Industry Experts CHALLENGE THE STATUS QUO ON CONTENT MANAGEMENT

For more than two decades, life sciences organizations have purchased, customized, configured, deployed, and maintained a series of ever-expanding and complex content management tools to help them efficiently manage content. The creation of industry-specific applications added to these technologies' ability to support more specific life sciences needs, such as regulatory submissions and document management. And while content management technology vendors have continued to tack on new functions and increase capacity, the platforms themselves have not fundamentally changed. In stark contrast, the life sciences industry has undergone dramatic change in the last 20 years, including a greater focus on emerging markets, global operations, and strategic and tactical partnerships. These changes are calling into question traditional methods and tools for regulated content management.

What changes are needed, then, to bring content management technology to where it needs to be for today's life sciences organizations? To enable companies to collaborate closely, connect globally, comply swiftly, and manage costs effectively? Veeva Systems — makers of Veeva CRM and recently launched cloud-based content management solution, Veeva Vault — invited industry leaders to discuss how things need to change.

Q: Given the dramatic changes that the life sciences industry is undergoing, what are some of the ways in which content management technology will need to change?

PIERRE MORGON: The No. 1 issue that content management vendors need to address surrounds global compliance. Today, compliance challenges — and more broadly, regulations and policies — extend well beyond the domestic borders. As an example, take a look at the ICH, aimed at aligning various international regulatory guidelines. The Chinese are working with French authorities. Brazil, too, has reformed the way it evaluates the regulatory submissions. In all of these instances, each country looked mostly to the U.S. and Europe for best practices to follow when establishing their compliance requirements. So while countries like Brazil, Australia, India, Mexico, and others strive to be self-sufficient, there is still a convergence of regulatory requirements across the globe while some maverick countries — especially China — seem to be willing to take an altogether different approach and create their own standards. This creates problems when managing regulatory content in any consistent way around the globe so we need our systems to be able to adapt rapidly to this ever-shifting global compliance landscape.

RUEDI BLATTMANN: Traditional content management systems only manage the authoring of content without any efficient mechanism to manage the distribution and use of that content, which is one of the most important aspects of content management. After all, what good is a document if you don't know who also has access to it, or whether it has been sent to the health authority? This problem multiplies as companies go outside their country to submit content to global health authorities in areas such as Latin America, China, Russia, etc. CM systems have always included document metadata, and this is associated at the document level. In order to relate documents together, the same property needs to be populated in the same way on each document and across applications, which can be difficult. A property that associated with one kind of document may have a different label when associated with a different type of document. The point is that content management systems need to address metadata as much as they do content. Both the content and the information about each content component must be considered in any content management system.

STEVE HASLER: The most important way content management systems need to change is cost; the cost of content management must decrease considerably. Life sciences companies of all sizes have been struggling with this issue; they are stuck using systems that cost a lot with huge annual maintenance and initial implementation costs. Content management technology needs to evolve to be more cost-effective. In addition, the pharmaceutical industry needs a content management system option that is more flexible and that more easily enables collaboration with external partners and resources. With existing technologies, the most challenging question is: how to provide third-party access to the content management system across the firewall without making the company vulnerable, without incurring a huge expense, and without taking weeks to implement?

IAN TALMAGE: It is incredibly important for new content management systems to be built upon new technology that allows for computing elasticity; this is the real value of cloud computing. Content management systems need a flexible user interface that allows people to add user-generated content so that it can be easily uploaded and shared (but not edited) for regulatory purposes and clinical trials in particular.

Q: What are the benefits and challenges of the cloud platform for content management applications?

STEVE HASLER: One of the greatest benefits of the cloud is cost savings. Costs are lower than traditional technologies because it's a pay-as-you-go model. In addition, the cloud has the potential to better enable functional outsourcing by making it easier to collaborate with partners. The cost-savings potential is not incremental, but rather, transformational.

JOHN COGAN: One of the cloud's greatest advantages to life sciences companies is the tremendous potential cost savings. In addition to maintenance, hardware, and software usage savings from the massive economies of scale afforded, cloud computing offers a dramatically less costly data storage mechanism.

Five prominent life sciences executives from around the globe debate the past and future of regulated content management systems.

