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WHITE PAPER
2026 EDITION

COMPLIHUB

One system of record. One audit trail. Every standard you are held to.

How a multi-site manufacturer builds ISO 9001, ISO 14001 and ISO 45001 conformity, statutory occupational-safety compliance and a defensible 21 CFR Part 11 position on a single platform — and what that is worth in audit days, closure times and avoided findings.

ISO 9001:2015 ISO 14001:2015 ISO 45001:2018
ISO/IEC 17025:2017 21 CFR Part 11 Factories Act 1948
OSH Code 2020 29 CFR 1904 / 1910 PSM ISO 19011:2018

Prepared for evaluation committees, QA/EHS leadership and IT. · Coverage statements in this paper are traceable to the product's own clause-by-clause mapping documents.

Contents

HOW TO READ THIS DOCUMENT

This white paper distinguishes three things that vendors routinely blur. **Covered** means the application holds the record a clause requires, with the workflow and the evidence an auditor expects to see attached to it. **Partial** means some of it is there, and the text says exactly what is not. **Procedural** means the requirement is a written policy, an identity check or a letter to a regulator — something no software will ever discharge for you.

"Covered" never means "you are compliant". Certification and accreditation are granted to an organisation, never to its software. Any vendor who tells you otherwise is selling you a finding at your next surveillance audit. Every coverage statement in this paper is traceable to the product's own clause-by-clause mapping documents, which are maintained as working gap analyses against the current code and are available to your evaluation team on request — including the sections where they say we fall short.

A Appendix — clause-to-module index

A one-page reference for your certification body.

SECTION 1

Executive summary

Most manufacturers do not fail audits because they are careless. They fail because the evidence that they were careful lives in eleven different places — a spreadsheet of findings, a shared drive of signed PDFs, a WhatsApp group where the permit was actually approved, a training register in HR's system, and a CAPA tracker maintained by one person who is on leave the week the auditor arrives. The work was done. Proving it was done, in the order it was supposed to be done, by people authorised to do it, is a separate project — and it is the project that consumes the fortnight before every audit.

The CompliHub closes that gap by making evidence a by-product of doing the work rather than an activity that follows it. Forty-five workflow modules — audits, findings, CAPA, controlled documents, objectives, management review, risk, compliance obligations, incidents, management of change, HAZOP, PSSR, permit to work, occupational health, exposure monitoring, PPE, the statutory registers a labour inspector opens first, the consents, waste log and annual returns a pollution control board asks for, behavioural safety, emergency preparedness, batch manufacturing records, recall and the rest — run on one authorisation model, one approval engine, one notification pipeline and one audit trail. A finding raised from an audit checklist, an unsafe act observed on the shop floor and a corrective action arising from an incident are the same workflow in the same place, not three systems reconciled by hand at quarter end.

45	17	10/14	1
WORKFLOW MODULES, INDEPENDENTLY LICENSABLE	FRAMEWORKS MAPPED CLAUSE BY CLAUSE	OSHA PSM ELEMENTS COVERED	AUDIT TRAIL ACROSS EVERY MODULE

What this paper argues

One. Compliance is an evidence-architecture problem, not a document problem. Section 3 sets out the five properties every auditable record must have — attributable, sequenced, meaningful, protected, retrievable — and shows that a certification auditor, a factory inspector and an FDA investigator are asking for the same five things in three vocabularies. A system that gets the architecture right satisfies all three audiences at once. A system that treats each standard as a separate module set satisfies none of them without duplication.

Two. The architecture is the product. Section 4 describes the specific engineering decisions — approvals that refuse to run out of order, records that become immutable on approval, state changes that are transactional services rather than silent callbacks, a site boundary enforced in exactly one place and regression-tested — that cause the evidence to exist. These are not features on a comparison grid. They are the reason the evidence is trustworthy when someone finally reads it.

