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White Paper

Veeva Vault

Into the Cloud

New Technology Set to Deliver Heavenly Benefits for Regulated Content Management in Life Sciences

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Introduction

The life sciences industry is packed with docs – not doctors, but documents. Each day, thousands of important documents are created in nearly every area of the life sciences enterprise, from nonclinical reports to regulatory submissions, from clinical trial protocols to promotional materials and every type in between. Many of these documents fall under the category 'regulated content,' which means that specific content management practices are required to create, approve, track, and update them. Often, these practices are enabled through the use of content management software applications.

For more than two decades, life sciences organizations have purchased, customized, configured, deployed, and maintained a series of ever-expanding and complex content management technology solutions. At first, these systems had to be heavily customized by each company for the unique needs of life sciences companies. Over time, industry-specific applications that better supported life sciences-specific processes like health authority submissions evolved. Today, content management tools continue to tack on new capabilities and increase capacity, but have failed to fundamentally change to meet the new challenges of the current business and economic environments.

In stark contrast, consider how the life sciences business has changed in the last 20 years:

- **Collaboration - Broad Ecosystems of Partners**
  What was once an industry almost solely reliant on internal resources is now quite the opposite. As a result of expanding partnerships and increasing use of cost-saving outsourcing strategies, the life sciences industry is now made up of broad ecosystems of partners. From co-development and co-marketing partners to ad agencies and contract manufacturers, life sciences companies are working with partners across the value chain to support drug development, manufacturing, and marketing. With so many external touch points, it is now mission critical for companies to share content seamlessly within a controlled environment.

- **Globalization – Focus on Emerging Markets**
  The new millennium has brought the life sciences world closer together than ever before, requiring companies to operate in an increasingly global environment. It's no longer enough to simply work with partners across town or even across the country. Today, organizations must work with affiliates and partners all around the globe. Fueled in part by the unprecedented growth in emerging markets like China and Brazil, companies are continually adapting their business processes. As such, it is crucial that business technologies like content management also continue to change so that enterprise level IT capabilities are available to even the smallest affiliates and partners around the world.

- **Compliance – Increasing Rate and Pace of Change**
  Compliance has always been a part of the life sciences industry, but in recent years, the pace and frequency of compliance-driven change has increased exponentially. New technologies have also helped to fuel this change, as life

Cloud Computing and Software-as-a-Service (SaaS)

"Cloud Computing" is a common term in today's business environment and is often used synonymously with Software-as-a-Service (SaaS). But what do these terms really mean?

Put simply, the cloud delivers computing as a utility while SaaS delivers an application (such as CRM or regulated content management). Therefore, cloud and SaaS can be mutually exclusive. Just because an application runs in the cloud does NOT necessarily make it multi-tenant SaaS.

Why is this important? As a customer, SaaS in the cloud offers benefits that the cloud alone cannot achieve. How can you recognize SaaS in the cloud? True SaaS applications deployed in the cloud display the following traits:

- **It's a turnkey service.** The customer is completely insulated from the operation of the application and its supporting infrastructure. No maintenance required.
- **Its capacity is elastic.** The vendor can flexibly scale capacity up or down as needed.
- **It runs in a shared environment.** The application is multi-tenant to achieve economies of scale and flexibly allocate available capacity to whichever users may need it at any given time.
- **It uses standard Internet protocols.** The application requires minimal or no changes to the customer's existing computing environment – users simply need an Internet connection.
- **You only pay for what you use.** Simply put, a cloud platform is analogous to a utility, like electricity. You don't have to build a power plant to get electric power to your home. You don't have to manage the distribution grid either. All you have to do is pay your bill.

sciences organizations and health authorities alike try to understand the impact of such capabilities on an ever-shifting compliance landscape. From a content management perspective, each time new guidelines are issued, life sciences companies are faced with the need to update aging systems in order to support new compliance requirements. However, in IT, where installation, validation, retrofitting, and other actions need to occur before any kind of change is implemented, keeping up has become almost unmanageable.

- **Cost Pressures – An Intense Focus on Cost Reduction**

The growth of consumerism, intensified competition, and expiring patents on blockbuster drugs have made cost reduction an ever-present objective across all departments. This intense focus on costs is calling into question the need to invest hundreds of thousands and even millions of dollars into the creation and maintenance of complex content management applications. Indeed, regardless of size or location, organizations are looking for new ways to simplify and reduce costs associated with the implementation and maintenance of these mission-critical systems.

