GAINING A COMPLETE VIEW OF REGULATORY ACTIVITY

Life Sciences organizations must keep current, complete records of all documents and communications associated with the drug applications submitted to regulatory agencies—both directly and through their affiliates. This means you need to keep complete records of exactly what was submitted for each market where you have applied to conduct business, including related communications such as emails, meeting minutes and phone records that are typically scattered across a variety of EDMS, laptops, collaboration spaces and shared drives.

As explored in this paper, the tools typically used for the archiving and retrieval of these items simply cannot meet today's business requirements. For example, you need the ability to quickly respond to agency queries, which requires immediate access to relevant, up-to-date information. In addition, regulatory compliance dictates that records are protected and access controlled—functionality not normally available with methods such as fileshares.

There has to be a better way. For example, what if all of your regulatory submissions for medicinal products were centralized and easily searchable, allowing you to view all regulatory documentation and activity—including sequences, queries, telephone calls, meetings and email exchanges—along a single timeline?

THE CHALLENGES OF MANAGING REGULATORY SUBMISSIONS INFORMATION

The process of submitting a drug application to regulatory authorities is much like the process of applying for a mortgage—complex, cumbersome and notoriously difficult to track and manage. It is best for your company to keep a current, complete and concise record of all drug applications submitted to government agencies for each product and in each market of the world. This requires maintaining a record of exactly what was submitted, plus a thorough collection of correspondence from the initial contact to the last.

The challenge, of course, is knowing exactly what was submitted, and when. If you are relying on contracted affiliates to support this process in some countries, the complexity increases. Not only do you have to trust your affiliate to know the local regulations, submit applications and maintain an open dialog with the local regulatory agency, but you also have to stay informed of all interactions throughout the process. What if a representative of an agency calls to discuss a point concerning the records, and you can't locate the right document or the right version? What happens if your affiliate changed the submission (which frequently happens due to local variables), and does not communicate all of the modifications to you? In that case, you will be neither informed nor prepared. This example illustrates why it's critical that all records are singular and authoritative, without any duplication or ambiguity. This level of consistency can be difficult to achieve if communications are being stored across several systems and departments.

These issues are repeated for every market where you submit an application and for every product filed in those markets. It is common practice that submissions to a regulatory authority are maintained for the life of a product on the market, and even for an extended period after that.

THE DEMANDS OF ARCHIVING

Given the mission-critical nature of regulatory submissions and communications, most bio-pharmaceutical companies devote a great deal of time and effort to maintaining a complete, concise and current record of all of their drug applications. Typically, they rely on publishing solutions that write their output ready for submission to agencies onto large-scale fileshares—specifically, with output in eCTD, NeeS or paper formats. As we'll see, fileshares are not designed to handle the tasks and demands associated with archiving. Let's take a closer look at why.

THE LIMITATIONS OF FILESHARES

Fileshares provide a convenient, consolidated location for pushing a submission to an agency through a gateway or via physical distribution. But these fileshares are intended to be temporary locations, not an archive of the submission, as suggested by regulators. This approach prevents compliance with key business requirements—for instance, to securely control all submission information for easy and rapid recall.

And there are other serious limitations. For example, these repositories are not capable of protecting the integrity of a submission with role-specific version-control functions and audit trails. All of this functionality is necessary to comply with 21 CFR Part 11 for electronic records.

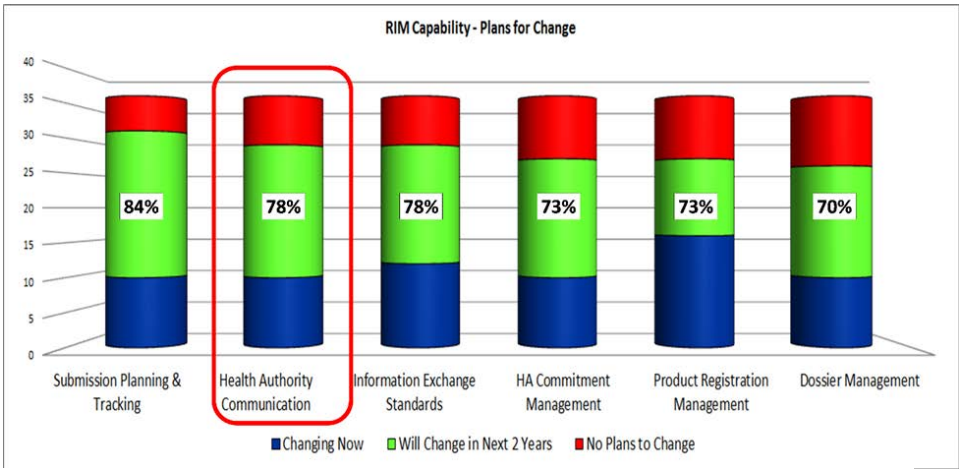
Simultaneously, numerous agency queries and response documents, meeting materials and telephone conversation records are saved in emails, shared drives, laptops or collaboration tools. Responding to inquiries and keeping track of communications between the sponsor and the agency can quickly spiral into a complex, unorganized mess: hours wasted searching multiple systems and repeated calls to affiliates asking for the latest information or status. Integrating all related correspondence becomes a serious challenge.

