

COMPLIHUB

Audit & CAPA

Plan, conduct and report internal audits, track every finding from raising to verified closure, and manage corrective and preventive action from any source — not only audits, but incidents, customer complaints, management reviews, and regulatory observations.

Annual audit programme

Checklists with evidence

Five-severity findings

Root cause analysis

Effectiveness verification

Multi-source CAPA cases

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

● Executive Summary

CompliHub Audit & CAPA covers the two processes that every management system standard requires and every certification audit examines: the internal audit programme (ISO 9001 §9.2, ISO 14001 §9.2, ISO 45001 §9.2) and the corrective action process (ISO 9001 §10.2).

The module replaces the audit schedule spreadsheet, the finding tracker in Excel, the CAPA log maintained by email, and the effectiveness checks that nobody follows up on. It does this by connecting the programme to the audits, the audits to the findings, the findings to the actions, and the actions to the effectiveness verification — as one workflow, not four disconnected artefacts.

The result is a system where nothing falls through the cracks: every finding has an owner, a due date, a root cause, a corrective action, and a verified outcome. When the certification body asks 'show me your last three audit cycles and prove the corrective actions were effective,' the answer is three clicks, not three weeks of archaeology.

100%

Findings with assigned owners

Zero

Overdue effectiveness checks

< 1min

Time to produce audit report

Any

Source can raise a CAPA case

● The Problem

Internal audit and corrective action are the two clauses that certification bodies examine most closely — and the two that organisations most commonly manage in disconnected tools. The typical state:

The audit programme is a spreadsheet. It says which departments will be audited when, but it does not generate the audits, track their execution, or report completion. The audit itself is conducted on paper checklists or a Word template, and the report is emailed to management. Findings are logged in a separate Excel file. Corrective actions are assigned by email. Effectiveness verification is a calendar reminder that someone dismisses.

The consequence is a trail of open findings that age without visibility, corrective actions that are declared closed without verification, and an audit programme that looks complete on paper but has no traceable connection to the actual audits conducted. Certification auditors see through this immediately.

Programme and Audits are Disconnected

The annual plan exists in one file; actual audits exist in another. Nobody can prove that the programme was executed as planned.

Findings Age Without Visibility

Open findings live in a spreadsheet. There are no escalations, no aging reports, no dashboards. Leadership sees the problem only when the CB arrives.

Root Cause is Skipped

The pressure to close findings fast means root cause analysis is a single sentence, if it exists at all. The same finding recurs next cycle.

Effectiveness is Not Verified

A corrective action is marked 'closed' when the action is done, not when it is proven to have worked. ISO 9001 §10.2.1(f) requires this proof.

CAPA From Other Sources Gets Lost

A customer complaint, a regulatory observation, a management review action — all need CAPA treatment, but none of them feed into the same tracker.

Reports Compiled Manually

The audit report is a Word document assembled from notes. The management review input on audit results is compiled from fragments by the MR owner.

● The CompliHub Solution

CompliHub Audit & CAPA connects the four stages that standards require into a single traceable workflow: **programme → audit → finding → action → verification**.

Audit Programme. An annual programme is created with approval, covering the standards, clauses, departments, and frequencies in scope. Each entry expands into recurring audits at the defined interval. The programme shows completion status in real time — not as a year-end exercise.

Audits. Each audit is generated from the programme (or raised ad hoc). It carries the scope, the team, the checklist, and the schedule. Evidence is attached against checklist items. The report is generated from the recorded results, not written from memory afterwards.

Findings. Findings are raised during the audit with a severity (major NC, minor NC, observation, opportunity for improvement, positive practice). Each finding has an owner, a department, a due date, and a required root-cause analysis. The aging report shows every open finding ranked by age — the single most useful view for management.

Root cause and corrective action. The finding workflow requires a root cause analysis before corrective actions can be planned. Actions have their own owners and due dates. The finding is not closable until all actions are complete and an effectiveness check is recorded.

Effectiveness verification. A separate step, performed by someone other than the action owner, after a defined elapsed period. The question is not ‘was the action done?’ but ‘did it work?’ Until this step is completed and approved, the finding remains open.

CAPA Cases (standalone). Not every corrective action comes from an audit. Customer complaints, incident investigations, regulatory observations, management review actions, supplier failures — all can raise a CAPA case that follows the same root-cause → action → verification workflow. The CAPA register is the single source of truth for improvement actions from any source.