Three. Honesty about scope is a commercial advantage, not a weakness. Sections 6 to 10 state, without softening, what the system does not do: ISO 9001 §8.2 contract review, ISO 45001 §8.1.4 contractor pre-qualification, statutory registers and working-hours records, workplace exposure monitoring, the ISO 17025 laboratory itself, and — most consequentially for regulated life sciences — the fact that the 21 CFR Part 11 position is *strong in its foundations and incomplete in its package*. You will find every one of those gaps in our own internal documents. You would otherwise find them in month four of your implementation.

Four. The economics work at the second site. A single plant buys a better way of running its management system. A group with a corporate HSE function buys something no amount of local diligence produces: one definition of a major

nonconformity, one aging clock on corrective actions, and a corporate view that drills into any plant without that plant maintaining a parallel report for head office. Section 11 gives the cost model, with the inputs left blank for your own figures rather than filled with someone else's.

THE ONE-SENTENCE VERSION

If your management system is real but your evidence of it is scattered, this platform converts the second problem into a by-product of solving the first — across quality, environment, occupational health and safety, process safety, the pollution control board's consents and returns, and — with the qualifications stated in Section 9 — the FDA's electronic-records expectations.

SECTION 2

Why compliance fails in well-run plants

Four failure modes account for most of what surveillance audits actually write up. None of them is a failure of intent, and none is solved by trying harder.

Failure mode 1 — Parallel systems that must agree

The audit team keeps findings in a spreadsheet. The safety department keeps incidents in a different one. The document controller keeps a register of SOPs in a third, and the actual files on a shared drive. HR owns training. Maintenance owns calibration. Each register is competently maintained; the problem is that a single corrective action arising from an incident, strengthening an SOP and requiring retraining now exists in four of them, with four owners, four status fields and no mechanism that makes them agree. The reconciliation is manual, so it happens once a quarter at best — which means that for most of the year, at least one of the four is wrong, and nobody knows which.

What the auditor sees: a corrective action closed in the CAPA tracker whose underlying document revision was never issued. That is an ISO 9001 §10.2 nonconformity written against a company that did the work.

Failure mode 2 — Evidence reconstructed, not recorded

The permit was approved. The approval happened at 06:40 by phone, because the authorised signatory was in the control room and the form was at the gate. The signature was added later, in good faith, and dated to the time of the call. Every part of that sequence is normal, and none of it is defensible when an investigator asks how the authorisation is evidenced. The same pattern appears with back-dated toolbox talks, training attendance sheets signed in a batch, and minutes typed up from memory a week after the meeting.

What the auditor sees: records that are complete but not contemporaneous — the second letter of ALCOA+, and the observation that most often escalates from a note to a finding, because it puts every other record in the file into question.

Failure mode 3 — Authority that is assumed rather than enforced

Who may approve a hot-work permit on night shift? Who may close a major nonconformity? Who may release nonconforming product on concession? In most plants these are answered by an organogram in a manual and by the good sense of the people involved — which works until the person who normally decides is on leave, and a well-meaning deputy signs. Where the system of record is a spreadsheet or a PDF, there is nothing that could have refused.

What the auditor sees: a signature from someone outside the authority matrix, or — more commonly and more damagingly — the same person raising, investigating and closing the same nonconformity. Segregation of duties is not a policy question if the software will happily let one person do all three.

Failure mode 4 — Records without meaning

A row in a database says **approved_by: 4471** and **approved_at: 2026-03-14.** It does not say what user 4471 believed they were attesting to, whether they were reviewing the technical content or accepting responsibility for its release, what the record said at the moment they approved it, or what happened to it afterwards. Three years later, user 4471 has changed their name, moved departments, or left.

What the auditor sees: an approval that cannot be interrogated. For an FDA-regulated site this is a direct §11.50(a)(3) failure — the meaning of a signature is a regulatory requirement, not a nicety.

What the four cost

The visible cost is the fortnight before each audit: pulling files, chasing signatures, rebuilding a trail that should have been a by-product. The larger costs are quieter.

