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*

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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.

Q: Smart phones, tablet PCs, iPads, and other mobile devices are changing the way that people consume and contribute information. How could these devices enhance or change existing content management processes and functions for life-sciences organizations?

JOHN COGAN: These devices are already enhancing, and changing the game. We need to urgently embrace mobile collaboration. The sooner life-sciences companies invest in mobile device applications for corporate functions, the better. Security and infrastructure teams often list all of the reasons not to invest in mobile technologies, but it's time to get these concerns into the right context. It doesn't matter anyway because business is and will continue to march

forward on this front without IT if we don't embrace and enable mobile technologies. Do you think a business team can't find a third-party to develop an iPhone or iPad application for them? Of course they can. As a matter of fact, I really hope there is a content management vendor out there right now developing an iPad or iPhone app. This is the new frontier and we better be ready for it.

STEVE HASLER: I couldn't agree more. Working with document authors and reviewers in R&D over many years, I've found that one of the most important items of functionality missing from current CM systems is support for mobile working.

IAN TALMAGE: We need to be able to use mobile tools and technologies efficiently, but in a way that enables change. One of the struggles now with content is that when a change is made, it doesn't cascade throughout the content management system. We need to simplify processes and find a way to incorporate mobile technology so that it allows users to change, alter, or update programs simply.

Q: How has the nature of both internal and external collaboration changed in the last five years? What are some of the most important types of collaborations today? And how must content management change to support this in the future?

IAN TALMAGE: The short answer? A lot. Today, there are more internal cross-functional partners and more external collaboration than ever. When it comes to promotional materials, specifically, there are dozens of different people touching documents, from internal brand teams and operations to writers, designers, and programmers at marketing agencies. We need a clear audit trail so we know exactly where these content assets go, when, and who they were transferred to internally and externally. Today's systems have failed to keep up, especially considering the fact that there is a greater expectation of control over the distribution and tracking of content assets. First, content management applications need to allow companies to control the supply chain of promotional assets and detail what has happened to those assets via a comprehensive audit trail. Second, they need to allow companies to quickly search for and find assets so that when an asset needs to be pulled back or retired, we can respond quickly and accurately. Third, we need to know with certainty that the promotional asset we sent into the market is the very same asset that was reviewed and submitted to the health authority. This last item has proven particularly difficult to control. It's hard to believe, but we used to have to complete a word-by-word check on every single piece to ensure we were working on the approved version.

PIERRE MORGON: Collaborations are on the rise throughout the entire life sciences organization — R&D, industrial operations, commercial, IT. Anything that is critical to the business is still performed internally, but anything else is contracted out today. Content management vendors need to provide systems that can protect the all-important confidentiality of documents and enable efficient information sharing across all partners.

STEVE HASLER: In the last couple of years, I've noticed that GSK, for example, has significantly increased its number of external collaboration partnerships. In fact, many large pharmaceutical companies are adopting a similar strategy. But one of the collaboration challenges with content management is that many partners know little or nothing about how to use a content management system. Given this, CM systems must be simplified so that trusted third-parties — from academia to marketing agencies — will find them easy to learn and use.

RUEDI BLATTMANN: Additionally, too often, employees only look at content in relation to their specific job function rather than across functional areas, creating silos of information. For example, drug safety content might include a note that says "this medication should not be used by a pregnant woman," which is something that appears in many different locations like promotional materials, package inserts, labels, medical information to the provider community, and more across functional areas. Therefore, that single piece of content needs to be available to everyone. If the wording needs to be changed to meet a new regulation, employees need to be able to apply changes quickly across all instances in all published documents one time. Content management systems must not only allow traditional collaboration, but also allow the re-use and re-purposing of content across functional areas so that not just the document, but the information it contains, can also be controlled, re-used, and tracked.

Q: Regulatory requirements continue to evolve across the life sciences business. Promotional materials, for example, have come under increased scrutiny and the growing use of social media for communications has raised additional questions around regulatory requirements. How do organizations and the technologies they use need to evolve to support the changing regulatory landscape?

