Document Management for Small Biotech Companies

An Executive's Viewpoint

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How is a small biotech company to know whether a system is needed, which features are important, and how much investment is appropriate?

There is a lot of talk these days about document management systems. There are dozens of products on the market – some targeted for general information storage and others specifically aimed at the pharmaceutical industry. Some products are very simple, have limited features (e.g., file sharing), and are relatively inexpensive whereas other products are complicated, feature a multitude of "bells and whistles" (e.g., complex security models, built-in annotations, system-generated notifications, electronic signatures, work flows), and are very expensive to implement.

How is a small biotech company to know whether a system is needed, which features are important, and how much investment is appropriate?

What Are My Priorities?

Assume I am an executive in a small biotech company with one product. My goals are to efficiently progress development of that product and protect the product as an asset. I outsource many of the key activities for development (e.g., regulatory expertise, animal research, clinical trials, and manufacturing) because it is more cost-effective than building expert capabilities for these activities in house. I want to channel as much of my financial and operational resources as possible into achieving product development milestones. However, I do need to spend money on tools that protect my investment and enable my team to work efficiently. A document management system can do both these things and is a regulatory requirement if you intend to interact with the US FDA.

Does My Company Need A Document Management System?

- My company's product information is stored in a variety of formats (e.g., paper, physical media [Zip, CD, DVD]) and/or in a lot of different locations (personal computer hard drives and/or on network drives)
- My colleagues and I spend a lot time struggling to find our product documentation and sometimes we don't find it
- My team and I struggle to collaborate on documents, especially when we work in different time zones or while we travel
- I have trouble identifying the latest version of a document when I need to make changes
- I worry about how secure my product documentation is
- I am getting ready to make a regulatory submission (e.g., IND, NDA, CTA, BLA, MAA, NDS, 510(k), PMA)
- My company is actively engaged in due diligence and/or divesting activities
- I worry about complying with FDA requirements and passing an inspection

If you can relate to one or more of the statements above, then your company would likely benefit from having an electronic document management system.

What Do I Need in a Document Management System?

Storage My Company Can Trust

As part of my day to day operations, my company needs a reliable, organized place to store product documentation – E.g., patents, protocols, product specifications, and the results of the company's scientific work. Having these documents kept safe and secure in a single electronic repository ensures I can find what I'm looking for when I need it. No more digging through emails, filing cabinets in basements, or recalling documents from off-site storage facilities! Having the information in an organized electronic repository adds value to my company's asset.

Working With Others and Maintaining Control

I need to share product documentation with my colleagues, key opinion leaders, and vendors. The ability to grant access, have a trusted space for where we can securely exchange ideas and still maintain control over document versions is important. Email is insufficient because of size limitations (I can't send big files) and an inability to maintain version control (2 people can be working on the same document that was attached to an email simultaneously without even knowing it).

Keeping Information Safe

I need the ability to protect product documentation from competitors or unauthorized users. However, I also need the ability to show product documentation to those who can help advance the company's product (i.e., investors), and I don't want to lose sleep doing it. A security model that allows me to control what I want to share with others will help with business operations. Again, email is insufficient because an attachment can be forwarded to anyone without the company's knowledge. That's a risk to the asset and the company.

Being Compliant and Protecting Against Litigation

When my company is preparing submissions to a health authority, we need to adhere to the regulatory requirements for document management. Although health authorities like FDA make risk-based decisions about who to audit, I don't want to risk the value of my asset by not adhering to FDA's regulatory requirements. Using a compliant electronic document management system (eDMS) can help my company avoid surprise inspection violations (FDA 483s) as well as product lawsuits.

Meeting Corporate Development Goals – Regulatory Submissions

To meet our corporate objectives, my company's focus must be on " advancing the regulatory ball" with health authorities in the US and around the world. I need a tool that can help my company quickly and easily take product documentation and prepare a regulatory submission. Such a tool would be of enormous utility, particularly if it can reduce the time and costs involved from document concept to submission.

Facilitate Due Diligence or Management Reviews

At any stage in development, I want to share information with management, outside investors or position my company/asset for acquisition. I want full control to grant read only access to specific product documents. I do not want the risk, inconvenience, and cost of setting up a separate system.

Real Time Document Collaboration

As a research and development organization, I want a document management system that does everything I need with documents in one place. It should be one easily accessible and secure place for the team to create, store, share, edit, approve, and archive documentation. Any on-line document management and collaborative authoring system I choose should be designed specifically for life sciences organizations to help us get further faster.

How Much Should I Invest?