- **Findings that recur.** When corrective actions close on a date rather than on verified effectiveness, the same nonconformity returns at the next audit — and a repeat finding is judged far more harshly than a first one.
- **Aging that nobody owns.** Actions overdue by ninety days are invisible in a spreadsheet with no reminder engine. They become visible when an auditor sorts by due date.
- **Certification risk concentrated in individuals.** If one person can rebuild the evidence and nobody else can, the management system is that person, not a system.
- **Group-level blindness.** A corporate HSE head with five plants and five spreadsheets has five definitions of “closed”, and cannot compare plants without first normalising them by hand.

> **THE COMMON CAUSE**
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> All four failures share one root: **the record of the work is created separately from the work**. Every remedy in this paper follows from inverting that — the approval *is* the workflow step, the signature *is* the transition, the audit trail *is* written by the same transaction that changed the record. There is no second activity to forget, defer, or reconstruct.

SECTION 3

What an auditor, an inspector and an investigator actually ask for

A certification body auditing ISO 45001, a factory inspector under the Factories Act, and an FDA investigator applying 21 CFR Part 11 use three vocabularies and ask for the same five properties. Recognising that is what makes a single platform possible.

Property	The question behind it	Stated as	How the platform satisfies it
Attributable	Who did this, and were they entitled to?	ISO 19011 objective evidence · ALCOA+ “A” · 21 CFR §11.10(d), §11.50(a)(1)	Every record carries its actor. Approvals snapshot the signer's name and title at signing time, so a later rename cannot rewrite history. Authorisation is checked in the controller, the query, the export and the admin console — not by hiding a button.
Sequenced	Did the steps happen in the order the procedure requires?	ISO 9001 §8.5.1 · OSHA 1910.119(i) · 21 CFR §11.10(f)	State transitions are transactional services with explicit guards. An approval at step 3 is refused while step 2 is pending. A permit cannot be issued while a gas test is outside limits. A major nonconformity cannot close without an approved root cause and an approved CAPA.
Meaningful	What did the signer believe they were attesting to?	ISO 9001 §7.5.3 · 21 CFR §11.50(a)(3)	For regulated records, the signature carries one of five declared meanings — authorship, review, approval, verification, responsibility — resolved per model and per stage, rendered as a declaration and frozen onto the record at signing.
Protected	Could this have been changed after the fact without trace?	ISO 9001 §7.5.3.2 · ALCOA+ “O” · 21 CFR §11.10(c), §11.10(e)	Approved and effective document revisions are immutable — a change is a new revision, never an edit. Version history records prior values rather than overwriting them. Controlled records are archived, not deleted.
Retrievable	Can you produce it now, completely, while I am sitting here?	ISO 9001 §7.5.3.1 · Factories Act inspection · 21 CFR §11.10(b)	Every list is searchable, filterable, sortable, paginated and exportable to CSV. Audits, HAZOP studies, permits, medical registers and controlled

Property	The question behind it	Stated as	How the platform satisfies it
			documents render as printable PDFs with their approval history embedded.

THE SAME PREMISE, BUILT INTO THE PRODUCT

Because these three audiences ask the same five things in three vocabularies, the application ships a screen that says so out loud. **Audit Readiness** is organised by *visitor* rather than by clause — a factory inspector, an ISO auditor, an OSHA compliance officer, a NABL assessor, a GMP or food safety auditor, a Part 11 assessor — and under each one it lists the questions they typically ask, in their own words, with the screen that answers each and a statement of what that screen proves. Each answer links directly to the record; the whole thing filters by framework or by gap and exports as a list.

