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COMPLIHUB

Document Management System

Control the documented information your management system depends on — revisions, approvals, controlled distribution, acknowledgement, periodic review, and a master document register that is always current because it is the system, not a report compiled from it.

- Sequential version approval
- Controlled distribution
- Acknowledgement tracking
- Review date reminders
- Immutable approved revisions
- Master Document Register

Independent module — no other CompliHub pack required. · Integrates into a full IMS when additional modules are licensed.

Executive Summary

CompliHub Document Management System (DMS) controls the documented information that underpins every management system — procedures, work instructions, policies, forms, registers, and external documents of reference. It replaces shared drives, email-based approvals, and the manual acknowledgement logs that nobody maintains.

The module addresses the single most common category of audit findings in ISO management systems: failures of document control. Documents with no evidence of approval, obsolete versions still in circulation, no record of who has acknowledged the current revision, and reviews that slip past their due date without anyone noticing.

CompliHub DMS is not a general-purpose file store. It is a controlled-document workflow: a document is drafted, submitted for approval through a defined chain, published as the effective version, distributed to acknowledged holders, and reviewed on a defined cycle. Every step is recorded, immutable, and auditable.

Zero
Obsolete documents in circulation

100%
Documents with recorded approval

Tracked
Every access and download logged

Auto
Review reminders before due date

The Problem

Document control is the foundation of every ISO management system — and the clause that generates more findings than any other. ISO 9001 §7.5 requires that documented information be approved for adequacy, reviewed and updated, available at points of use, adequately protected, and subject to distribution control. In practice, most organisations fail on several of these simultaneously.

The typical state: documents live on a shared drive. Version control is by filename ('SOP-012_v3_FINAL_REVISED_v2.docx'). Approval is by email, and the approval evidence is an email thread buried in someone's inbox. Distribution is a PDF emailed to a list. Acknowledgement is not tracked. Review dates are in a spreadsheet that nobody owns. The Master Document Register is compiled manually twice a year, and is out of date by the time it is printed.

The consequence: certification auditors find obsolete procedures at points of use, cannot verify that the current revision was approved by an authorised person, and discover documents past their review date. These are minor nonconformities on a good day and majors when they affect critical processes.

Version Chaos

Multiple versions on the shared drive. Filename conventions break down. Workers use whichever version they find first. Nobody can prove which version is current.

Approval Evidence is Email

The approver replied 'OK' in an email. The email is in their inbox, not against the document. During audit, the evidence cannot be produced.

Distribution is Uncontrolled

A PDF is emailed to a list. The email goes to the wrong list, or someone prints it and the printout outlives three subsequent revisions.

Acknowledgement is Not Tracked

ISO 45001 §7.3 and ISO 9001 §7.5.3 require that relevant personnel are aware of documented information. There is no mechanism to prove they received and read it.

Reviews Slip Past Due

The review-date spreadsheet depends on someone checking it. Documents go years past review without anyone noticing — until the auditor asks.

MDR is Always Out of Date

The Master Document Register is compiled periodically by a quality coordinator crawling the shared drive. It is obsolete the moment a new document is published.

The CompliHub Solution

CompliHub DMS implements document control as a lifecycle workflow: **draft → submit → approve → publish → distribute → acknowledge → review → revise**. The Master Document Register is not a report — it is the system itself.

Metadata and categories. Every document carries structured metadata: document number, title, category (procedure, work instruction, policy, form, external), department, owner, approver, review interval, and applicable standards/clauses. Categories are administrator-defined.

Sequential version approval. A new version is uploaded as a draft. It passes through a defined approval chain (single or multi-level). Each approver sees the draft, the previous approved version for comparison, and records their decision with timestamp and comments. The chain is configurable per document category.

Effective/current version control. On final approval, the new version becomes the effective (current) version. Previous versions are retained as immutable records but clearly marked as superseded. Only the effective version is served to users at points of use.

Controlled distribution and acknowledgement. Publication triggers distribution to a defined list of holders (by role, department, or named individuals). Each holder receives a notification and must acknowledge receipt. The system tracks who has acknowledged and who has not, with reminders for the latter.

