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Collaboration Conundrum

How to Share Content in Today's Global Life Sciences Industry

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> *– Ian Talmage*
> *Senior VP, Global Marketing at Bayer Schering Pharmaceuticals*

Introduction

Ten years ago, life sciences companies were largely autonomous. Drug development, research, manufacturing, and marketing were often handled in house. Today, it's another story. Expiring patents, the rise of generic competition, the growth of more specialized and personalized medicine, and the fall of blockbuster drugs have caused the industry to shift both in its approach to innovation and its approach to operations. These changes have inextricably linked organizations across the value chain. What was once an industry almost solely reliant on internal resources is now made up of broad and heavily interconnected ecosystems of partners, vendors, and global affiliates.

However, while external collaborations have increased at a rapid pace, the systems used to manage these group efforts have lagged behind. Built on aging on-premise client/server platforms, current systems lack the flexibility to enable complex collaboration on a global scale. Because of this, organizations are forced to get by with workarounds that are barely compliant and, worse, unsustainable. Many companies provide VPNs and company laptops to give their partners access to the systems that enable them to work together. Often it takes too long, is too complicated, and is too expensive to give secure access to tens or even hundreds of external collaborators that are now an important part of life sciences teams.

According to Senior VP, Global Marketing at Bayer Schering Pharmaceuticals, Ian Talmage, "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."

With so many external touch points, it is now critical for companies to be able to seamlessly share content within a controlled environment while protecting their intellectual property. But there's the rub: how do you efficiently open doors to partners without opening doors to everyone? It's a collaboration conundrum.

Collaboration in the Cloud

Forget all that you currently know about how regulated content management systems function, and focus instead on the processes that need to be completed. In building a new solution to meet those specific needs, the cloud allows simplification. Think of the technology behind solutions such as Snapfish. This technology is used every day by millions of people around the world. It allows sharing in secure environments to only people specified; requires little or no training; and is very cost effective. If we can make our personal lives run so easily with applications such as these, why do we let ourselves be tortured by technology at work everyday?

"We need a simpler, more streamlined mechanism for addressing regulatory change. By using cloud-based content management, this might be possible," says Steve Hasler, independent consultant and former executive at GlaxoSmithKline.

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Top 5 Clues Your Collaboration Isn't Working

5. You have to set up a separate site or area for each type of collaboration

4. In the last 30 days, someone in your organization has emailed a document because it was too hard to share it.

3. You need a separate software user license for each external collaborator.

2. You need to send a laptop, VPN token, or other hardware to your external collaborators.

1. Adding a new external collaborator into your system is measured in days or weeks, not minutes.

Cloud technologies are taking the life sciences industry by storm, and for good reason. Cloud-based solutions offer undeniable advantages not possible with traditional, on-premise systems. Namely, when it comes to collaboration, the cloud makes systems easy to access, administer, and use all in a cost-effective manner. In a content management system, these benefits provide life sciences companies with a solution that will aid their business processes and reduce the time and money it currently takes to facilitate collaboration.

Ease of Access and Administration

Imagine you wanted to collaborate with a friend to create a photo album, but he or she lives halfway around the world. In the old days, to get your project done you would need to either fly your friend to your house or give him or her secure access to your entire home network. Ridiculous? Yes, but it is exactly what the life sciences industry does every day by, for example, issuing VPN access and company laptops.

Today's life sciences approach to content collaboration is best summed up by Steve Hasler: "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 3 months – way too long. Next, you need to figure out an economical and efficient way to get all of your external partners trained to use your system. Again, not an easy feat with today's cumbersome content management systems."

Use a system in the cloud, however, and it's a whole new ballgame. For the photo album example, consider using a cloud-based service, such as Snapfish, where you can create a shared site, establish your users, and begin work immediately. Similarly, when you extend this analogy to a business scenario, such as collaborating on a clinical study report with a Clinical Research Organization (CRO), you can do the same thing – provide a username and password to a secure environment where partners, vendors, and others can actively participate in the creation of content. All with no additional hardware, VPN tokens, waiting period, or need to share access to your internal network.

Cloud-based content management technologies aid access and administration by:

- Eliminating the need for external users to access your internal network

- Providing a neutral ground for secure sharing of information

- Reducing the complexity of administration for user accounts and account maintenance

"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," added Bayer's Talmage in a recent industry roundtable discussion. "Cloud technology is a viable solution here because it allows equal access to one system via the web."

