ADVISE

ADVISE includes the "how to" articles you have become accustomed to reading in the former Best Practices section: Time management, skill development, technology, software topics and more are examined for day-to-day implementation in your own jobs and offices.

Into the Cloud: New Technology Blowing In Big Benefits to Regulated Content Management in Life Sciences

JENNIFER GOLDSMITH

Vice President Vault, Veeva Systems

For more than two decades, life sciences organizations have purchased, configured and deployed a series of ever-expanding and complex content management systems. At first, these systems had to be heavily customized for the unique needs of life sciences companies. Over time, industry-specific applications that better support life sciences-specific processes have evolved.

These content management tools continue to tack on new capabilities, but they have failed to fundamentally change to meet the new business challenges facing the life sciences market: greater collaboration, fast-paced globalization, increasing compliance and stronger focus on cost reduction.

Despite these radical shifts in the business environment, life sciences content management systems have remained largely unchanged. They are built on the same basic platforms and technologies, and they are often only affordable to larger organizations with significant time and resources to invest in systems development projects and customization.

Consequently, many life sciences organizations have grown frustrated with the cost and complexity of implementing, maintaining and updating inadequate content management systems — a process that can

often cost hundreds of thousands of dollars every year. Even worse, smaller companies are left with few, if any, good options for the implementation of IT systems supporting their regulated content management processes.

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. (See sidebar.)

CLOUD COMPUTING FOR REGULATED CONTENT MANAGEMENT

Cloud computing may be the key to regulated content management in the life sciences industry. One of the biggest reasons is the fact that multitenant 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 provides 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 meet the needs of the current business climate to collaborate closely, connect globally, comply swiftly and manage costs effectively.

COLLABORATE CLOSELY

Over the last 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 as much as 50% or more. The use of these partners has reduced costs and increased speed to market. However, this new model has also created significant content management challenges, specifically surrounding collaboration.

While traditional on-premise content management systems often support working collaboratively within an organization, they are not designed for external collaboration. It takes too long, is too complicated and too expensive to give secure access to all external collaborators. Rather than deal with these obstacles, companies tend to simply pull content out of their controlled repositories and distribute it via e-mail 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 simply administrate. New users, both internal and external, can be added in minutes, not weeks or months. By enabling secure access to appropriate content in
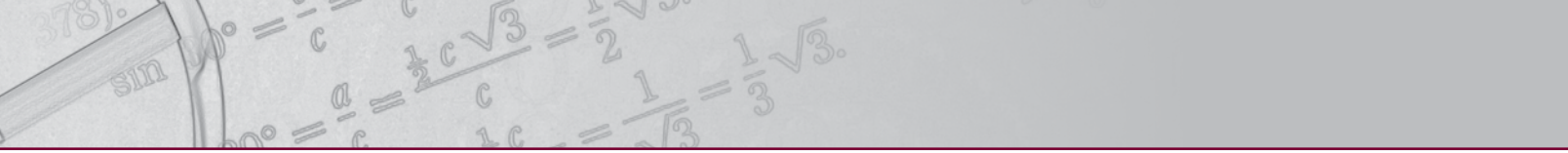
real time via the web, life sciences organizations can work closely with their partners and affiliates around the globe, as well as with various departments across the organization.

The Cloud: 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 — from Amazon to the U.S. Department of Defense —began adopting cloud computing for everything from the management of customer information to the management of sensitive government materials.

From a content management perspective, cloud 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 applications are often considered even more secure than other systems because they enable access to world-class security infrastructures.

Administrators simply provide a secure log-in. 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.

CONNECT GLOBALLY

Annual global spending on pharmaceuticals is expected to grow to nearly $1.2 trillion by 2016, according to a report from the IMS Institute for Healthcare Informatics.[1] In addition, the IMS reported that annual global spending growth will increase from $30 billion in 2012 to $70 billion in 2016. This is driven, overall, by volume growth in emerging pharmaceutical markets and higher spending by developed nations.

