DASSAULT SYSTEMES

BIOVIA

SOUND DOCUMENT MANAGEMENT

LAYS THE GROUNDWORK FOR LIFE SCIENCES REGULATORY PUBLISHING

WHITE PAPER

INTRODUCTION

When publishing a dossier, life sciences companies typically struggle with efficiently compiling supporting documentation. Usually, this is the result of dealing with paper and electronic documents, legacy versions and incomplete or inaccurate data due to human error. This does not need to be the case. To prevent documentation from becoming a costly issue, companies can take steps (on the front end and throughout the entire document lifecycle) to enable a smooth submission process.

Document management is nothing new to regulatory affairs professionals. Long before the Food and Drug Administration (FDA) and other regulatory bodies began developing their first guidance for submission format and content, regulatory affairs professionals had to contend with the challenges of gathering and managing documents from disparate functional groups including clinical, non-clinical, manufacturing and drug safety. This information then had to be organized to facilitate the bidirectional exchange of information between the applicants and regulatory agencies to meet guidelines such as those imposed for an Investigational New Drug Application (IND) or a New Drug Application (NDA).

For both industry and regulators, the implementation of submission formatting standards was a welcome relief from the previous ad hoc submission process. Still, there remained a "disconnect" between the content and documents generated by the functional areas and what was eventually submitted to the regulatory bodies.

As most regulatory affairs professionals know, from the time the investigational application—such as an IND—is submitted, until the time when the marketing application is finally filed, often there are hundreds of amendments filed and submitted. This makes it difficult both for the reviewer, who must at any given moment be sure what the product's current and effective information is, and the sponsor, who must manage the previous information that was submitted and the reasons for each amendment.

EDMS Functionality	Value for Regulatory (RA) Professionals
System Notifications	This functionality, if used efficiently, can minimize communication "falling through the cracks" and reduce or even eliminate a number of failures to comply with reporting period regulations (study and investigator information, adverse event reports). An EDMS with notification functionality serves as an automatic communicator, sending an alert when documents are changed, under review or approved. This information can help a regulatory affairs professional plan and facilitate upcoming submissions by initiating communications with the functional areas preparing documents for submission.
System Messaging	An EDMS with properly set system messaging alerts users about documents in the system requiring their action. The level of detail and number of messages vary from system to system. Examples include notification of a document change and document distribution to a recipient required to execute a workflow action on it (e.g., document editing, review or approval).
Versions	Most EDMS allow incremental document versioning as files are modified and brought back into the system. Increments can vary using minor versions (0.1, 0.2) as well as major versions (1.0, 2.0). According to generally accepted guidelines, major versions represent effective versions that have passed the approval stage, while minor versions connote in-process drafts and reviewed versions.
Searches & Audit Trails	These are invaluable tools when regulatory affairs professionals need to: • Search for all relevant content that will be used in a current submission • Find out which document version was used in a previous submission

EDMS Functionality	Value for Regulatory (RA) Professionals (continued)
Lifecycle States	These are used as labels for document versions to indicate their status in the document's lifecycle (Draft, Approved, Superceded, Retired, etc.). Some EDMS permit configurable lifecycle states for documents, making it possible to assign such lifecycle status as "Submission Ready" to documents that have been approved for submission by a regulatory affairs professional. Lifecycle states provide more value to version numbers, as some EDMS permit attributing multiple lifecycle states to the same version. This is important for regulatory affairs. For example, if a functional area approves a document as version 1.0 (Approved), the same version can be circulated for submission approval without changing the version number (1.0, Approved, Submission Ready). It would be misleading to have 1.0 Approved, 2.0 Submission Ready as it would appear that the document had changed after being approved by the functional area and before regulatory affairs' approval for use in a submission.
Permission Models	Permission models enable documents to be seen by or hidden from users, depending upon their roles or groups. This is a particularly powerful tool if set permissions can be defined by lifecycle state, thus eliminating the accidental use of incorrect, superseded or unapproved document versions in submissions.
Document Types/Classes	Document types allow relevant information to be used to refer to documents. For example, when using an attribute to search for a clinical document, one may look for the study number or the clinical study component (protocol, CRF, Investigator CV) that classifies it. Careful labeling of attributes and metadata is critical for both searching and organizing such documents. Similarly, document types can be used to label published output with such information as submission date, application type or submission category if the documents have been submitted to an agency.
Review Period Notification	Review period notifications can be applied to documents that require periodic review or submission. This sends a "reminder" message.
eSignature Capabilities	eSignatures eliminate the time wasted in creating a paper document and then scanning it back into electronic form. In order to be compliant with 21 CFR Part 11, electronic signatures must include the user's name, signature date and time, and meaning of signature.

