

White Paper

Nuxeo™ and the Life Sciences

**CARNEGIE
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Introduction

What do all life sciences companies have in common? No matter the size or stage of development all life sciences companies need to create and manage documents (e.g., intellectual property, policies and procedures, regulatory correspondence, product licenses).

The need for and benefits of document management are commonly known and acknowledged in the life sciences industry. Less common, however, are document management systems that satisfy the core requirements most often specified for the industry (i.e., business, regulatory, technology, and financial).

With this in mind, Carnegie Technology Associates partnered with Nuxeo to create the Life Sciences ECM System* to address the specific needs of the life sciences industry.

In the sections that follow we define a set of core requirements and evaluate the system against these requirements to show that it is an ideal solution for the life sciences industry.

Core Requirements

Our first step is to define a set of core requirements to evaluate. Following

is a set of requirements defined in the life sciences industry as “must-have” and often used to evaluate document management systems:

Business Requirements

- *Ease of use*
- *Security*
- *Library services*
- *Business rules*
- *Life cycle*
- *Searching & reporting*
- *Backup & restore*

Regulatory Requirements

- *FDA 21CFR11 compliance*

Technology Requirements

- *Compatible*
- *Scalable*
- *Training*

Financial Requirements

- *Minimize deployment costs*

Evaluation

Now that we have defined our core requirements, our second step is to evaluate the Life Sciences ECM System against these requirements.

Ease of use

If a document management system is not easy to use, the user community

* A natural extension of the Nuxeo™ ECM platform developed in collaboration with Nuxeo, Inc.

Evaluation (continued)

will not readily adopt it. While this is a subjective requirement, users do know it when they see it. Since the browser-based user interface of the Life Sciences ECM System is so flexible, it can be easily configured to meet the needs of the most demanding user community.

Security

Access to a document management system must be limited to authorized users, and the tasks completed within the system must also be controlled.

Access to the Life Sciences ECM System is limited to authorized users via an out-of-the-box membership system, and can easily be configured to work with common authentication mechanisms (e.g., LDAP).

Access to the documents stored in the system is limited by a configurable role-based security mechanism that controls how users create, share, update, view, and delete documents.

The system has a built-in audit history that tracks the full life cycle of all documents stored in the system (e.g., user, date/time stamp, and actions that create or modify documents).

Together, these features meet all the business and regulatory requirements

related to security (i.e., FDA 21CFR11 11.10(c), (d), (e), (f), (g), and (h)).

Library services

Basic library services (e.g., check-in, meta-data extraction, check-out, and versioning) must be supported by a document management system.

Single documents can be added to the Life Sciences ECM System using the browser-based user interface, or a bulk document loading mechanism.

During the document loading process, an automatic meta-data extraction, document check-in, and document versioning are performed. The system can easily be configured to extract additional meta-data as needed.

Document check-out creates a lock in the system and a working copy of the document which can be modified. Once the modifications are completed, the check-in process replaces the original document with the working copy and releases the system lock so other users can check-out and modify the document as need.

Together these features meet all the business and regulatory requirements related to basic library services (i.e., FDA 21CFR11 11.10(g) and (h)).

Evaluation (continued)

Business rules

The ability to control the sequence of events must be supported a by document management system (i.e., business rules).

Built-in business rules can be applied automatically to documents when they are loaded into the Life Sciences ECM System (e.g., check-in, PDF transform, and version).

Simple and complex business rules can be developed using JavaScript and Java respectively and added to the system to extend the set of built-in business rules.

Together these features meet all the business and regulatory requirements related to business rules (i.e., FDA 21CFR11 11.10(f)).

Life cycle

A life cycle must be supported by a document management system (e.g., workflows, digital signatures, records management).

Simple workflows in the Life Sciences ECM System can be developed using folders (e.g., draft, pending approval, and published), and actions (e.g., submit, approved, and re-submit) to move documents to the appropriate folder within the workflow.