Fifty-three questions ship configured: **thirty-nine** the system answers outright, **six** it answers with a stated caveat, and **eight** it declares as gaps and tells you what to bring instead. Every one of those eight is declared somewhere in this paper as well — six in Section 10's list, the annual return in Section 7 and the validation package in Section 9 — so the screen your team uses and the document your evaluation committee reads name the same shortfalls. It marks them in the same colour scheme too, and for the same reason: the worst moment in an audit is discovering a gap while somebody is waiting for the answer. An automated check in the codebase fails the build if a partial or missing item is listed without an explanation of what to show instead — so the page cannot quietly drift into overstating coverage between releases.

Why one platform rather than three

The temptation, when a company holds three certifications and answers to two regulators, is to buy or build three systems — a QMS tool, an EHS tool and a compliance tool. The argument against it is not licence cost. It is that **the same underlying record is in scope for all three**, and three systems produce three versions of it.

A worked example. A chemical release from a pump seal is, simultaneously: an **incident** under ISO 45001 §10.2, an **environmental event** under ISO 14001 §8.2, a potentially **reportable occurrence** to the State Pollution Control Board and the Chief Inspector of Factories, a **process safety event** to be tiered under the plant's own PSM programme, the trigger for a **corrective action** that will amend a maintenance SOP, and — because it amends an SOP — a **controlled document revision** requiring approval and re-acknowledgement by everyone who works to it. In three systems that is one event entered three times, with three reference numbers, and a manual undertaking to keep them aligned. Here it is one incident record with one investigation, one root cause, one corrective action, and one document revision linked to all of it — and the ISO 14001 auditor, the ISO 45001 auditor and the inspector are each shown the same trail from their own angle.

THE INTEGRATION TEST WORTH APPLYING TO ANY VENDOR

Ask them to demonstrate, live: raise a finding *from* an audit checklist item; raise a second finding *from* an environmental aspect review; raise a third *from* a supplier evaluation — and then show all three in one aging report, with one definition of overdue, one escalation path and one closure rule. A suite that is genuinely integrated does this in four clicks. A suite that is three products behind one login cannot do it at all.

SECTION 4

The design decisions that make evidence a by-product

This section is written for the technical and QA members of an evaluation committee. It describes seven architectural decisions that are the reason the evidence exists and can be trusted — the things that are expensive to retrofit and impossible to see in a demonstration.

1 — One authorisation model, enforced everywhere

Permissions are defined once, per role, and enforced in the controller, in every database query, in every view, in every CSV export, in every background job and in the administration console. There is no screen that renders a record its viewer is not entitled to, and no export that widens what a person can see. Hiding a button is not authorisation, and the system does not treat it as such.

Roles ship as a working set — system administrator, IMS administrator, top management, audit manager, auditor, department head, document controller, approver, employee, viewer, and corporate safety roles — and a user may hold several. Document visibility carries its own access level, so a controlled procedure can be published to a department without being published to the plant.

2 — A multi-site boundary that is structural, not conventional

One deployment serves one organisation, which may run a corporate office and any number of plants. Every operational record belongs to exactly one site. A plant sees its own records; corporate sees all of them and can drill into one at a time through a site switcher that only ever narrows what is visible, re-validated on every request so a stale or tampered selection is ignored rather than honoured.

The boundary is applied in exactly one place in the code, after every permission has been granted, across a registry of every operational model. It is the single deliberate restriction in a permission system where everything else only ever widens — because tenancy has to intersect, not add. A regression test fails the build if a new module is added without joining the registry. Two deliberate exceptions exist and are configurable: a corporate-issued policy document readable at every plant, and a corporate-led audit that spans sites.

Why it matters commercially: a group can roll out plant by plant without each plant's data becoming visible to the others, and without a separate installation, a separate database or a separate upgrade cycle per site.

3 — One approval engine, used by everything

Root cause analyses, CAPA plans, document revisions, management review minutes, change requests, permits and design projects all route through the same ordered approval engine. It has three properties that matter to an auditor:

- **It refuses out-of-order decisions.** A step that is not the current pending step cannot be actioned — a textbook operational system check.
- **It refuses self-approval.** The submitter of a record cannot approve it, enforced in the service rather than in the interface.
- **It refuses to guess.** Where an authority matrix is not configured for a given permit type and shift, the system declines to route the approval rather than silently approving or picking a default. A system that degrades gracefully in the wrong direction is worse than one that stops.

