-to-market and ability to compete.



Track the wasted time

As an eye-opening exercise, try mapping out the individual steps and time spent on relatively simple tasks – like verifying that your Submission Report was sent on schedule, creating a Health Authority Contact Report or indexing a document file.

First off, check whether you can accomplish the task on your own, or if you need to contact someone else, inside or outside your organization. If you are lucky, the communication can be handled with a quick email, phone call or just a question to the person sitting across from you. But what if that person is stuck in a meeting or your email sits unopened in an overstuffed inbox? Suddenly, what should have taken no more than a couple of minutes can take hours, sometimes stretching over several work days.

Next, keep track of the different steps involved in what you're doing. Do you find yourself moving data from one application to another, entering the same meta-data multiple times or saving your work locally to make sure you don't lose it in the process? How many times have you had to open or close a window or type something manually? How many different applications did you use? Can you brew a fresh cup of coffee and drink it too before your system is done uploading and rendering your latest input?

Consider compliance

Apart from the time that is lost due to inefficiency, there is also another aspect to consider when working across multiple applications – compliance!

Can you ensure that any changes you might have made have been updated consistently across applications? And if your clinical trial manager changes something in the eTMF, will those changes affect the work your Quality Control staff is doing, the application your Regulatory Affairs is preparing or the claims your marketing department included in the latest content? Without a unified system acting as a single source of truth, how will you know which information to trust if conflicts occur?

Reinventing the wheel

A final aspect to consider, is the loss of efficiency due to inefficient reuse of content. Experience shows that countless hours and resources are spent producing material that could easily be assembled from existing data or content. But due to a lack of transparency and cross-application functionality, the people doing the work rarely realizes that the information is already available.

The solution: A unified platform

So, what can life sciences companies do to improve efficiency? A main reason for the ineffective state of affairs is that the many different applications needed by pharma companies have been developed to handle a narrow task and are effectively function as silos, trapping your data.

Fortunately, today there are unified cloud-based systems available that can handle all the needs of the life sciences company, from clinical operations and data management to quality and regulatory affairs. This means that the technical barrier is gone, and the right tools are available to enable greater efficiency across the entire organization.

And while the task of choosing the right unified platform, migrating all your data, performing the necessary validation afterwards should not be underestimated, the benefits of a unified platform will quickly outweigh your investment.

For a detailed introduction to the benefits of moving to a unified platform like Veeva and the steps involved in implementing it, you can go to:

www.nnit.com/veeva-powerhouse to watch a recording of our webinar: Veeva Powerhouse – Accelerate your transformation to a unified platform.

With our extensive experience working with clients in the life sciences industry, as well as our expertise with the Veeva platform, we strive to be your preferred partner with both the technology and business insight to help you maximize the benefits of Veeva for your life sciences organization.

— NNIT

The value of agile development – how a unified platform can accelerate your business

Adopting the agile methodology in a life sciences company can seem like a challenge – especially compared to the familiarity of waterfall methods and legacy system maintenance. Agile development is not only faster, it can also increase quality. A cloud-driven unified platform will ease the transition towards a more agile way of working and save both time and money.

Certain ways of working become the norm because they, at least on a certain level, are known to reliably yield usable results. An example of this is the waterfall method, which has been a classic choice for software development and project implementations in life sciences for decades.

However, in a rapidly changing business environment, choosing the quickest and most cost-effective ways of fulfilling your business objectives is more vital than ever. The same goes for being able to react and adapt, if you suddenly find yourself on the wrong course. And while the waterfall method may be reliable, it is also slow and cumbersome.

This is the main reason for the increasing popularity of the agile methodology; it values close collaboration and producing working software over rigid processes and comprehensive documentation. Simply put, agile cuts down the time-to-market, with the bonus of increasing the quality of the finished product because the business owners are deeply involved from Day 1.

Agile over linear

By following the traditional waterfall steps of determining specifications, completing the paperwork before developing, coding or configuring the solution and then finally implementing, you are effectively creating a huge blue print for the entire project. This makes quick changes and decisions as well as adapting to new requests as they arise

costly and difficult to manage. Being able to follow a plan to the end and create solutions to meet specifications certainly has merit – but why not adapt according to circumstances?

Enabling work on several levels simultaneously

The agile process can be applied to any type of platform or technology and is independent of technology and business domains and thus works for both cloud and legacy systems. There is, however, certain benefits when working agile within a cloud-driven unified platform such as Veeva Vault. The shared backlog, which naturally follows the agile process, fits perfectly into unified platforms where several applications draw data from the same, shared dataset. The next chapter in this White Paper will delve further into the benefits of Veeva Vault and NNIT Veeva Powerhouse.

