The Regulated Cloud

Using the regulated cloud is a fully compliant, highly secure and very advantageous approach… and the way of the future.

Rik Van Mol explains why cloud computing is the key to the future of content management in life sciences.

Much of a life sciences company's most precious intellectual property falls into the category of regulated content, ie, content that must be created, approved, tracked, stored and updated in accordance with specific government regulations. For the past two decades, companies have managed their regulated content by maintaining elaborate content management systems within their firewalls.

Today, however, given fundamental changes in the healthcare landscape and companies' business models, these solutions are obsolete, inefficient and, in many cases, ineffective. The best practice in managing regulated content is to deploy solutions in the regulated cloud — an environment that conforms to the strict technical and quality standards established by global health authorities. Manufacturers may at first be hesitant to send proprietary intellectual property and regulated content off to the cloud and to use software that a vendor manages across multiple tenants. Using the

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regulated cloud is, however, a fully compliant, highly secure, and very advantageous approach … and the way of the future.

A Demanding Industry

Perhaps no industry is as heavily regulated as life sciences, since laws dictate not only how various clinical and operational processes are performed, but also how they are documented and even how that documentation is handled electronically. Regulated content includes clinical trial protocols, safety reports, health authority submissions, manufacturing processes, formulations and promotional materials. Non-compliance with regulations such as 21 CFR Part 11 and EU GMP Annex 11 that govern the creation, storage and use of such documents can cause safety issues and result in criminal liability as well as civil and regulatory authority penalties or fines.

For years, life sciences companies have managed their regulated content using software designed for general, industry-wide platforms that is then modified for specific uses. These general-purpose tools, especially once customized, are complex systems to deploy, master and maintain. Consequently, they are no longer suited to the industry's current environment and business requirements.

A Changing Climate

As it relates to regulated content, the life sciences industry has changed significantly since content management software was first introduced:

• *Companies are no longer autonomous.* While life sciences companies once performed nearly all of their business functions internally, they now rely on a mix of external partners from CROs to co-marketers. They need to be able to exchange content and collaborate with their external partners, while maintaining system security, regulatory compliance and the integrity of their information. Any shared content management system must maintain tight security and at the same time allow users to be added quickly, provide easy role-based access to content and be intuitive to use.

• *Companies operate globally.* To remain competitive and to serve a global marketplace, life sciences companies are doing business with partners and affiliates around the globe. Their technology platforms and software solutions must therefore be flexible and affordable enough to serve even the smallest, most remote partners and affiliates. All users need the same easy access, speed and performance from the software that central offices enjoy, and the consistency of content must be maintained across borders.

• *Regulatory demands are growing.* Regulatory restrictions and the pace of regulatory change are intensifying. In general, regulatory bodies have placed more and wider restrictions on the storage, distribution and tracking of content, as well as the validation of storage systems. Thus, any system for managing regulated content must accommodate constantly changing regulations, and system changes must be readily validated as compliant.

• *The budget is constrained.* Declining revenues have forced companies to reduce costs — including those associated with mission-critical systems. Companies, therefore, need a more cost-effective alternative to implementing and maintaining the complex customized solutions of the past, the cost of which can run into millions of pounds per year.

Antiquated Solutions

Traditional content management software solutions are ill-suited to these new working conditions and no longer deliver what companies need, particularly

when it comes to collaboration. Companies that maintain their regulated content within their firewalls have three options for sharing it with partners:

1. They can grant partners access to their internal systems through virtual private networks (VPNs) or by issuing company laptops, with all of the logistical complications that entails. This process can easily take up to three months to complete.

2. They can implement a second level of technology to share content externally. This model quickly degrades into an environment with uncontrolled sharing, version confusion and an inability to maintain a single master file that reflects the authoritative version of the truth.

3. They can take the path of least resistance and simply e-mail documents to partners or use an electronic drop box. Inevitably, this leads to the same uncontrolled environment described above.

Existing systems are painfully difficult and expensive to deploy, update, maintain and support. Often, the hassles and expense involved mean that affiliates do not get the same functionality as headquarters, that smaller companies must manage their regulated content manually, and that companies fall behind in their upgrades.

Failing to upgrade the software regularly can impact user acceptance, as performance and functionality are stagnant in the face of changing needs.

Making even simple changes (such as adding new fields or document types) involves many elaborate steps in system validation, installation and deployment, requiring considerable IT resources.

Technology to the Rescue

Fortunately, all of these challenges can be met by adopting new technologies.

The first advance that can be brought to bear on managing regulated content is a very

simple, intuitive user interface. Consumers using software on the Web, such as Facebook, Amazon and Google, can use these tools instantly, with no training, because the navigation and functionality is obvious. This same type of easy, user-friendly experience is now available to business users working with their regulated content management systems.