A rejection is signed with withheld wording and recorded as a decision, not treated as a non-event — because the fact that a named person declined to approve something on a particular date is frequently the most important record in the file.

4 — Transitions are services, not callbacks

Every state change — issue a permit, publish a document revision, close a finding, verify a CAPA — is an explicit transactional service with guards, run inside a database transaction, with notifications sent only after it commits. The system deliberately does not use hidden model callbacks to change status or send mail. The practical consequence: a state change either happens completely or not at all, the reason a refusal happened is a stated error rather than a silent no-op, and no future developer can bypass a guard by writing a new caller.

5 — Approved records are immutable; nothing is quietly deleted

An approved document revision cannot be edited. A correction is a new revision, sequentially approved, with the whole history retained and readable. Submitted, approved, effective and historical records are archived rather than hard-deleted. This is what allows the system to show an auditor not only the current SOP but the revision that was effective on the date of the incident being investigated — which is the version that actually matters.

6 — One audit trail, written by the transaction

Record versioning runs across the model set with the acting user attached, storing prior values rather than overwriting them, so a change never obscures what was there before. Downloads of controlled copies, audit reports and permits are logged separately, because for a controlled document the question “who took a copy of this, and when” is itself a control.

7 — Configuration by your administrators, not customisation by ours

Permit forms, approval matrices, check sheets, audit checklist templates, MOC checklists, risk matrices, email templates and examination protocols are all built and edited from inside the application by your own administrators. Crucially, these configurations are **versioned**: a permit already issued always shows the form version it was issued against, and a training assessment score is frozen at submission, so editing the question paper next year cannot retroactively move a result recorded last year.

> **THE TEST OF AN EVIDENCE SYSTEM**
>
> Not “can it store the record?” — every system can. The test is: **can the record be shown to be the record it was at the time it mattered?** Immutability on approval, versioned configuration, frozen signature declarations and prior-value version history are four independent answers to that one question.

SECTION 5

The module map

Forty-five workflow modules, each independently licensable and switchable, all sharing the same authorisation, approval, notification and audit-trail infrastructure. A module that is off is hidden from the sidebar and blocked at the controller for every user — not merely unlinked.

Domain	Module	What it holds and enforces
Audit & improvement	**Audit Programme**	The year's programme with period, owner and approved schedule; frequency expands into dated audits; coverage percentage; a programme cannot close while a planned audit is neither opened nor cancelled with a reason.
	Audits	Schedule, team roles (lead auditor, auditors, lead auditee, auditees, observers), checklists, evidence, report workflow and approval; findings raised directly from checklist items.
	Findings	Open points, observations, OFIs, minor and major nonconformities; owner, due date, comments, attachments, RCA, CAPA, effectiveness verification, closure, aging and reminders.
	CAPA Cases	Corrective and preventive action arising from any source, not only audits: scope, team, containment, root cause, plan, actions, effectiveness check.
Governance	**Controlled Documents**	Metadata, uploaded versions, sequential approvals, effective version, immutable approved revisions, controlled distribution and acknowledgement, review dates, master and control copy PDFs with download logging, and Read & Understood assessments pinned to one revision.
	Management Reviews	Schedule, participants, the consolidated sixteen-point quality/environment/OH&S agenda, minutes, decisions, approval, and action items with owners, due dates and overdue status.
	Quality Objectives	Multiple objectives per department, multiple assignees, target, comparator and frequency, periodic actual results with evidence, review and achievement calculation.
	Context & Interested Parties	Internal and external issues; parties, needs, expectations, compliance relevance, owner and review date.
Risk & compliance	**Risks & Opportunities**	One register across quality, environment and OH&S; scored on a configurable matrix, with treatment actions and periodic review history.
	Compliance Obligations	Your own statutory and regulatory register with owner and evaluation frequency; a noncompliant evaluation raises a finding through the same path as everything else.
	Environmental Aspects	Likelihood × severity scoring, computed significance with justified override, control measures and periodic review.
Process safety	**Permit to Work**	Versioned permit form builder, permit types clubbed onto one permit, approver-level matrix escalating by shift, named check sheets snapshotted onto each permit, gas tests with limits that block issue, renewal as re-approval, contractor crew with gate-