The cloud is also well adjusted, when it comes to working incrementally and in an iterative fashion. Instead of laying down a detailed plan for the final product, you gradually work on all aspects of the product, securing ongoing deliverables and not the fulfillment of a single deadline. This means considering the deliverables for compliance parallel to producing required documentation and letting the two evolve simultaneously and not as a linear process where the development and testing activities are subsequent to the specification activities.



Getting Line of Business involved – and slashing the decision process

Another way of ensuring the success of agile projects is to secure relevant input from relevant sources within your business in a timely manner and where this input adds the most value.

Working agile means working in for instance Scrum teams. Regardless of the chosen agile framework, the benefits are high when assigning team members from relevant business areas, who as individuals have the mandate to make decisions on behalf of the business and the project on the daily meetings conducted using Scrum or Kanban.

This means the decision-making process is a quick paced exercise instead of a long-drawn discussion between different areas of business. The increments ensure demos and early understanding of the requirements defined making use cases that are testable; misunderstandings, and insufficient details, are detected early on, which provides an overall lower cost compared to traditional waterfall development projects.

Working in an agile framework, the process of ongoing progress and increments ensures quicker decision-making and has the benefit of continuously testing and less complex testing of the deliverables.

Going agile with SaaS

One important consideration many companies have, is how to implement an agile way of working, when at the same time considering – or having already placed – your infrastructure needs and several services with either SaaS or cloud hosts.

In brief, the agile approach is applicable to more aspects of the business than the development stages of solutions. A leaner approach in deploying infrastructure services can be applied through automation and qualification of the deployment of these services, so the use of the cloud services adheres to regulatory requirements. This means some of the focus is moved from qualifying stand-alone systems to working leaner through the entire service stacks. Not least, when the need to develop services and infrastructure is placed with cloud vendors, your business can focus purely on configuration, functionality and adding value to the business using SaaS solutions.

NNIT Veeva Powerhouse: What it is – and why you need it

With a unified, cloud-based platform such as Veeva Vault, life sciences companies have a new power tool to consolidate all aspects of life sciences business critical data. However, in order to realize the full benefits, business areas need to adapt to and adopt new habits and a new mindset. This is where NNIT Veeva Powerhouse comes in.

With the arrival of platforms like Veeva, a major technological barrier has been breached in life sciences. Pharma companies are no longer forced to utilize a dozen different systems to get their products to market. With Veeva Vault handling all the tasks previously done by your RIMS, eTMF, CTMS, QMS and more, you have every opportunity to increase your efficiency significantly.

Barrier shift: From tech to business

Realizing this potential is no trivial matter, however. Veeva doesn't just replace your legacy systems, allowing you to carry on with the same old routines. It provides a new suite of options and tools to take all aspects of your business-critical R&D data beyond what has previously been possible. Thanks to updates several times a year, those options keep expanding. But new options and tools require new business strategies, different tactical decisions and new ways of working across your organization.

Subsequently, the main barrier for increasing your efficiency has shifted from technology to business processes and culture.

To help you make the transition, NNIT has created NNIT Veeva Powerhouse to be your full-service partner for Veeva. With NNIT Veeva Powerhouse, NNIT has assembled a team of dedicated specialists with knowledge, training and experience to ensure that you gain the continuous benefits of the Veeva potential.



First: Get your strategy right

Your organization should ensure that a comprehensive strategy is in place before getting onboard with any new platform, and Veeva is no exception. Without a comprehensive plan for the project, including the long-lasting implications for your business processes, there is a high risk of making costly mistakes and missing valuable opportunities. This is why NNIT Veeva Powerhouse offers a full suite of strategy and advisory services, including cloud strategies, best practices, business case development, technological evaluations, security advisory and more.

You can read more about our advisory services by going to the webpage:
www.nnit.com/veeva-powerhouse

Agile implementation: Getting safely to Veeva

Once your strategy and the project outline are in place, the next step is to get your project designed properly with integrations, migration, validation and configuration. Getting data migrated safely to Veeva is no trivial task, and requires careful consideration, detailed planning and sharp project management. And once the migration is complete, you need to validate that your data has been successfully migrated. Fortunately, with Valiance Partners LLC on board as a NNIT Group company, NNIT holds the absolute gold standard in GxP data migration expertise.

