

Ease Your Audit Preparation with Automated Document Control

Organizations operating in a regulated environment continually face the daunting task of managing volumes of documents and achieving a positive audit score during inspections. With the growth of competition and regulatory pressure, many companies may come across an unexpected inspection by authorities such as the US FDA. In such instances, ensuring effective document management and a reliable audit trail can help in preparation at short notice as documents and processes are the pillars of a sound enterprise-wide quality system.

One of the key issues that surfaces in relation to a poor audit score is the lack of synchronization between documents or underlying processes and actual change management. For instance, in many cases, due to multiple locations or suppliers, a change in the document may not result in the actual change in the process. This can easily result in non-compliance to a documented process and thus a negative inspection outcome following an audit. Effective document management demonstrates the organization is following the industry best practices across a wide range of activities and departments.

This article sheds light on the features of an effective document control system that plays a critical role in raising the audit preparedness.

1. **A document system that offers document control in a secure environment:** With the introduction of an electronic document system, you can fully automate the document life cycle while ensuring secure access to critical information. The system acts as a controlled document repository and offers automation features such as templates library, document revision control, electronic signatures, easy document search facilities, notifications, escalations and approvals - all of which result in an effective audit trail and traceable document history.
2. **A web-based document control system for remote access:** As the supplier and customer networks expand around the globe, many document systems fail due to their inability to provide a mobile document management solution. These 100% web-based, document control solutions are designed to allow the field auditors and suppliers to trigger a process change in real-time, attach the evidence documents to a non-conformance, remotely access, and fill in the audit questionnaire that elicits a change in the process. This reduces time and errors in transcribing the documents and carrying out the actual change.
3. **A centralized document control solution that integrates with training management across the enterprise:** A well-developed document control system can seamlessly integrate with processes and trigger a process change throughout the organization, be it a change in the manufacturing process or supply chain process, a comprehensive document control system will alert the affected departments and trigger training requirements. These training requirements could be for the personnel directly involved, or to enhance the competencies required for an audit type. A tight integration between document control system and staff training management can assist in enhancing the audit score.

By integrating a document control system with the organization's core processes and other business areas, organizations can significantly enhance their audit preparedness. A robust document control system is the backbone of flawless audits and a high audit score - all of which will undoubtedly result in motivated, success driven employees and happy customers!

For more information, visit us at www.proquis.com.

Please note this article was published in April 2010 edition of Proquis Newsletter. Proquis' e-newsletter is a complementary information source mailed to subscribers on a monthly basis. We take pride in keeping our worldwide subscriber base of 11,000 up to date with the recent company news, product tips and hot topics in the compliance industry. Subscribe today to receive our monthly newsletter!