



SOLUTIONS

The life sciences industry is challenged with increasingly stringent regulations, requiring enormous volumes of documentation. Electronic document management has helped to streamline these documentation processes, and the way in which it is governed is known as 21 CFR Part 11. 21 CFR Part 11 mandates that companies that develop pharmaceuticals, medical devices, or other health care products must:

- Demonstrate a specific amount of due diligence in quality control; and
- Identify the parties responsible for specific tasks in research and development.

“Xythos is the best choice for providing that technology to our SAS Drug Development framework.”

Andrew Fagan
Research and Development
Director of SAS Pharmaceutical
Software Development

How Xythos Can Help

Providing a secure centralized document repository

Xythos offers an enterprise-class solution which allows documents to be safely accessed, managed and shared over the web. Xythos systems can be used to store millions of documents or files regardless of how they were created; even printed research results can be scanned into Xythos to simplify compliance. Folder and file-level access controls can be used to create independent document permissions or completely lock down data as records.

Directory service integration with Xythos also provides an added layer of system-level protection, allowing research organizations to control access to Xythos and related systems. Finally, all documents stored within the Xythos system become web addressable resources. This allows researchers to exchange secure links (URLs) instead of email attachments, helping to avoid data exposure or mismanagement.

Securing and maintaining documents and emails as records

21 CFR 11 mandates that organizations maintain records of any document is significant to the research and development process, such as research protocols, results of experimental trials, and logs of regular maintenance for research equipment.



Benefits

Manage compliance standards

Re-deploy paper-dependent administrative functions

Guarantee content integrity

Save shipping and handling costs

Keep critical information safe in case of disaster

Optimize existing IT investments

Improve collaboration between departments, clinics, labs, and other facilities

Empower all levels to work in one secure online environment

Xythos Enterprise Document Manager allows all content, including emails and attachments, to be stored as records according to the U.S. Department of Defense (DoD) 5015.2 standard for integrated records management systems. Users can define and modify Document Classes, Properties, Retention Rules, Permission Templates and more—all according to DoD 5015.2 specifications. According to 21 CFR 11, every record must include a history of who created, revised or reviewed it. A complete change history associated with key documents must also be maintained so that regulators can reconstruct every aspect of a research project if necessary.

Xythos also allows records to be searched, filtered and reported on. Xythos also provides version control and file auditing features to preserve a comprehensive document history, including a document's earlier drafts. Users can also configure directories so that auditing and versioning of files occurs automatically. Finally, Document Classes can be established for each research protocol stage containing unique disposition rules; Document classes can then be saved and re-used to support best practices exchange and aid in 21 CFR Part 11 compliance.

Fitting the way researchers work

The familiarity of accessing files from the desktop and the usability of Xythos' web UI makes it easy for researchers and regulators to manage and access relevant documentation. If an organization's requirements go beyond what they can configure with Xythos' out-of-the-box solution, Xythos provides flexible APIs to customize the entire system.

Customer Example

SAS wanted to provide a single repository for all of its research and development information and allow clinicians, scientists and other researchers to safely access that information from multiple locations—all while maintaining compliance with 21 CFR Part 11.

SAS reviewed several options to web-enable its Drug Development application and chose Xythos. Although traditional ECM systems could address their access control and tracking requirements, they introduced unnecessary complexity, making system adoption more difficult for SAS customers. Xythos, on the other hand, was a user-friendly WebDAV solution that provided version control and a complete audit history of all unstructured files related to research analysis. SAS customers now have the benefits of a single, integrated solution to manage all of their information from a secure web interface. Improved system control also means that SAS customers can be comfortable that project access rules are applied universally to all content, while versioning and logging functions ensure that projects can be easily audited for compliance review.

To learn more about how Xythos' products are used to help address compliance requirements, please visit www.xythos.com.

**For more information please call 1.888.4XYTHOS
or visit www.xythos.com**

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