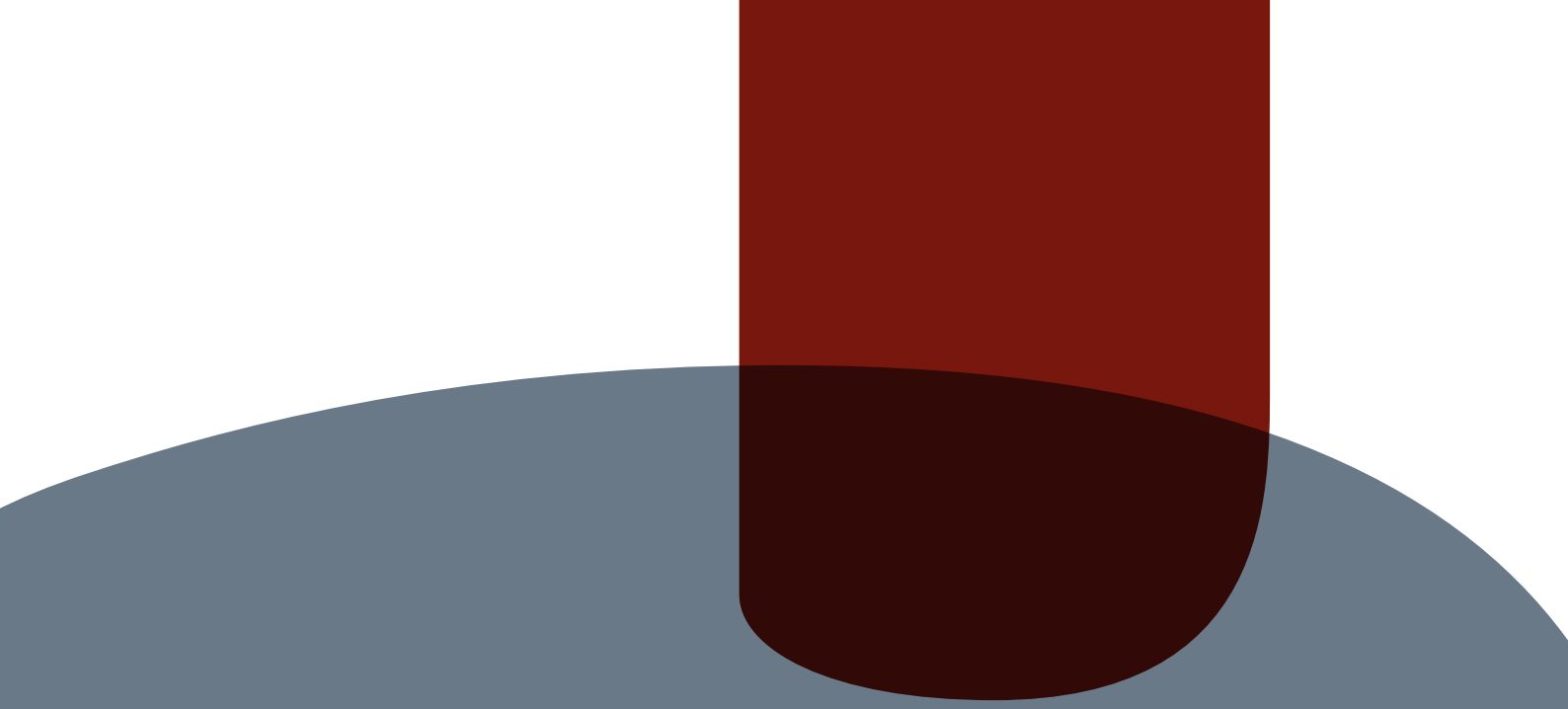
In addition, NNIT implements more than 45 system integrations between a number of platforms in life sciences per year, giving us the skillset to ensure that all your applications are always in perfect sync with Veeva. Furthermore, we have a well-proven validation set of services including automated UAT/PQ for fast, efficient and secure validation. All the phases are supported by business SMEs with practical knowledge within the business domain.

Veeva Application Services: Keep up with constant improvements

Veeva strongly supports an agile methodology which challenges your organization to also adopt an agile mindset as the primary business driver. To assist you with just that, NNIT offers Veeva Application Services as part of NNIT Veeva Powerhouse. The service is composed of three elements:

- *Veeva Support:*
Classic support and operations team to secure the constant quality, stability and availability of your Veeva application. Offers both incident management and release management.
- *Continuous Improvement:*
This team works alongside the Veeva Support team to help you identify and realize opportunities for improvement, for instance introducing new functionality, configuration management and change management.
- *Business Life Cycle Management:*
Armed with business understanding and a holistic approach, this team will help you orchestrate the application in a business context and enterprise IT landscape.

Put together, Veeva Application Services will provide you with both the business and technical support and advice to reap the full benefits of moving to a unified platform.



We understand that transitioning from siloed applications towards a unified platform is no small task. And it's not "only" a migration task. In order to realize the full benefits of the Veeva platform, business areas need to adapt to and adopt new habits and a new mindset. This is where NNIT Veeva Powerhouse comes in.