The second is cloud technology. Cloud computing is an architectural model through which a vendor provides software to multiple subscribers, or tenants, from a single, shared instance of the application which is maintained centrally. (Common consumers examples are Spotify and Apple's iCloud and business examples include LinkedIn and Salesforce.) Users can access the software with an Internet connection and need no special hardware. Customers maintain full custody of their content, which is separated from others' by impenetrable partitions.

This turnkey arrangement delivers a number of benefits over single-tenant instances of software that apply directly to the challenges of managing regulated content today:

• *Speed and adaptability.* Administrators can configure and update an application using simple point-and-click tools. Thus, a change that takes months to develop and deploy with a hosted/on-premise environment takes just a few minutes. New users, both internal and external, can be added just as easily.

• *System performance and quality.* The provider offers technology that would not be feasible for any one customer and can maintain a continuous stream of innovation. The provider handles all system upgrades centrally, so all users are always working on the latest release. Additionally, the system can continue to sustain peak performance, even as usage increases.

• *Cost savings.* The solution is hosted by the vendor who can achieve economies of scale and spread costs across multiple companies, so subscribers need not invest in any equipment or data centre space. Companies pay only for the capacity and storage that they use. This makes content management affordable to even the smallest organisations or business units.

• *Flexibility and scalability.* The system's capacity is elastic, so the vendor can adjust capacity for any subscriber as business parameters change.

It is important to make the distinction between true, multitenant software implementations and software programs that are simply hosted off premises by vendors. The latter are still single-tenant solutions, meaning that each customer has its own dedicated server running its own version of the application, which the vendor configures and maintains for the client. Each time there

is a change, the application must be redeployed for each customer — an expensive process with no economies of scale. Plus, the arrangement is subject to annual maintenance and support fees. It is the multitenancy aspect of an application, not strictly the off-premise hosting, that delivers the benefits of the cloud.

The Regulated Cloud

When cloud computing is used for managing regulated content, the solution must go beyond what is required of non-regulated business applications. Given the security issues and validation requirements involved, the regulated cloud must offer:

• An environment that is both validated and auditable. For other applications, users do not need to know exactly where their information is stored within the cloud. Regulated content, however, should be stored in a fixed location that can be visited, audited and validated to the company's

satisfaction. All software releases must be validated by a trusted system validation service.

• Adherence to Standard Operating Procedures for quality software development and system maintenance.

• A world-class security infrastructure. Multiple layers of firewalls ensure high levels of protection against intrusion, and security measures identify and close vulnerabilities.

• Robust and flexible security at the content level. Security policies must be user-based, and advanced controls are needed to enable user authentication, log user activity and define user profiles by document stage.

• Business continuity and disaster recover measures that match, if not exceed, what companies would maintain on their own.

• Data segregation for content files, metadata, full-text search indexes and application configurations. The exact location of each should be clear.

Ron Calderone, executive director of Information Services and Management at Unigene Laboratories, maintains, "A system in the cloud is as secure as its host." When security measures include nightly backups, inherent redundancy, regular external security audits and a tested business continuity plan, he advises, "… the cloud can be a highly secure computing environment."

Beyond these basic protections, the ideal software solution can support global collaboration, compliance with changing regulations and more cost effective operations.

Users anywhere in the world can log into the secure environment using any device with an internet connection, a web browser, and a username and password, and then begin work with little or no training.

Content is visible to all authorized team members (internally and externally) immediately, and documents stay in a controlled environment throughout the collaboration process.

The logic behind document lifecycles, workflows, properties and actions is easily configured, yet strictly controlled. Updates are made within the underlying application by the vendor and are pre-validated before being released simultaneously to all subscribers. New functionality is turned off by default and must be activated by the business administrators.

By combining a user interface that is intuitive with a world-class infrastructure that is rigorously protected, cloud-based platforms offer companies the best of all worlds for managing their regulated content.

Systems maintained in the regulated cloud are accessible to partners and affiliates globally, supporting collaboration between internal and external partners. Yet content remains in a secure, controlled, audited environment.

The best solutions mimic the usability of popular, consumer software on the web — even while providing all the powerful features that users need for peak efficiency.

The multitenancy structure also means that upgrades are deployed automatically. Users are always on the most current release, business systems are validated and business practices remain current with legislation. The cloud platform also spreads costs across multiple clients and permitting companies to pay only for the capacity they need.

About the Author
Rik Van Mol is Vice President Veeva Vault, Europe, Veeva Systems. Rik has over 15 years of business/IT consulting and regulated content management experience in life sciences.