Creating, approving, and distributing product promotional materials is a great example of how multiple teams must work together to create an asset, such as a

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brochure or website. Within this process, external creative agencies work with the brand team sponsors to draft new content, the brand teams work with the internal medical, legal, and regulatory teams to review and approve the content, and the commercial organization works with multiple distribution partners to get that content to healthcare providers and consumers. How is this done today? Typically, this promotional materials process is a patchwork quilt of emails and multiple system and network access, a situation that, at best, is difficult to manage and, at worst, leads to errors in the content that is used in the market. Cloud-based content management, however, changes this dynamic. By creating a collaborative workspace that is both comprehensive and secure, life sciences companies can be sure that internal and external team members are working together with the right promotional information – all without having to provide any additional network access, hardware, or software.

Ease of Use
Today's content management processes demand both easy access and easy administration, but those are only two pieces of the collaboration puzzle. Think about that photo album again. Sites like Snapfish are successful because they are made for the consumer. They are intuitively built so that they require little or no training — just log on and dig in.

Frequently overlooked, ease of use is the third critical component in solving the collaboration conundrum. Collaboration systems also need to be intuitive – not requiring hours or days of training. This is especially true for life sciences content collaborations that involve multiple partners and vendors, such as ad agencies and CROs. According to Hasler, "One of the collaboration challenges is that many of these 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."

In this fast-paced business world, where external partners may work with multiple life sciences companies, there simply isn't time or bandwidth to get up to speed on multiple custom, in-house applications. When applications are too hard to learn, use, or access, external collaborators will again resort to less secure, less compliant, but more expeditious means of communicating, such as email and FTP sites. Cloud platforms are much more flexible and allow us to re-imagine, rethink, and reinvent our business applications.

To facilitate ease of use, reinvented, cloud-based content management systems can leverage a presentation paradigm familiar to everyone – the consumer web. By using elements from sites like Amazon.com and LinkedIn in a content management setting, cloud-based systems provide a more approachable interface that does not require the level of training typically needed for on-premise solutions. This results in greater user adoption, making it far more likely that all collaborators are working together in the same system with the same content, thereby reducing redundancy, error, and wasted time.

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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.

The Cost of Collaboration

Before the cloud, the costs associated with collaboration were high. Life sciences companies had to spend excessive amounts of time and money to overcome the hurdles of collaborating with external partners. Often, companies would have to provide partners with costly VPNs or company laptops to allow teams to work together – a significant effort. Add to that the amount of time and money needed to train partners on a company's on-premise system, and you can see how collaboration costs can get out of control.
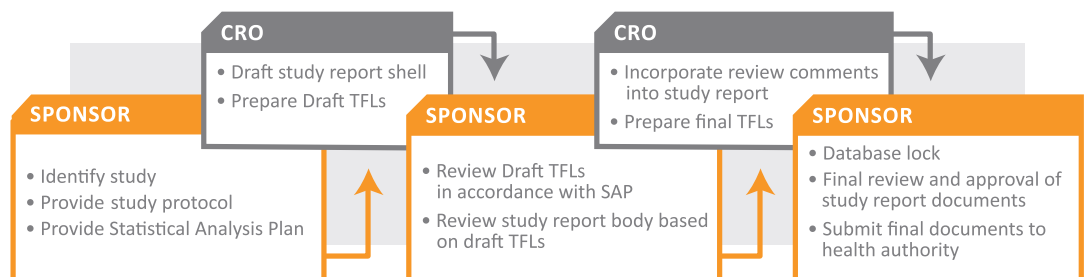
The cloud offers an alternative. Cloud computing lets companies pay only for what they use instead of investing hundreds of thousands on equipment, such as servers and data center space. By removing the cost barrier, cloud computing allows life sciences companies of all sizes to work in a system that fosters collaboration in a validated environment.

"One of the greatest benefits of the cloud is cost savings," said Hasler. "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 here is not incremental, but rather, transformational."

Even large companies can leverage the cloud to significantly reduce the cost of collaboration. Before, granting access to partners often took many months and significant manpower. With the cloud, life sciences companies can redirect resources previously spend on those efforts to processes critical to their business. "Cost-appropriateness, not cost-reduction, is the ultimate goal – meaning, life sciences companies need to get smarter about how we spend money," says John Cogan, Managing Director at JPCogan Consulting and former Vice President, IS Shared Services at Shire Pharmaceuticals.