New Content Management Blueprint

So, what do increasing collaboration, growing globalization, rapidly changing compliance requirements, and increasing cost pressures all mean for life sciences content management? It means that content management as we know it must change—and quickly. However, despite these radical shifts in the life sciences business environment, life sciences content management systems have remained largely unchanged. They are built on the same basic platforms and technologies. They are often only affordable to larger organizations with significant time and resources to invest in systems development projects. They are still difficult to update, maintain, and support, and they continue to make collaboration with external partners difficult, if not impossible. What was once revolutionary is now out-of-date. And, while content management software providers have sometimes tried to alter their applications and platforms to meet these new needs, they have failed.

Consequently, many life sciences organizations have grown frustrated with the cost and complexity of implementing, maintaining, and updating antiquated content management systems – a process that can often cost hundreds of thousands if not millions of dollars every year. Even worse, smaller companies are left with few, if any, good options for the implementation of IT systems to support their regulated content management processes.

The solution cannot be just another system update – the proverbial square peg for a round hole. The life sciences industry requires an entirely new solution, a content management technology that truly fits the new needs of all life sciences companies regardless of their size. One technology has emerged that may support this kind of change: cloud computing. In fact, in its list of Top 10 Predictions for the U.S. Life Sciences Industry, IDC predicts "significant advances in the use of IT clouds within the life sciences industry in 2010 with subsequent rapid growth in the years to follow."[1]

"To effectively enable today's demand for collaboration, content management systems must be able to handle confidential and complex information sharing across all partners."
– Pierre Morgon
Vice President, Franchise & Global Marketing Operations at Sanofi Pasteur

Is cloud computing the answer for content management? Possibly, and one of the biggest reasons is the fact that multi-tenant Software-as-a-Service (SaaS) applications built in the cloud enable the sharing of resources, resulting in massive economies of scale. It's this model that also enables many of the benefits hailed by pundits such as scalability, flexibility, fast implementation, low maintenance, simple integration, cost efficiency, and easy configuration. When it comes to content management specifically, the cloud enables life sciences companies to collaborate closely, connect globally, comply swiftly, and manage costs effectively.

Here's how.

Collaborate Closely

Over the last three to five years, the number of external partners (co-development partners, clinical research organizations, co-marketing partners, ad agencies, and more) that life sciences companies employ has increased by 30, 40, even 50% or more. The use of these partners has brought costs down and increased speed to market. Unfortunately, however, this new model has also created significant content management challenges – specifically surrounding collaboration. Steve Hasler, an independent consultant to the life sciences industry and former vice president of Global Regulatory Operations at GlaxoSmithKline, describes two of these challenges:

"First, you need to figure out how to give third-party access to your systems across the firewall without making the organization vulnerable. With traditional content management systems, this process takes at least three months. Next, you need to figure out an economical and efficient way to get all of your external partners trained to use your system. Modern content management systems must be simpler to use and easier to access securely."

While traditional on-premise content management systems often support working collaboratively within an organization, they are not designed for external collaboration. As Hasler suggests, it takes too long, is too complicated, and is too expensive to give secure access to tens or even hundreds of external collaborators. Rather than deal with these obstacles, companies tend to simply pull content out of their controlled repositories and distribute it via email or secure FTP. These methods, however, are inherently risky because they skirt the compliance checks and audit trails maintained by the core content management system.

In contrast, cloud-based content management systems allow life sciences companies to truly collaborate rather than administrate. New users, both internal and external, can be added in just minutes. Administrators simply provide a secure log-in. By enabling secure access to appropriate content in real-time via the Internet, life sciences organizations can work closely with their partners and affiliates around the globe, as well as with various departments across the organization. Content is visible by all authorized team members immediately and without significant IT intervention. Additionally, the documents stay in a controlled environment throughout the collaboration process, providing a more compliant system and reducing risk.

Open Collaboration, Secure Content

When cloud computing was first introduced to the mainstream, skeptics tried to find vulnerabilities in the security of cloud applications. However, these concerns were quickly dismissed as respected organizations such as the U.S. Department of Defense began adopting cloud computing for everything from the administration of public information to the management of sensitive government materials. From a content management perspective, cloud-based content management solutions often include advanced access-control frameworks that enable secure authentication, provide advanced logging of user activity, and allow administrators to control which users have access to highly sensitive documents. Multiple layers of firewalls also ensure high levels of protection against intrusion and identify and close security vulnerabilities. Today, cloud-based applications are often considered even more secure than on-premise or hosted systems because they enable access to world-class security infrastructures.