Table 1

Lack of communication between content contributing functional areas and regulatory affairs professionals have often been a primary challenge for companies trying to create an effective internal regulatory submission procedure. For regulatory affairs to function properly, regulatory affairs professionals must be made aware of new information and changes to existing documentation. Failure to comply can lead to extended reporting periods, increased scrutiny from regulatory agencies and increased costs in bringing products to market.

Fortunately, the use of spreadsheets to track which documents have been submitted for agency review and when amendments to those documents have been filed is disappearing. Companies around the globe are replacing those labor-intensive spreadsheets with more advanced and heavily automated electronic technology called Electronic Document Management Systems (EDMS). Today's regulatory professionals rely on EDMS —also referred to as Content Management Systems (CMS)—to control the submission and compliance process. A good EDMS, properly configured, can easily track when documents should be submitted, when different versions of a document are submitted and what amendments have been made to existing files.

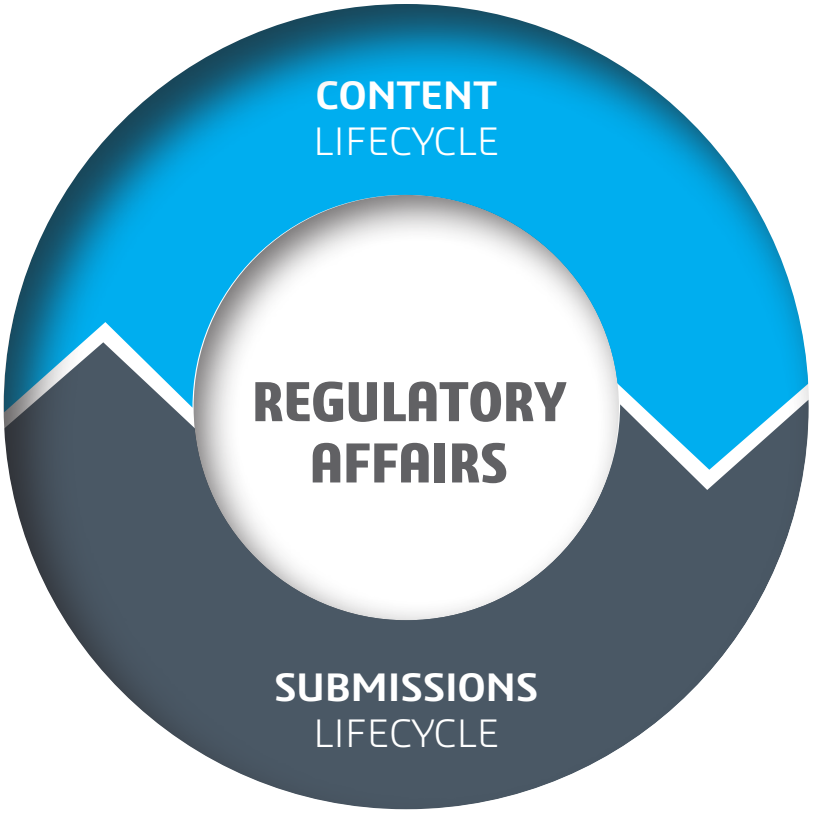
Today's EDMS are not just for archiving and storing documents; an EDMS must bring management value for the stored content and automate many of the old manually performed functions. Table 1 (listed on page 1) lists a few examples of the features found in some of the better EDMS on the market today and how it brings value to both the regulatory professional and the organization.

These are just some examples of how an EDMS functionality can play a vital role in automating, organizing and reducing the complications inherent in a regulatory affairs professional's day-to-day tasks. A good EDMS allows easy access to information created by the function groups and facilitates the bi-directional submission and compliance process.

The Circle of Content

Content and submission lifecycles comprise the full spectrum of regulatory affairs' critical lifecycle management needs. Regulatory affairs professionals' management and use of documents comes full circle when source documents need to be stored in the EDMS as the "Regulatory Archive." Associations can be created between source files used to compile the submission and the regulatory archive's output, allowing quick access to referenced source and submission files which, in some cases, can be bidirectional. A good EDMS is the foundation of a solid, complete lifecycle management solution. Finding the right documents in a timely and efficient manner can not only reduce a regulatory affairs professional's stress, but also reduce the time required to approve, publish and submit documents. Selecting the correct EDMS and combining it with a submission publishing tool that meets the firm's business needs are critical.

An EDMS must be flexible and configurable enough to fit business needs with no customization. A configurable system allows a company to expand the system's use to other functional areas, if needed, and can grow with the company. Many EDMS on the market today have existing integrations with multiple submission publishing tools. The key to selecting a publishing tool is knowing how the company plans, manages and controls its content. Understanding content management requirements allows a company to choose the EDMS that fits its needs and processes. If the documents intended for use in a submission are being managed well, the firm can be more confident of their use in its published submissions.



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