IAN TALMAGE, Senior VP, Global Marketing, *Bayer Schering Pharmaceuticals*

JOHN COGAN, VP Information Technology, *Shire Pharmaceuticals*

STEVE HASLER, Life Sciences Consultant and former VP of Global Regulatory Operations, *GSK*

PIERRE MORGON, VP of Franchise & Global Marketing Operations, *Sanofi Pasteur*

RUEDI BLATTMANN, Managing Partner, *Life Sciences Consulting Partners (LSCP)*

STEVE HASLER: In terms of potential challenges, security comes to mind. However, security concerns are no different than the ones the industry confronts today when outsourcing business processes to other organizations or countries. Life sciences companies have already faced security issues with information sharing, and have found ways to manage and mitigate these risks. Five years ago, the industry would not have allowed mission-critical content to be accessible to anyone outside of the mother ship. But the industry realizes that it is possible to secure the information, so companies are prepared to be convinced. I would want to see proof, but I am much less skeptical today than I was.

JOHN COGAN: Security may be a hindrance to cloud technology adoption, at least initially. Some CIOs are still nervous about moving wholesale, primary data to the cloud. Old data and back-ups are no-brainers, but current data are often a concern. For some, it will take a leap of faith. But if the content was stored internally on a company's own servers, how much safer would that data be? Public clouds offer a great alternative and low-cost opportunity, especially for smaller life sciences companies.

Q: Content management applications are often described as cumbersome and difficult to use. What are the top three things that most users would change about content management if given the opportunity?

STEVE HASLER: The first thing I would change would be to have access to the content management system from anywhere at any time. With a lot of users creating and reviewing content, in-house systems can be slow and cumbersome when accessed remotely; so users definitely want a quick, easy way to access the system when on the go. Secondly, users need a faster, easer way to search and find old content. In the regulation space, a lot of content that is submitted to U.S. and European health authorities is used more than once and then reused for China and other countries, but users struggle to find it again. Lastly, systems need to be easier to use and there needs to be more easily accessible avenues for help.

RUEDI BLATTMANN: Technically speaking, one the top three things that should happen is the use of Structured Component Authoring (SCA) so that content can be easily found, used, and reused across functional areas and across the world. Clinical is not the only group to create and use content, so content components need to be available consistently across the entire organization. Next, users want a system that is as close to off-the-shelf as possible or that requires the least possible customization, because increased customization increases cost and complexity. A system in the cloud would not require any of this customization, just some simple configuration. Third, users want a single source for content to avoid excessive re-work and to maximize content reuse throughout the product life cycle.

PIERRE MORGON: It is very important for life sciences companies to be able to track what claims have been used where, basically a content audit trail. CM systems today need to enable an unbroken chain of custody for all content, essentially linking the different pieces of the process from authoring to work flow, publishing, and withdraw/archiving. In promotional materials, especially, these are all separate systems so there is no one system with end-to-end audit trail tracking of content. This is also particularly important as companies are being put in the line of fire more and more when it comes to regulatory oversight. An unbroken chain of evidence sets users up for success with fewer chances of mistakes. Secondly, we need a system that enables consistency in use of product data. Sure, there would still be different countries that want to tweak the storyline a little to mirror the local culture or customer expectations but we need a CM system that ensures the approved product/clinical data remains consistent and that any deviation is spotted immediately to help reduce risk. And, closely tied to this, is the critical requirement for CM systems that enable global consistency with the ability to share assets across all different stakeholders.

IAN TALMAGE: There are probably dozens of ways that traditional content management systems can be improved upon. They need to become simpler to use and safer and more reliable. But, accessibility to a single system by all departments is paramount. Life sciences companies must move away from the days of working in isolated narrow silos towards working closely together and leveraging all of the knowledge and data collected by different teams. Cloud technology may be a viable solution because it allows equal access to one system via the web. PV

CONTINUE THE DISCUSSION

EXPERT Q&A
Provided by: Veeva

For the complete transcript of the roundtable discussion, visit http://bit.ly/VaultCM.

Veeva Systems *is a provider of cloud-based business solutions for the global life sciences industry.*
For more information, visit veevavault.com.