GAINING A COMPLETE VIEW OF REGULATORY ACTIVITY

Ensuring Accessibility and Compliance of Regulatory Content

EMC PERSPECTIVE

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INTRODUCTION

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 electronic document management systems (EDMS), laptops, collaboration spaces and shared drives.

As explored in this paper, the tools and processes typically used for the archiving and retrieval of these items simply cannot meet today's business requirements. For example, you need easy access to regulatory correspondence linked with the submission to see the big picture, and the ability to quickly search and retrieve archived submissions and associated documents to respond to queries. Fileshares are quite limited in this capacity.

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-REGULATED 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. Your company has 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 local 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 to meet a local variable, 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. And of course, submissions to a regulatory authority must be 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 biopharmaceutical 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 required by regulators. Because fileshares are not organized and structured, this approach prevents compliance with key business requirements—for instance, to securely control all submission information for easy and rapid recall.

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 recast the core set of regulatory systems with an intelligent, interconnected framework for regulatory information management (RIM) and communications. They are using archived submissions to help authors quickly find and reuse content, and to quickly link from the published submissions to the original source documents to streamline processes. In fact, according to a recent report by Gens & Associates, RIM is now being viewed as "a strategic asset that needs to be managed as a vital part of an organization's business infrastructure."[1]

Thus, the drive toward a much more dynamic approach to information and communications management is an understandable development. The Gens survey found that top priorities include providing an integrated view of regulatory information, improving affiliate information access, and upgrading submission planning and tracking.[2] In addition, the report cited a high degree of planned change in regulatory archiving and dossier management.[3]

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

[1] Gens & Associates, "Next Generation Regulatory Information Management and Intelligence: Strategy, Investments, and Status," Winter Edition, 2015, page 7.
[2] Ibid., page 7.
[3] Ibid., page 8.

repositories, you will need a comprehensive view of all agency interactions in chronological order.

SELECTING A GLOBAL ARCHIVING SOLUTION FOR REGULATORY SUBMISSIONS

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:

- Access for affiliates to critical submission documentation
- 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, providing an at-a-glance look at all interactions to date and furthering accuracy in responding to agency queries
- The ability to refer back to exactly what was submitted at a specific point in time to support consistent communications with different people and agencies, whether a given submission was submitted by the sponsor organization or an affiliate
- Scalability and global support services, which are needed to enable the necessary internal process changes on a worldwide basis

At the same time, compliance is an ever-present concern. Avoiding issues that can hold up approvals requires a way to:

- Limit access to files to appropriate personnel
- Support the deep file-folder structures created under eCTD rules
- Support active hyperlinking between files—as is often used in eCTD submissions
- Make submissions navigable and viewable from the repository, enabling the sponsor to see the submission exactly as the reviewer sees it
- Archive submissions for long-term retention while providing easy information search and rapid recall, fully in compliance with 21 CFR Part 11 for electronic records

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

EMC DOCUMENTUM FOR LIFE SCIENCES

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, compliance and scalability.

For over 25 years, EMC Documentum has helped Life Sciences organizations meet compliance requirements, increase productivity and securely collaborate across the extended enterprise. For additional information about EMC Documentum for Life Sciences solutions please visit www.emc.com/documentumforlifesciences.

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