Reports and management review input. The audit report is auto-generated from the audit record. The management review input on audit results (ISO 9001 §9.3.2 c) is a pre-built report that shows programme completion, finding trends, aging, and closure rates — ready for the MR agenda without manual compilation.

● Detailed Feature Breakdown

Audits

Plan, conduct and report internal audits against the standards and clauses in scope.

ISO 9001 §9.2; ISO 19011

- Scheduling and team roles
- Checklists and evidence
- Department and location tagging
- Report workflow
- Report download log

Audit Programme

Agree the year's audit programme up front and generate each audit from it automatically.

ISO 9001 §9.2.2 a); ISO 19011 §5

- Annual plan with approval
- Recurring entries expanded per interval
- Standard and clause coverage
- Lead-time automatic audit generation

Findings

Track every nonconformity and observation from raising to verified closure, with root cause and corrective action.

ISO 9001 §10.2

- Five severities
- Assignment and due dates
- Root cause analysis
- CAPA actions
- Effectiveness verification
- Aging report

CAPA Cases

Manage corrective and preventive action arising from any source, not only audits.

ISO 9001 §10.2

- Standalone triage
- Investigation team
- RCA
- Plan and actions
- Effectiveness check
- Closure

● Standards & Compliance Coverage

Internal audit and corrective action are explicit requirements in every management system standard — ISO 9001, ISO 14001, ISO 45001, IATF 16949, and ISO/IEC 17025. The clauses are almost identical across standards, and CompliHub satisfies all of them with a single process.

The table below maps the module's capabilities to the specific sub-clauses that certification auditors examine.

Standard / Regulation	Clause	How This Module Addresses It
ISO 9001:2015	§9.2.1	The audit programme with planned intervals, methods, responsibilities, and reporting requirements.
ISO 9001:2015	§9.2.2 a–f	Each audit: scope, criteria, auditor selection, objectivity, reporting to management, and corrective action without undue delay.
ISO 9001:2015	§10.2.1 a–f	Nonconformity reaction, root cause determination, action implementation, effectiveness review, and risk/opportunity update.
ISO 14001:2015	§9.2 & 10.2	Identical audit and corrective action requirements for the environmental management system.
ISO 45001:2018	§9.2 & 10.2	Identical requirements for the OH&S management system, with additional emphasis on worker participation in audit planning.
ISO 19011:2018	Clauses 5–6	Audit programme management and audit activity execution guidance — the module's workflow follows 19011's structure.
IATF 16949:2016	§9.2.2.1–4	QMS audit, manufacturing process audit, product audit, and second-party audit planning within the same programme.

● Why CompliHub

Every IMS suite has an audit module. CompliHub's difference is traceability: you can start at the programme and follow one thread to the finding, to the action, to the verification — and prove it to an auditor in under a minute.

Programme-to-Verification Traceability

One unbroken chain: programme entry → audit → finding → root cause → action → effectiveness verification. No gaps, no disconnected spreadsheets.

Multi-Source CAPA

CAPA cases from audits, incidents, complaints, regulatory observations, and management reviews — all in one register with the same workflow.

Effectiveness as a Gate

A finding cannot be closed until effectiveness is verified by someone other than the action owner. This is what ISO 10.2.1(f) actually requires.

Aging Report

Open findings ranked by age. The single most useful view for management and the one certification auditors look at first.

Auto-Generated Reports

The audit report and the management review input on audit results are produced from recorded data, not compiled from memory in Word.

Works Standalone

No other module required. Add Incident Management, Document Control, or Quality Operations to feed more sources into the CAPA register.

When Combined with Other CompliHub Modules

- **+ Incident Management:** An incident investigation that identifies a systemic cause raises a CAPA case automatically. The investigation is the source evidence.
- **+ Document Control:** A finding that requires a procedure change links to the document revision workflow. The action is not 'done' until the new revision is approved.
- **+ Quality Operations:** Nonconforming output dispositions, supplier evaluation failures, and customer complaints all raise CAPA cases that feed the same register.
- **+ ISO Governance:** Management review actions and risk treatment actions follow the CAPA workflow, ensuring they receive the same root-cause rigour and effectiveness verification.

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: audit programme entry, standard/clause scope, auditor pool, finding severity definitions. Week 2: CAPA workflow configuration, effectiveness verification rules, report templates. Week 3: import of open findings from the current tracker, training, cutover.

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