Complex, multi-state, workflows can be developed within the system using the embedded JBoss Business Process Management engine (e.g., applying digital signatures to PDF documents).

The content model and user interface of the system can be configured to support records management concepts such as records retention, archive, and destruction.

Together these features meet all the business and regulatory requirements related to document life cycle (i.e., FDA 21CFR11 11.10(f), (g), 11.50, 11.200, and 11.300).

Searching & reporting

The ability to perform searches and to generate accurate reports containing the search results must be supported by a document management system.

The search methods offered by the Life Sciences ECM System include full-text searching (e.g., documents are converted to text, indexed, and are fully searchable), Boolean searches using Google-style query syntax (e.g., nuxeo + life + sciences), as well as advanced search methods (e.g. location, title, description, author, date range).

Custom searches can be developed by

Evaluation (continued)

extending the content model of the system and configuring the search user interface.

The system also supports full business intelligence reporting and can generate report output in PDF, XML, HTML, CSV, and XLS formats.

Together these features meet all the business and regulatory requirements related to searching and reporting (i.e., FDA 21CFR11 11.10(b)).

Backup & restore

The ability to protect documents, and to ensure accurate and ready retrieval of documents must be supported by a document management system.

All documents in the Life Sciences ECM System are stored in two separate data stores. The documents are stored on the file system and all meta-data is stored in a relational database. Together, these data stores are referred to as the repository.

A repository backup procedure can be created using standard file system and database backup methods.

A repository restore procedure can be performed using standard file system and database restore methods.

The backup and restore procedures should be documented and tested to ensure the procedures are accurate and complete, and to show that the repository can be fully restored in the event of data loss or corruption.

Together these features meet all the business and regulatory requirements related to backup and restore (i.e., FDA 21CFR11 11.10(c)).

FDA 21CFR11 compliance

As we have shown in the previous sections, the Life Sciences ECM System satisfies all the internal controls for a closed system, and all the internal controls for non-biometric electronic signatures defined in FDA 21CFR11.

Additional controls can easily be added so that the system can be used in the open system environment defined in FDA 21CFR11 (i.e., 11.30).

The external controls for the validation of computer systems, user training, access control, change control, and the use of electronic signatures are all part of the standard validation document deliverables for the system (i.e., 11.10(a), (i), (j), (k), 11.70, and 11.100).

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Evaluation (continued)

Together these features satisfy all the controls for electronic records, as well as all the controls for non-biometric electronic signatures defined in FDA 21CFR11.

Compatible

Following are the components that make the Life Sciences ECM System compatible with a large number of existing computing environments:

- Operating system (Windows, Linux)
- Application server (JBoss)
- Database server (MySQL, Oracle)
- Web browser (IE, Firefox)
- Zero-footprint web client

They also provide a rich set of choices for the specification of new computing environments (note that this is only a partial listing of the most often used components).

Scalable

The computing environment for the Life Sciences ECM System can be as simple as one server or as complex as a clustered server environment.

The system can manage document repositories ranging in size from small (100s of MB) to large (10s of TB).

Keep in mind that the volume of data to be managed by the system, and the

number of users that will access the system will have a direct affect on the scale and cost of the computing environment.

Training

Training for the user community is a key component of the Life Sciences ECM System.

User community training is provided to ensure that users are completely familiar and comfortable with all the features of the system so it can be fully utilized, and so it can be easily supported (i.e., 11.10(i) of FDA 21CFR11).

Minimize deployment costs

A primary reason why so many life sciences companies do not implement document management systems is the prohibitive deployment costs.

The total cost of deploying the Life Sciences ECM System (i.e., hardware, software, and services) is only a fraction of the cost associated with competing systems.

This cost difference offers life sciences companies a much-needed alternative to costly, proprietary systems.

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Conclusion

As shown in the previous sections, the Life Sciences ECM System satisfies the core requirements often specified in the life sciences industry for a document management system (i.e., business, regulatory, technology, and financial) making it an ideal solution for life sciences companies of all sizes.

Contact us

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