STEVE HASLER: Regulatory requirements, and the pace of regulatory change, have grown tremendously. In the submissions space, this can impact both the content and format of the submission. Today, every time we need to update our CM systems to meet a new compliance requirement, we have to go through a long process that includes development, installation, and testing in multiple environments, validation, implementation, and training. In many cases, it takes four to six months just to complete a software upgrade required to meet a new regulatory requirement. During that time, we might have four to five people working for weeks just on the revalidation of the system and this is a conservative estimate. The bottom line is that the process is complex, time-consuming, and costly. We need a simpler, more streamlined mechanism for addressing regulatory change. By using cloud-based content management, this might be possible. Within the cloud, a software vendor can make a change once for all clients and the costs are spread across a number of companies rather than each company tackling it on their own. Additionally, validation time and costs are mitigated because installation as well as some of the validation are handled by the vendor. We focus on testing our specific configurations. In the end, this makes particular sense for life sciences companies because we are all subject to the same set of regulations.

PIERRE MORGON: While we work in a global economy today, the U.S. law has no geographical limitations to its reach. Any employee of a company that's trading securities in the United States, any contract signed by such an employee, and any trading partner with a tie to the United States must comply with U.S. regulations. Essentially, this means that companies either play by the U.S. rules or they don't play in the United States. The way information is being managed internally is directed by this reality, so while organizations need to comply with local regulations, oftentimes the tougher regulations are set by the U.S. government and often overrule local regulations. The net result is that companies tend to go by a simple rule: between the company regulations (aligned with the U.S. compliance standards) and the local rules, the toughest applies.

IAN TALMAGE: In addition to thinking about

regulatory requirements from a geographic perspective, we really need to consider the how the geographically neutral World Wide Web affects things. Social media is changing the way in which patients and other stakeholders consume information. For example, the site www.patientslikeme.com allows the sharing of drug information, such as side effects, efficacy, and more. The pharmaceutical industry in general — and regulators specifically — must develop a better awareness and understanding of these kinds of social media channels with regard to the regulations that govern them. If we want to leverage the benefits of such new media, then content management technology needs to enable parallel conversation, controlled management of data, and real-time response.

Q: Emerging markets and globalization of key capabilities have been persistent themes at many organizations recently. How can content management tools and processes evolve to better support this shift, and what technologies will most influence this area?

STEVE HASLER: Current content management technologies simply do not allow us to quickly and easily share information around the globe. As emerging markets continue to grow, this will have to change. Today, in most cases, we are able to share documents across the U.S., Europe, and Japan. However, these same document management systems are not easily accessible in other markets and extending these systems to smaller countries is often too costly. As such, sharing information with local affiliates is not easy. We usually have to find a different way to transfer even using non-audit trail approaches, such as e-mail. One of the top priorities for content management providers must be to find an easy, cost-effective way to connect other countries to a common document management system.

RUEDI BLATTMANN: Globally speaking, content management technology must consider language translation issues as well. Obviously, the more you go global, the more important it is to establish terms that are consistent in all languages and approved by all authorities. The semantic model can help here as can the Darwin Information Typing Architecture (DITA). Both DITA and semantic approaches can be applied, such intelligent XML technologies allow metadata to be linked to content components in published documents. Set up this way, companies would save money and time when they need to make a change to a regulatory document or when required thereby increasing the level of granularity to accommodate country-by-country variations rather than reconstructing every content component in published documents to meet the needs of different regions or countries.

Q: While much has already been done to cut costs, how can new technologies lead to even greater cost savings when it comes to content management?

JOHN COGAN: Cost-appropriateness, not cost-reduction, is the ultimate goal, meaning life sciences companies need to get smarter about how they spend money and specifically, IT departments need to carefully consider what is "appropriate" because the answer may be different whether you are on the IT side or the business side of an organization. At Shire, data are one of the biggest growth areas in terms of cost. Our data grew by 50% in just 12 months, this is astronomical. And this trend is only going to continue if we do not move away from the store everything forever world that we work in now. Even though the price for data storage continues to go down, the sheer volume of data being stored is increasing faster than the cost is decreasing. Cloud computing offers a low-cost option to store data, and a good content management system could really help to bring the total cost of storing data way down. As an example, consider Amazon's Platform-as-a-Service. Massive amounts of data can be stored here, but because it is a cloud service, the cost associated with that storage is tiny in comparison to on-premise systems. This presents an opportunity. I want to put the massive amount of data that are being backed up every night somewhere where there is no manpower and no maintenance fees because those services are not necessary for this type of data storage and the cost savings could be tremendous. PV

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