Given this explosive growth, both small and large life sciences companies will be challenged with managing their content globally. 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.

Because the cloud is ubiquitous, cloud 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 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, less secure approach where central offices email or FTP documents out to local affiliates to make their changes and then back again.

This approach resulted in a lack of visibility (for example, 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 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, regulatory authorities are fundamentally changing the way in which life sciences organizations conduct business.

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 difficult and costly to change. Even simple changes, such as adding new fields, tracking document distribution and changing security structures require elaborate system validation, development, installation and deployment. This can require thousands of dollars and as long as four to six months to implement. That's too long for teams that need to focus on creating, assembling and delivering content, rather than implementing and validating system changes.

In contrast, cloud systems can reduce the time to deploy and validate such changes by more than 50%. This is because cloud 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.

MANAGE COSTS EFFECTIVELY

Technology is notoriously expensive, and life sciences content management systems are no exception. But with an increasingly challenging global

economic environment, greater competition, expiring patents and a shift from the blockbuster drug models of yesterday, companies must find ways of maximizing technology effectiveness while reducing overall costs.

Cloud computing makes content management affordable to even the smallest organizations or business units by reducing both up-front costs, as well as costs associated with ongoing system updates and maintenance. As a result, companies typically save anywhere from 30% to 50% over 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 (upgrades and back-ups, for example) 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.

2013: THE YEAR FOR FUNDAMENTAL CHANGE IN CONTENT MANAGEMENT

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 – and, according to analysts, are the fastest growing technology. For the first time, companies of all sizes can meet the challenges of today and tomorrow, without the complexity, cost and uncertainty of traditional, enterprise on-premise or hosted content management implementations. ●

References/citations from this article are available upon request.

Divide and Conquer

MARTIN MAGAZZOLO

Global Practice Director, Software Solutions Group, CSC Life Sciences

In an aggressively competitive and fast-changing market, pharma organizations need to make some tough choices - particularly as growing compliance requirements drain internal resources. Staying ahead means remaining lean and agile - which increasingly means letting go of non-core activities.

Whilst life sciences organizations are known for being risk-averse, clinging protectively to their data, this strategy will hold them back going forward. With markets showing no immediate sign of recovery and competitive pressures fiercer than ever, pharma organizations must now rethink their business models in order to stay lean and agile.

Yet at the same time intensifying regulatory demands are creating new complexity around content management. In the face of these two conflicting scenarios, companies are realizing they have no choice but to entrust aspects of their operations to specialist service providers - those offering superior economies of scale in handling non-core activities.

AstraZeneca SHOWS THE WAY

AstraZeneca's chief technology officer Angela Yochem has been pretty open about the company's need to relax its internal controls, and to reach out to a wide range of external sources. Her view is that shifting the responsibility for certain aspects of IT delivery to third parties frees the company to focus on opportunities that improve the business's bottom line. Yochem is not alone either: to improve their abilities to collaborate and expand mobility other large pharma organizations too are making significant changes to the ways they function, having recognized that such capabilities as content management are commodity components of their business, not competitive differentiators.

Harnessing external services adds up too. Buying or building vast, costly internal solutions that cater to peak workloads is wasteful. Owning systems and running them carry cost burdens too, in terms of license fees, maintenance and upgrades. Also, systems' fitness for purpose could be short-lived as the needs of the business evolve and change.

Whilst outsourcing services have not always had good reputations, virtualization technology and cloud-based delivery models have proven transformational - enabling

rapid access to new technologies, facilitating easy scalability and leading to substantial cost savings. The ability to scale IT infrastructures both up and down in terms of capacity is a huge pull for companies — especially when companies will most likely only need to pay for the resources they actually use — because the services are being provisioned as a service.

As well as introducing additional cost efficiencies — because staff are freed from repetitive administrative burdens — the prospect of holding content somewhere external and central offers other benefits. In the life sciences industry, information is continually being created, updated, used and read by multiple people in different departments and locations. The more global markets have become, the more widely content needs to be shared. Whatever companies feel about entrusting valued assets to third parties, there is now a competitive imperative that scientists and thought leaders have seamless access to information that has the potential to advance discovery.