When you combine the constraints of fileshares along with highly fragmented correspondence management, the result is duplication of effort, inefficient business processes and lack of confidence in the quality of information.

A NEW APPROACH TO MANAGING REGULATORY INFORMATION AND COMMUNICATIONS

The submissions management process is sure to increase in complexity. To get ahead of the curve—and in an effort to improve overall efficiency—companies are beginning to look for alternative approaches to managing regulatory information and communications. In fact, the recent report by Gens and Associates Inc., "Managing Regulatory Information as a Corporate Asset—Industry, Health Authority, and Vendor Trends," makes it clear that bio-pharmaceutical companies are revising their business and technology plans for global submission management. The report, based on an industry study, highlights an increasing focus over the next several years on health authority communications. As Managing Partner Steve Gens writes, "… global expansion is requiring consistency of interactions across regions. … The ability to provide consistent information across global Health Authorities is critical and difficult to achieve." Survey responses showed that only 40% have an authoritative source for health authority correspondence, indicating a need for additional IT investment in this area.

Thus, the drive toward a much more dynamic approach to information and communications management is an understandable development. “Global submission management is predicted to be the top area of change over the next two years,” according to the report. The figure below from the survey shows the areas of greatest forecasted change.



1 Steve Gens, Gens and Associates Inc., and Greg Brolund, Chicopee Falls Consulting, LLC, “Managing Regulatory Information as a Corporate Asset—Industry, Health Authority, and Vendor Trends,” 2013.

To meet today’s complex business requirements, you will need a 360-degree view of all submissions, along with fast access to agency correspondence concerning every product that your company has in the market. Agency representatives will continue to assume that you, the sponsor of a given product, have visibility into everything submitted for that product, along with complete access to previous queries. And because most organizations store regulatory correspondence across multiple repositories, you will need a comprehensive view of all agency interactions in chronological order.

SELECTING A GLOBAL ARCHIVING SOLUTION FOR REGULATORY SUBMISSIONS

As noted by the Gens research, there is growing market demand for solutions that can simplify the search and retrieval of archived submissions and their associated correspondence—all while improving security and compliance. As you evaluate solutions, what should you look for? Based on our work with customers, it’s clear they want a solution that will deliver:

- Closed-loop reporting between affiliates and sponsors—so they know exactly what was submitted and when
- An integrated chronological view with correspondence linked to the submissions so that sponsors can refer back to exactly what was submitted at a specific point in time to support consistent communications with different people and agencies
- Long-term retention of archived submissions with easy search and rapid recall
- Submission viewing and navigation from the repository with functionality equal to a regulatory review (enabling the sponsor to see the submission exactly as the reviewer sees it)
- The ability to limit access to files to appropriate personnel

- Support for deep file-folder structures and active hyperlinking between files - as often used in eCTD submissions
- Scalability and global support services to enable necessary internal process changes on a worldwide basis

Finally, the right solution must be flexible, dynamic and rapidly responsive to changing business conditions and requirements.

EMC: DELIVERING A 360-DEGREE VIEW OF REGULATORY ACTIVITY

EMC addresses the challenges discussed in this paper with EMC® Documentum® Submission Store and View, which is part of the EMC Documentum for Life Sciences Solution Suite. The software simplifies the search and retrieval of archived submissions and their associated correspondence while improving security and compliance. All emails, meeting minutes and telephone records are linked with all sequences to the application, giving you complete access to your regulatory submissions and associated communications. In addition, you can drag and drop emails from Outlook and use easy-search features for more efficient tracking of queries. Learn more at www.emc.com/documentumforlifesciences.

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