Review date reminders. Each document has a review interval (e.g., 12 months, 24 months, or as triggered by change). The system sends reminders in advance of the review date — typically 30, 14, and 7 days before. Overdue reviews are escalated to the quality manager.

Download and view logs. Every access to a document — view, download, or print — is logged with user, timestamp, and version. This is the evidence for 21 CFR Part 11 environments and for demonstrating that procedures are available at points of use.

Master Document Register. The MDR is a real-time view of all controlled documents: current version, status, owner, next review date, distribution list, and acknowledgement completion. It is always current because it reads from the same database the workflow uses. No manual compilation, ever.

Detailed Feature Breakdown

Documents

Control the documented information the management system depends on: revisions, approvals, distribution, acknowledgement and review.

ISO 9001 §7.5

- Metadata and categories
- Uploaded versions with sequential approval
- Effective / current version control
- Immutable approved revisions
- Controlled distribution and acknowledgement
- Review date reminders
- Master Document Register
- Download and view logs

Standards & Compliance Coverage

Document control is required by every management system standard (ISO 9001 §7.5, ISO 14001 §7.5, ISO 45001 §7.5) and is the foundation of regulated environments (21 CFR Part 11, GMP Annex 11). The module satisfies these requirements at the process level, not merely by storing files.

The table below maps specific capabilities to the sub-clauses that auditors verify.

Standard / Regulation	Clause	How This Module Addresses It
ISO 9001:2015	§7.5.2	Creating and updating — identification, format, review, and approval for suitability and adequacy.
ISO 9001:2015	§7.5.3	Control of documented information — availability, suitability for use, protection, distribution, access, retrieval, storage, preservation, and control of changes.
ISO 45001:2018	§7.5 & 7.3	Documented information control plus awareness requirements — workers must be aware of relevant documented information.
21 CFR Part 11	§11.10	Controls for closed systems: access controls, audit trails (view/download log), authority checks (approval chains), and exact copies of records.
ISO/IEC 17025:2017	§8.3	Control of management system documents — approval, review, identification, distribution, and prevention of unintended use of obsolete documents.
GMP Annex 11	Principles	Electronic records replacing paper — audit trails, access controls, and version management that ensure data integrity.

Why CompliHub

A shared drive with naming conventions is not document control. CompliHub DMS is a workflow that ensures every document is approved before use, distributed to the right people, acknowledged by them, and reviewed before it grows stale.

Lifecycle, Not File Store

Draft → approve → publish → distribute → acknowledge → review. A workflow that enforces the standard's requirements, not a folder that hopes they happen.

Acknowledgement Tracking

Distribution is not complete when the email is sent. It is complete when every holder has acknowledged receipt. The system tracks and chases.

MDR as a Live View

The Master Document Register is never compiled — it is always current because it reads from the workflow database, not from a crawl of the file system.

Immutable Approved Revisions

An approved revision cannot be edited. It can only be superseded by a new draft that passes through approval again. This is what 'control of changes' means.

Access and Download Logs

Every view, download, and print is logged. For 21 CFR Part 11 environments, this is the audit trail that proves a document was available and accessed.

Works Standalone

No other module required. The DMS controls procedures, policies, and forms for any management system — add more CompliHub modules as the organisation matures.

When Combined with Other CompliHub Modules

- **+ Audit & CAPA:** A finding that requires a procedure change links to the document revision workflow. The finding stays open until the new revision is approved.
- **+ ISO Governance:** Management system policies, the quality manual, and the context document are controlled through the DMS with the same approval and review lifecycle.
- **+ Permit to Work:** Permit forms and named check sheets are controlled documents. The permit system always uses the current effective version.
- **+ Training:** Training on a new procedure revision is triggered automatically. The training record links to the document version that was trained on.

See It in Action

Thirty minutes on your worst workflow. We show one complete process end to end, on your terms.

Book a Demo

We walk through your specific use case — your forms, your approval chains, your pain points — in a live session on the actual product.

No slides. No generic walkthrough. Your workflow, your data shape, your approval matrix.

Typical Implementation

Typical go-live in 2–3 weeks. Week 1: category structure, approval chains, review intervals, metadata fields. Week 2: bulk import of existing documents (as approved versions with historical metadata). Week 3: distribution lists, acknowledgement rollout, training, cutover from shared drive.

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