A Real-Life Example: Collaborating with CROs

Life sciences companies have long leveraged clinical research organizations (CROs) to streamline drug development processes and cut costs. CROs can provide a wide range of services such as study design and integrated analyses. The content generated by these tasks is subject to specific retention schedules and regulations, and it will eventually be sent to a health authority for review and approval. As such, the sponsor of the clinical trial must be very involved with the review and approval of outsourced content. To see the complexity of the collaboration required when working with CROs, let's focus on the process of creating a clinical study report, which may follow these steps:

CRO
- Draft study report shell
- Prepare Draft TFLs

CRO
- Incorporate review comments into study report
- Prepare final TFLs

SPONSOR
- Identify study
- Provide study protocol
- Provide Statistical Analysis Plan

SPONSOR
- Review Draft TFLs in accordance with SAP
- Review study report body based on draft TFLs

SPONSOR
- Database lock
- Final review and approval of study report documents
- Submit final documents to health authority

In this example, content is shared between individuals and organizations many times over, and participants in this process are asked to collaborate on the update and review of content. Today, this typically means taking one of the following approaches to content sharing:

1. **Grant external users access to controlled internal systems and enforce** the same **rules as internal authors.** While this seems like the most logical fix, implementing this is not an easy process. There are technical issues to overcome (both for the sponsor and the CRO – think firewalls, user names, security, setup, etc.) followed by a training process for on-site system access. This also creates a burden on the CROs as each life sciences company likely has their content management system customized, making the system especially complex for new users. Overall, it could take up to six months to get an external user to use an internal system. By that time, the study may be complete.

2. **Implement a second level of technology to facilitate content sharing, such as SharePoint, FTP servers, or eRooms.** This model is user-friendly during the sharing phase, but it often results in multiple copies of regulated documents on both the sponsor and CRO sides. Additionally, most of the sharing systems are neither validated nor audited. Because they are not seen as a repository of record, all finalized and approved content must also be imported into the controlled repository. These controlled repositories, originally designed to aid users from authoring to archiving, are instead being used simply as a final dumping ground. Because these controlled systems cannot meet companies' collaborative business needs, investments used to build them are going to waste.

Because these methods are often time consuming and difficult to implement, companies will sometimes break the rules and pull content out of their controlled repositories, distributing it via email, secure FTP, shared drives – all non-regulated and untraceable channels. This type of collaboration often results in:

- **Compliance Risk**
  Without full custody of the content, life sciences companies and their sponsored CROs increase their compliance risk.

- **Version Mismatch and Errors**
  Having multiple versions of these documents, inevitable during the review process, also increases the chance of version mismatch and errors.

- **Uncontrolled Sharing of Controlled Information**
  Because audit trails and security mechanisms are bypassed, content sharing is uncontrolled.

In order to address the CRO-Sponsor collaboration scenario, as well as many others, the industry needs to strike a balance of openness and security. "To effectively enable today's demand for collaboration, content management systems must be able to handle confidentiality and complex information sharing across all partners," says Pierre Morgon, VP of Franchise and Global Marketing Operations, Sanofi Pasteur.

By moving these types of collaborations into cloud-based content management tools, the CRO-Sponsor collaboration scenario described above changes dramatically,

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adding a third and better means of supporting collaboration: direct access in a secure, yet open, system. In this model, the Sponsor simply adds the CRO as a user to the system, provides them with an access profile for the content, and begins work – no additional hardware, no secondary technology, and no need to provide access to an organization's corporate intranet. Conundrum solved.

Conclusion: A Sunny Outlook for Collaboration in the Cloud

The technology behind regulated content management has been handled in the same way for nearly two decades even though the industry has changed drastically. Autonomy and self-reliance have been replaced by shared partnerships across nearly all areas of a life sciences company. Organizations that find a way to collaborate efficiently and effectively will have the advantage – especially as markets continue to expand globally. Today's on-premise and hosted content management systems do not support that growth. With consistently shifting regulations, increased teamwork with external parties, and the necessity to be nimble, organizations need to embrace new technologies that enable them to collaborate successfully.

As many industry leaders are discovering for themselves, the answer is in the clouds — literally. Cloud-based platforms foster greater collaboration and permit the easy access, administration, and use that are vital to the life sciences industry. For example, by eliminating the need for VPN access, company issued laptops, and risky workarounds such as email and FTP, these systems can provide fast, secure, and easy access over the Internet. With a few clicks, a trusted user can be added, streamlining the administrative process and allowing life sciences companies to share content almost instantly. And by incorporating familiar, straightforward elements from the consumer web, life sciences collaborators can easily log into the system and begin work with little to no training. Add the well-known value proposition of the cloud in terms of overall cost savings and scalability for companies of all sizes, and it's easy to see why content management systems built to run in the cloud replace the collaboration conundrum with collaboration success.

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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.veeva.com.

For more information

Veeva Systems
4637 Chabot Drive
Suite 210
Pleasanton, CA 94588
925.452.6500

veeva.com
info@veevasystems.com

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.

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