My company's financial and personnel resources are limited and valuable. I must make choices about how and where I spend those resources. My primary corporate goal is to advance the development of my company's product, but I know that I will get further faster and add more value if I provide appropriate tools to facilitate productive, collaborative work. There are certain basic features I need in a document management system:

- Secure, reliable storage
- Global access
- Easy to use
- Version control
- Compliant with regulatory requirements
- Supports staging regulatory submissions
- Low cost

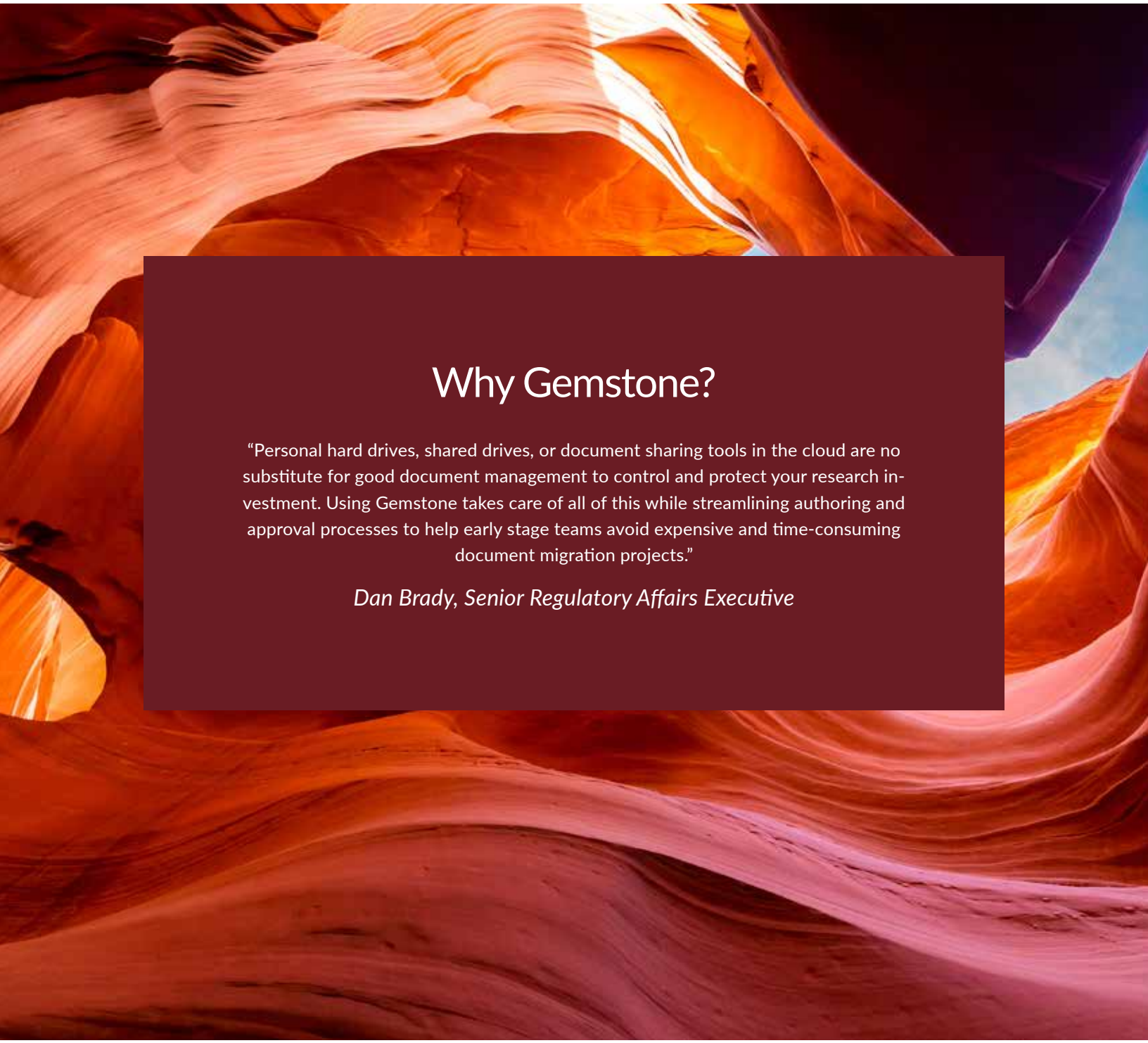
Some document management systems showcase additional features – complicated security models, system-generated notifications, work flows, and extensive reporting/dashboards. Although these may seem attractive and perhaps even fun, are they really needed? My company's staff work so closely together that they do not need a tool to tell them when documents have been uploaded or are finalized (system-generated notifications), who needs to work on which document next (workflows), or prepare progress reports for management.

As a good executive, I would be wise to save the tens if not hundreds of thousands of dollars on "nice to have" features or features that most people in my company would not use in a document management system. Instead, it makes sense for my company to channel that money into product development.

eDMS packages can range from ~$18K US - $1M+ US. Before I purchase an eDMS for my company, I need to know what I want and need in a system, what I'd like to have, and plan my budget accordingly.

Ready to take action?

Contact the experts at Facet Life Sciences to get insight into your specific needs or to schedule a live demo.



Why Gemstone?

"Personal hard drives, shared drives, or document sharing tools in the cloud are no substitute for good document management to control and protect your research investment. Using Gemstone takes care of all of this while streamlining authoring and approval processes to help early stage teams avoid expensive and time-consuming document migration projects."

Dan Brady, Senior Regulatory Affairs Executive

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