

Paperwise DM Compliance v6.10.15

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Introduction

For companies in highly-regulated industries, information management is a critical component of compliance. Quality and compliance requirements permeate an organization by necessity, not only due to a myriad of laws, regulations and “Good Practice” standards, but also because most organizations strive to improve operational excellence.

The content and process management demands that compliance and quality mandates place on organizations in regulated sectors are high. Additionally, these organizations are required to produce a substantial amount of documentation to fulfill governance, risk management and compliance initiatives. Thus, it is no longer practical to manage content separate from quality and compliance. As a result, enterprise content management must play a central, integrated role in effective quality and compliance management.

Audit Management

Most highly-regulated organizations are very familiar with audits, such as those performed for regulation and customers who require assurance that vendors are producing products according to their specifications and compliance requirements. There are also internal audits to ensure that organizations follow their own quality system policies.

The Paperwise Document Management (DM) solution streamlines audits by giving you the ability to quickly and efficiently produce evidence to satisfy auditors. Our versioning tools maintain create audit trails that officials can follow to ensure that your business remains compliant with legislative and industry-specific regulations.

Risk Management

It's not uncommon for companies to store millions of files in various forms across their organization. It's also not uncommon for those same files to get lost because of a lack of corporate control over how and where information is stored. When you cannot control the way information is mapped and stored, you cannot quickly identify or maintain the documentation necessary for risk assessments, such as audit reports, SOPs, training and maintenance records and government regulations.

Paperwise DM removes this risk by enforcing strict naming conventions based on pre-determined corporate policies, and allows specific keyword searches based on fixed index field data. This makes finding and maintaining compliance records simple to regulate across your organization.



Compliance & Policy Management

It is imperative that organizations, especially those with limited staff or resources, become as efficient and cost-effective as possible when it comes to managing compliance records.

An important aspect of achieving and proving compliance lies in the management and use of standard operating procedures (SOPs). The onus of documenting and managing the creation, collaboration and maintenance of SOPs is similar to that of audits, risk assessments and change requests. However, SOPs specifically document business operations and procedures. There are standards, like those that mandate employee awareness and adherence, placed on SOPs that make them uniquely difficult to manage. Should an incident, like an injury, occur, businesses must prove that (1) the employee was properly trained and (2) SOPs were followed.

Paperwise DM simplifies the process for creating audit records that prove employees were aware of the SOPs by requiring employees to read SOPs and confirm they've understood the material with a digital signature, all while recording employee actions and test results. When SOPs are modified, the system documents the collaboration and employee access to the modified SOPs for training purposes.

Should employers need to demonstrate that their employees read SOPs at given intervals, the system can quickly provide audit logs for auditors and risk and compliance managers.

Change Management

Change is the only constant in business, and the only organizations that can succeed are those that manage that change with efficient, transparent and auditable processes. When an incident or deviation occurs, many organizations have SOPs in place to determine and contain the root cause, manage the corrective and preventive actions (CAPAs), issue change requests (CRs), modify SOPs and re-train staff as needed.

Paperwise DM facilitates these change management processes and the related documentation by organizing the processes, content and collaborators around a commonly understood "business object", such as a CAPA or CR. This prevents documentation from becoming scattered across email inboxes, network drives, local hard drives and mobile devices.



Paperwise DM Multi-Layered Security

Paperwise DM provides exceptional flexibility and control over document access and system features with a multi-layered security system.

Database Security

Paperwise DM provides its own integrated security and does not rely on Windows security. Windows Administrators do not necessarily have administrator rights to the Paperwise DM system. The Paperwise DM security model is based on users and groups, file cabinets and query restrictions. It is enforced at the database level.

Image Security

Paperwise DM stores images in their original file formats wrapped and compressed in proprietary containers. Any attempt to modify the container invalidates the images making the system suitable for non-repudiation. The storage files are unreadable outside Paperwise applications. Once committed to the system, documents are not modifiable without resubmission to the system. This avoids any question of document authenticity and provides a natural audit trail.

Tracking & Reporting

Paperwise DM is capable of tracking detailed activities including log-ons, retrievals, modifications, deletions and security changes. These extensive logs are available for administrator export and inspection.

User Rights

Access is controlled by user name and password. File cabinet rights are assigned at the user or group level. File cabinet rights provide generic rights, such as view, modify, delete for images and notes, as well as view and delete rights for annotations.

Data Access

Access restrictions apply controls based on individual field values, such as account number, document type, queue status or data ranges. This allows specific security control down to individual document access.

Feature Security

Individual feature access can be granted or declined based on user or group rights. Approximately 50 functions can be hidden from view or disabled on menus. A common example is disabling print, email and export capabilities. This allows efficient use of the system in a "View Only" mode, but does not allow any information to be extracted from the system for unapproved use.

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