Connect Globally

The global pharmaceutical market is expected to grow between 5 and 7 percent in 2011 to $880 billion. That's up from 4 percent just one year ago. This increase is largely driven by robust growth in emerging markets such as China — now the world's third largest pharmaceutical market. In fact, IMS Health expects China to grow between 25 and 27 percent to reach more than $50 billion in 2011. The additional 17 emerging countries tracked by IMS are forecast to grow at light-speeds of 15 to 17 percent in 2011, to between $170 and $180 billion.[2]

Given this explosive growth, both small and large life sciences companies will be challenged with managing their content globally. Specifically, they will need to shift from processes and technologies that are restricted to local requirements to truly global operations. Affiliates around the world, including geographies where affiliate offices have only a few people, will need the same system access, speed, and performance that central offices have typically enjoyed.

"Existing content management systems fall short when it comes to enabling content consistency across international borders," said Sanofi Pasteur's Pierre Morgon, Vice President of Franchise and Global Marketing Operations. "Claims that support a given product and that are documented in the original repository must be made available to other countries and affiliates. The countries can tweak the storyline a little to mirror the local culture, the competitive situation, or the local regulatory requirements, but the product data that back the claims should...indeed must...remain the same. There's a need for content management systems that make sure that this content is not deviated at all globally."

Because the cloud is ubiquitous, cloud-based content management systems provide – for the first time – a truly global view of how content is created and used. Systems in the cloud are accessible from wherever users have an internet connection. Additionally, cloud-based solutions are cost-effective enough to deploy to even the smallest local affiliates. This enables content access to participants around the globe, thereby eliminating the common "throw it over the wall" approach where central offices email or FTP documents out to local affiliates to make their changes. In the past, this approach resulted in a lack of visibility (e.g. local content changes were not accessible to the central offices and vice versa), a proliferation of uncontrolled content copies, and a sense of version confusion, as people were unsure which document version was the most current. In contrast, by providing equal and immediate access for all, cloud-based content management systems avoid these issues, resulting in greater transparency and better communication.

Comply Swiftly

From product development to manufacturing, from drug safety to marketing, the rate and scope of regulatory change and reinterpretation are increasing exponentially. Across the globe, health authorities are fundamentally changing the way in which life sciences organizations conduct business. In Europe, for example, the Association of the British Pharmaceutical Industry recently voted in amendments to its Code of Practice

Cloud vs. On-Premise / Hosted Technology

To illustrate the difference between the cloud's multi-tenant SaaS architecture and the single-tenant architecture characteristic of typical on-premise and hosted/ on-demand applications, think of a neighborhood versus an apartment complex. In the neighborhood, each homeowner has his or her own yard to mow, plumbing to maintain, electrical system to operate, and walkway to clear. This is a common single-tenant infrastructure where each customer has its own dedicated server that runs its own version of the application.

Now think of an apartment complex. The lawn, plumbing, electrical system, water supply, and walkways are shared by all of the apartment's tenants. Residents never have to do any maintenance themselves because it is handled by a central office. They can, however, do whatever they want with the interior of their apartments. They can paint the walls any color, buy any style furniture, and hang their own art on the walls. This is multi-tenancy, and is the reason that multi-tenant SaaS applications in the cloud are so cost-efficient to deploy and maintain; the customer has no hardware to purchase, install, or maintain. The application is built on a shared infrastructure, where all servers, networks, and functionality are managed across implementations and the application is accessible through any web browser.

to increase the transparency of working practices between the industry and healthcare professionals. British life sciences companies will no longer be able to give healthcare workers any branded promotional items, and companies will be required to declare payments to healthcare professionals for services. In the United States, compliance requirements are continuing to evolve as both the FDA and life sciences companies increase their use of social media as a means of communication with consumers and healthcare providers.

"A lot has changed over the last few years," said Ty Howton, chief compliance officer at Vertex Pharmaceuticals, a global biotechnology company with a CRM system in the cloud. "The #1 concern was always criminal liability, but now we're becoming just as concerned with civil and state penalties, as well as how we are perceived in the court of public opinion. Compliance today is a very complex challenge for the entire industry."

Because much of a life sciences organization's information is contained in the form of content such as safety reports, promotional materials, and health authority submissions, the increasing rate of regulatory change presents a special challenge for today's content management systems. These on-premise or hosted systems are often difficult and costly to change. Even simple changes, such as adding new fields or document types, tracking document distribution, and changing security structures require elaborate system validation, development, installation, and deployment. All told, this can require tens, if not hundreds of thousands of dollars and many months to complete.

"Regulatory requirements have grown tremendously and continue to change especially in the area of regulatory submissions – so systems need to be upgraded to meet new requirements," said Hasler. "Right now, every time content management or submissions publishing systems are upgraded to meet new regulations, there are too many time-consuming steps involved including validation (which is expensive). Plus, there's employee training. All told, implementation could take 4-6 months with four to five people working for six to eight weeks just to revalidate the system."

