The holy grail of start-up biotech

An effective electronic document management system can significantly increase a company's purchase value.

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In the world of start-up biotech, the goal is to find the next breakthrough drug and then prepare for its commercialization and eventual purchase. When publishing a dossier, many life sciences companies struggle to efficiently compile supporting controlled documents. This is usually the result of having multiple formats and sources to compile that have been captured from a variety of paper and electronic documents, legacy versions and compounded by incomplete or inaccurate data from the outset.

To address this, life sciences companies have turned to electronic document management, at the front-end and throughout the entire document life cycle, to enable a smoother and more cost-effective submission process. For a start-up biotech company the way that data is captured is as important as the data itself to a potential buyer.

Capturing 'intellectual value'

The 'holy grail' for many start-up biotech companies is to bring a product to clinical trials as quickly as possible, capture and publish the results, and then implement an exit strategy to be bought. The only 'real' property that start-up companies possess is intellectual, but many companies are realizing that their research is a lot more valuable than originally thought. Maintaining the data in a controlled electronic repository can significantly increase a company's purchase value because the data is more up-to-date, readily accessible and more comprehensive in the event of an audit. A potential buyer is more likely to be confident that the proper data has been captured, and that there is no missing content or surprises. In this way, a sound electronic compliant document management system becomes critical to the potential acquirer.

Document management is nothing new to professionals in the life sciences industry. Long before FDA, the EMEA (or any other

Table 1 Examples of features in some EDMSs.

EDMS functionality	Benefits
System notifications (study and tionality changed, sional plan tional	This can minimize communication 'falling through the cracks' and reduce, or even eliminate, the number of failures to comply with reporting period regulations investigator information, adverse event reports). An EDMS with notification func- serves as an automatic communicator, sending an alert when documents are under review or approved. This information can help a regulatory affairs profes- and facilitate upcoming submissions by initiating communications with the func- areas preparing documents for submission.
System messaging	This sends users messages about the documents requiring the user's action. The level of detail and number of messages vary from system to system, but examples include: notification of a document change and the distribution of a document to a user of a work flow action required of the recipient (e.g., document editing, review or approval).
Versions	Most EDMS allow for incremental document versioning as files are modified and brought back into the system. Version 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-between drafts and reviewed versions.
Searches and audit trails	These required features are invaluable tools when regulatory professionals need to: • Search for content that will be used in a current submission • Find out what version of a document was used in a previous submission.
Life cycle states	These are used as labels for versions of documents to indicate where they are in the document's life cycle (draft, approved, superceded or retired). Some EDMS permit configurable life cycle states for documents, making it possible to assign the status "submission ready" to documents that have been approved for submission by a regulatory affairs professional, or "submitted" to indicate a document version that was submitted. Life cycle states provide more value to version numbers, as some EDMS allow for multiple life cycle state to the same version. This is important for regulatory affairs because if a functional area approves a document as version 1.0 (approved), regulatory affairs can circulate the same without changing the version number (1.0, approved, submission ready). It would be misleading to have 1.0 approved and 2.0 submission ready, as it would appear that the document had changed between being approved by the functional area and being approved by regulatory affairs for use in a submission.
Permission models	This enable documents to be seen by, or hidden from, users depending on their role or group. This is a particularly powerful tool if set permissions can be defined by life cycle state, thus eliminating the accidental use of incorrect, superseded or unapproved versions of documents in submissions.
Document types/classes	This allows relevant information to be used when referring 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 that document. Careful labelling of attributes and metadata is critical for searching for, as well as organizing, such documents. Similarly, document types can be used to label published output with information such as submission date, application type or submission category if they have been submitted to an agency.
Review period notification	This can be applied for documents that require periodic review or submission. This will send a "reminder" message.
eSignature capabilities	eSignatures eliminate the time wasted in creating a paper document and then scanning back into electronic form. To be 21 CFR Part 11 compliant, electronic signatures must include name of user, date and time of signature, and meaning of signature.

European regulatory bodies) developed the first guidelines for e-submissions, regulatory affairs professionals had to contend with the challenges of gathering and managing documents from disparate functional groups including clinical, nonclinical, manufacturing and drug safety. This information then had to be organized to facilitate the bidirectional exchange of information between the applicants and the regulatory agency. For both the industry and regulators, the implementation of standards in electronic submission formatting was a welcome relief from the previous *ad hoc*, nonstandardized submission process.

The demise of spreadsheets

From the time an investigational application is submitted, until the time the marketing application is complete, there are often hundreds of documents filed. This makes it difficult for the reviewer, who must be certain he has the most recent and effective information on the product, and the sponsor, who must manage the previous information that was submitted and the reasons for each update.

A lack of communication about critical updates, such as site enrollment information, changes in protocols or submission of adverse events, often leads to failure to comply with the agency guidelines, particularly those related to the reporting periods. This can lead to an extended reporting period, increased scrutiny from regulatory officials and additional costs to bring the product to market.

Fortunately, the days of using spreadsheets to track submitted documents and amendments are long gone. An electronic document management system (EDMS) — also referred to as a content management system (CMS) — has replaced the labour-intensive spreadsheets in controlling the submission and compliance process. A compliant EDMS, properly configured, can track when documents need to be submitted. It can also tell when different versions of a document are submitted and what amendments have been made to existing files.

The value of EDMS

Today, an EDMS is not just for archiving and storing documents; it must bring value to the content stored, as well as automate the many functions that were traditionally managed manually. Table 1 contains some examples of the features found in the better EDMSs offered on the market today and how they can play a vital role in automating, organizing and reducing the complications inherent in the daily tasks of a life sciences company. A comprehensive EDMS provides easy access to information created by the function groups, and facilitates the bidirectional submission and compliance process.

Foundation for success

Finding the right documents in a timely and efficient manner can significantly accelerate the time to approve, publish and submit critical 'controlled' documents. A start-up biotech can choose whaich EDMS best fulfils its needs and processes. Once the system is in place, the start-up biotech will be better placed to present the most up-to-date documentation quickly and easily. With intense competition among pharmaceutical companies, an EDMS could make the difference between being bought, and accelerate and increase the deal size by a significant amount. **PT**

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