



Press Release Contact Information:

Erroin Martin
Mystic Management Systems, Inc.
VP, Sales
190 West Town Street
Norwich, CT
USA, 06360
Voice: 8608872900
E-Mail: [Email us Here](#)
Website: [Visit Our Website](#)

Clinical Research Organizations Need Document Control Software

Independent clinical research organizations fall under FDA regulations. Their need for document control is paramount when registering volunteers, tracking results, and contracting with pharmaceutical and medical device companies.

/24-7PressRelease/ - NORWICH, CT, May 01, 2008 — Independent Clinical Research Organizations (CROs) are the front lines in the research of new cures and devices. CROs are instrumental in all Food and Drug Administration (FDA) mandated clinical trials, therefore like their customers - pharmaceutical, biotech, and medical device companies - they must keep a comprehensive control of all quality documents to meet their regulatory requirements.

There are many modalities that can be used by a CRO to maintain their FDA 21 CFR Part 11 compliance. The key factors of knowing when a quality document was accessed, revised, trained, and otherwise viewed by a member of the organization. Those actions can be tracked using paper, an electronic spreadsheet, or the preferred method of document control software. Tight internal regulation, trained policies and procedures, and constant vigil by the document control specialist are an essential part of the paper based approach. While the document control specialist is on top of documents and able to find requested documents by an auditor in a timely fashion, it is the failure to control the time it takes to review and approve documents. The delays and lack of immediate follow-up or escalation catch an organization in an audit.

The spreadsheet method, using hyperlinks and file shares, provide some control for the CRO. Most of the time it becomes a labor intensive process that requires a dedicated person or team to hunt down documents, check and recheck information, and maintain the spreadsheet. It leaves little room for other projects and does not tackle the delay it can take for review and approval.

A basic document control software system that helps a CRO meet its regulatory compliance should at least perform the following:

- Defined parameters around who can create, edit, and revise content in the system.
- Established date and time stamp of when content was sent for review and/or approval.
- Escalate overdue approvals and reviews.
- Electronic signature by reviewers and approvers.
- Established audit trail of all actions taken in the system and upon documents.
- Established controls in a closed repository - not an open file share.

A CRO should also look at a system that can help track more than just documents. A software system that can provide compliance for other standards, like the International Organization of Standards (ISO), can provide greater control over all quality processes involved. A system that can seamlessly track non-conformities, create an escalation protocol for complaints or incidents, and help maintain any other regulatory or compliance records (e.g. employee training records, content based training results, or audits) will have a greater positive impact on the CRO. Why? A complete system will allow the CRO to seek out larger customers and/or expand into many different clinical testing environments. It will help establish a strong quality track record that will result in repeat business and win even larger contracts.

There is a wide variety of providers of document control to choose from for the CRO. When searching for a software solution, affordability, usability, and value to the organization are a triad the CRO should use in its evaluation of vendors. A cross team of end users, IT, QA, and management should be brought together to establish the goals for the CRO's search. This cross-team, with each department having its own stake in any system, should be focused on their departments "must-haves" that meet the CRO's established goals of success. These departmental "must-haves" must be synchronized or the project can quickly become bogged down and the CRO will be at risk.

CROs are the backbone of live-saving research. They help their clients - pharmaceutical and medical device companies - meet their testing goals and launch projects. The service a CRO provides is indispensable. A CRO that exceeds its regulatory and certification requirements will see an increase studies and overall profitability.

About Mystic Management Systems, Inc.

Mystic Management Systems, Inc. is a twenty-five year old leading global provider of quality software solutions, including document control software, product lifecycle management, packaging/specification management and corrective and preventative action. Using applications from Mystic Management Systems, companies throughout the world have been improving profits, reducing costs, and producing better quality products since 1983.

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For companies interested in learning more about MMS products:

Worldwide: (01) 860-887-2900

<http://www.mysticmsi.com>

info@mysticmsi.com