The powerhouse approach: Data integration and migration made simple through partnerships and pharma expertise

Shifting to a unified cloud-based platform like Veeva requires proper tools and in-depth knowledge of the life sciences industry, if the process is to reach its optimal outcome. Through years of experience in life sciences as well as partnerships, NNIT Veeva Powerhouse can ensure your business a smooth transition.

Moving from aging, silo-based legacy systems to the unified cloud-based platform Veeva, can – depending on your current infrastructure, choice of applications and storage-solutions for important documents – prove quite a challenge.

To counteract the complexity, NNIT has created NNIT Veeva Powerhouse. We are a full service Veeva partner, which not only offers Integration as a Service (IaaS) to bridge the gap between legacy and cloud, but also safe and compliant migration and validation of your data through migration specialists.

Migration done right

To secure proper and compliant migration and validation of the client's data, NNIT enlists the capabilities of Valiance, an NNIT Group Company. With a track record of over 500 migrations for 100+ clients globally, Valiance brings the most proven GxP migration software and methodology to the table.

Valiance's TRUseries of migration tools ensures clients complete compliance, when migrating their data. With connectors designated more than 90 of the most widely utilized standard systems

(including API's, databases etc.) in life sciences, Valiance can commence migration of data, regardless of the legacy systems at hand. Subsequently, TRUcompare will step in and validate said data, ensuring your organization the needed documentation for compliance.

Integration is never a one-off

Offering IaaS (Integration as a Service) isn't something NNIT has created "just" for Veeva solutions, but a core competence driven by years of experience as a part of the life sciences industry.

Our subject matter experts are familiarized with the various applications and systems used by life sciences companies as well as the GxP requirements – and have thus created an extensive portfolio of standardized, ready-to-use accelerators. As a result, we can effectively help you integrate processes and data from your existing systems and applications into the Veeva Vault applications.

In short, integration of your company's chosen Veeva applications; be it RIMS, quality management or clinical functions; will run through an integration platform set up by NNIT Veeva Powerhouse. Having performed this exercise several times over in other life sciences companies, we know the kinks that arise, when handling the applications of the life sciences sector and how to ensure proper implementation. NNIT Veeva Powerhouse has developed several accelerators for integration on different platforms, to speed up integration efforts in the implementation projects.

Support after the fact

Teaming up with NNIT Veeva Powerhouse also ensures your organization access to ongoing assistance, when the need for further integration arises. For the majority of clients, integrating and migrating all applications and processes at once isn't an option.

We'll help you establish an integration roadmap, which ensures that all your applications and systems – new as well as legacy – will have access to all the required information throughout the transition period.

A powerhouse for all occasions

Making the shift from life sciences legacy towards a unified platform like Veeva, not only requires technical knowhow when it comes to integration, migration and the validation of those processes. It also requires the necessary business insight into the life sciences industry to identify errors in both processes and data, while simultaneously being able to correct and avoid similar issues going forward. This is what NNIT Veeva Powerhouse brings to the table.

What's next?

So, what now?

We understand that transitioning from siloed applications towards a unified platform is no small task. And it's not "only" a migration task. In order to realize the full benefits of the Veeva platform, business areas need to adapt to and adopt new habits and a new mindset. This is where NNIT Veeva Powerhouse comes in.

Industry experience and Veeva certifications

NNIT believes that successful projects are the result of sound methodology mixed with experienced resources and the right combination of business and IT understanding. Therefore, we are trained, and we have long experience from the industry. We certify consultants as Veeva Admins, and we train our solutions division internally.

- We have 40+ certified Veeva Vault Admin professionals
- We have more than 400 experienced life sciences consultants

Our profound understanding of Veeva Vault, your business processes and your legacy systems make NNIT an ideal partner to support your Veeva success.

Book an inspirational meeting

If you are interested in learning how transitioning to a more agile way of working within a cloud-driven, unified platform can benefit your business, you are very welcome to book a non-committal inspirational meeting with one of our inhouse Veeva consultants.

At an inspirational meeting you get "one to one" access to our most valuable learnings about the transformation from siloed to unified platforms in general – and the benefits of Veeva Vault in particular.

The session will focus on your unique position and options and we will illustrate how your organization can improve both compliance and operational effectiveness by transforming to a unified platform. Together you will uncover whether NNIT Veeva Powerhouse is the right solution for your organization – and how you best get started.

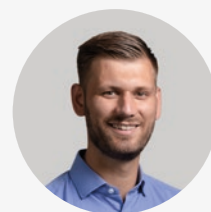
You are always welcome to contact us – for an inspirational meeting or other Veeva related matters.



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About NNIT

NNIT is an international consultancy in the development, implementation, validation and operation of IT for the life sciences industry. We create value for our clients by treating their IT as if it was our own. And of course, we meet the industry's strictest regulatory requirements. We apply the latest advances in technology to make our clients' software, business processes and communication more effective.

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