That's too long for teams who need to focus on creating, assembling, and delivering content rather than implementing and validating system changes. In contrast, cloud-based systems can reduce the time to deploy and validate such changes by more than 50%. This is because cloud-based content management systems automatically receive updates as part of the underlying application structure, are easily tailored to meet changing regulatory requirements through simple configuration, and significantly reduce the time and effort of validation by sharing that burden across organizations. The result is less time spent on IT systems and more time spent on core business functions.

Hasler continues, "With the cloud, you can make a regulatory change once for all clients and the costs are spread across a number of companies rather than every single life sciences company tackling it on their own. It just makes sense since we're all in the same regulatory boat, essentially."

An IT System End Users Like?

When's the last time you heard a sales rep, medical writer, or IT administrator say, "Wow, our on-premise system is so easy to use, so flexible, so intuitive..."?

We are all familiar with the complaints: "Performance is terrible.", "It's too complex.", "Why can't I find anything?"; "This little change will take **how** long?" In fact, we are so familiar that we often accept bad performance, poor function, and system inflexibility as a fact of life when it comes to content management systems. Content management in the cloud aims to change this perception.

Unlike their on-premise or hosted counterparts, cloud-based systems have a proven track record of remarkably high end-user satisfaction. In fact, according to InformationWeek's "Analytics Report on the Cloud," 92 percent of companies reported that their cloud implementation had mostly or totally met their expectations. Why? Because cloud-based software is simple, available, and easy to use and administer. For example, on-premise content management systems often require weeks, if not months, to upgrade. With cloud content management, new features are not installed, they are turned on, thereby dramatically reducing the time and cost associated with system changes.

Manage Costs Effectively

Enterprise software is notoriously expensive, and life sciences content management systems are no exception. However, with an increasingly challenging global economic environment, greater competition, expiring patents, and a shift from the blockbuster drug models of yesterday, life sciences organizations must find ways of maximizing technology effectiveness while reducing overall costs. This is especially true of on-premise or hosted content management technologies, where large implementations can run into the tens of millions of dollars, and even limited implementations can be cost prohibitive for small and medium businesses.

Cloud computing, on the other hand, makes content management affordable to even the smallest organizations or business units by reducing up-front costs and the costs associated with ongoing system updates and maintenance. As a result, companies can save anywhere from 30-50% versus their traditional on-premise or hosted systems. How? By completely avoiding the capital costs of servers, software, and maintenance and, instead, adopting a highly predictable pay-as-you-go model. Additionally, costly administrative tasks common with on-premise systems (e.g., upgrades and back-ups) are eliminated with cloud technology since there is no hardware or software to manage on site. All upgrades and back-ups are handled by the solution provider.

Conclusion

Collaborate closely. Connect globally. Comply swiftly. Manage costs effectively. These simple requirements are having a profound effect on how life sciences organizations need to manage their content today and in the future. It is no longer enough to patch, update, and upgrade existing, on-premise systems.

Fundamental business change requires fundamental technology change. New cloud applications provide that leap forward. For the first time, companies of all sizes can meet the challenges of today and tomorrow without the complexity, cost, and uncertainty of traditional, on-premise or hosted content management implementations.

One pharmaceutical executive sums it up best, saying "we, along with many other pharmaceutical companies, have had a lot of experience with big, complicated systems that take too long to deploy, are totally inflexible, overly expensive, and that don't change to meet changing business needs. Many companies are looking at cloud computing as a promising solution to many industry challenges – including, if not most especially, content management."

Veeva Systems is the leader in cloud-based solutions for the global life sciences industry. Committed to innovation, product excellence, and customer success, Veeva has over 80 customers, ranging from the world's largest pharmaceutical companies to emerging biotechs. Founded in 2007, Veeva is a privately held company headquartered in the San Francisco Bay Area, with offices in Philadelphia, Barcelona, Beijing, and Shanghai. For more information, visit www.veevavault.com.

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About Veeva Vault

Veeva Vault delivers regulated content management for the life sciences industry in the cloud. Vault enables organizations of all sizes to find content quickly, share with partners easily, and adapt to change rapidly.

Sources:

1 IDC, Health Industry Insights, "U.S. Life Science 2010 Top 10 Predictions: Life Science Business Systems Strategy Clinical Development Strategy and Technology," Doc.# HI221424, Jan. 2010.

2 Burrell Report, October 14, 2010 "Emerging Markets Bright Spot of Growth for Pharmaceuticals."