FACILITATING ADVANCED COLLABORATION

Collaboration is a driver too. This is increasing between academia, biotech companies and even competitors. With such a diverse group of people involved in the drug development and marketing process today, the ways content is gathered and managed must

evolve. Whilst intellectual property needs to be safeguarded, it has become clear that strategically organizations now need greater visibility than traditional bespoke electronic content management solutions have allowed.

Pharma organizations can take reassurance from the fact that content as a service, or cloud-based information delivery, has evolved considerably — to offer secure transmission and the ability to partition one company's data from that of others. This means that data that needs to be secured can be, whilst information vital to a collaborative effort can be made available to authorized parties via a common but secure Internet-based framework — removing a layer of complexity and permitting the participants in a project to access the same common core of data directly.

PLANNING IS KEY

Any shift from internal control to content as a service requires a willingness on the parts of IT and business leaders to surrender a certain amount of control over the location of their data, of course. But rather than needing control over where data is held, what companies really need is assurance that their data will be managed securely and a dedicated managed service provider with a purpose-built data centre will be much better equipped to ensure this than an internal IT department ever could be.

Where there is resistance to the proposed changes — in defense of people's jobs, legacy investments and the interwoven business processes linked to

those bespoke solutions — cloud-based solutions can provide a way forward here too, offering organizations a migration path.

So long as they plan well.

Success in adopting content as a service demands a best-practice approach that starts with the appointment of a high-level internal sponsor — such as the head of research and development, chief scientific officer or even CEO — to drive and support the initiative through all of its phases. Next, the project will need an IT leader — perhaps an external partner, or the chief information officer or chief technology officer.

A clear IT strategy is crucial: business processes must be well thought out and technology solutions considered in terms of both short-term and long-term implications and benefits.

FUELING COMPETITIVE ADVANTAGE

Any concerns about system performance have been largely addressed, as cloud-based services have matured and the success of software-as-a-service-based applications has been proven.

Sure, electronic content management is a more complex proposition. But increasingly IT leaders — and, close behind, business leaders — are beginning to accept that content-as-a-service will lift a costly and onerous burden from the industry.

Those quick to embrace the opportunity will gain most because of the extra agility cloud-based solutions offer them. As organizations begin to map out new growth strategies, innovative thinking and a dynamic, service-based approach to content management will go a long way in setting them up to reach out and exploit new markets. ●

References/citations from this article are available upon request.

43

NEW: DIA Online Career Center

Whether you are job hunting, want to expand your professional skills and knowledge, or are looking to connect with others in your field, you can find what you need at DIA's online Career Center.

DIA's newly launched Career Center is designed to meet the professional development needs of our stakeholders around the world. The new Career Center, found at **http://www.diahome.org/en-US/Career-Center.aspx**, provides comprehensive resources for every stage of your career.

The new Career Center features:

- **Job listings and Information:** Job seekers can search health care positions, or post their resume for employers to view. Employers can post positions and find employer strategies.

- **Career Resources:** Career Corner, a daily online newspaper featuring articles, blog posts, videos, and photos from hundreds of media outlets, is your partner in the job search process and provides many helpful resources to assist you along the way.

- **Meetings and Training:** This section is designed to help you find solutions to critical issues and challenges. Links to DIA conferences, live and online training courses, webinars, and eLearning modules provide timely and authoritative information to advance the overall medical product industry and individual professional development.

- **Membership:** Take advantage of all the benefits of membership to network, learn, and lead. This section will point you to free webinars, members-only publications, and other benefits of membership that can help your career.

- **Networking and Communities:** DIA has many opportunities to interact with a global network of professionals who share your interest in a particular topic. This section will help you navigate our Communities (formerly SIACs), ConneX, and Student and Patient Initiatives.