Domain	Module	What it holds and enforces
		pass checking, four-signature closure with fire watch, permit board and print log.
	Management of Change	Impact and risk assessment, checklists, approvals, implementation events, and closure that requires verification.
	HAZOP	Nodes with design intent, guide words and process parameters, deviations with causes, consequences, safeguards and scoring, recommendations with owners; closure refused while any deviation has an open action.
	PSSR	Pre-startup review checklists with an authorisation gate that refuses on an outstanding “No”.
	Incidents	Incidents, near misses, dangerous occurrences and complaints; investigation with team, process safety event tiering, chemical release detail, statutory notification tracking and medical forms.
Occupational health	**Employee Health Records**	Medical master, OPD visits, pre-employment and periodic examinations with structured test results, fitness certificates, vaccination tracking with batch and expiry, and a printable statutory examination register.
	Health Surveillance	Hazard-based programmes with their own examination clocks, dated exposure enrolment, exposure history and test-result trends.
	First Aid & Pharmacy	First aid case register with response time and hospital referral, first aid box register with periodic inspections, and batch-tracked medicine inventory.
	Contractor Clearance	Per-firm worker roster, dated medical clearances with printable certificates, revocation, and a computed gate-pass status with expiry reminders.
	Workplace Exposure Monitoring	Permissible exposure limits with their statutory citation; personal and area sampling with duration, method and instrument; a verdict computed against the limit in force when the sample was taken and stored on the sample; a mandatory major nonconformity on an exceedance; and automatic enrolment of the over-exposed worker into health surveillance.
	PPE & Respiratory Protection	Hazard assessment certified with all four fields 1910.132(d)(2) requires, enforced by a database constraint; issue and return per named person; and respirator fit testing with the annual clock and the minimum fit factor enforced, a failure withdrawing that respirator from its wearer.
Statutory compliance	**Statutory Registers & Formats**	Statutory appointments with the notice to the Chief Inspector tracked separately from the qualification; hazardous areas covering confined spaces, classified areas and energy isolation points, where reclassifying a space demands a written basis; and a form designer in which your compliance team defines a prescribed register's number, citation and columns and prints it from live data — each format marked unverified until checked against the published Rules.
	Workplace Inspections	Versioned inspection forms immutable once published, the Factories Act standard question set added in one action, inspection rounds per area with their own frequency where a

Domain	Module	What it holds and enforces
		never-inspected area counts as overdue, and a nonconformity raised automatically on a critical item answered “No”.
	Shift Roster	A week board rostering crews onto shifts, from which the §62 register of adult workers and the §61 notice of periods of work both print; the four hours limits computed against every row and shown, recorded rather than refused; and a resolved answer to who is actually on duty at a given moment, which the medical notification list and permit escalation both now use.
	Chemical Register & SDS	GHS classification, signal word, hazard and precautionary statements, incompatibilities and the safety data sheet, readable by every signed-in user because the statute requires the information to reach the worker; inventory by location against a licensed maximum; the MSIHC threshold determination summed per site; and statutory notification clocks derived from an incident's own injury classifications, chased hourly.
Pollution control board	**Consents, Clearances & the Board**	The consent or combined CAC/CC&A recorded once whatever regimes it carries, with every consented quantity and prescribed limit as a condition; the numbered narrative conditions as tracked obligations where “never evaluated” is reported separately from “compliant”; the application that produced the consent, with its fees, the board's query and the decision; directions and show-cause notices with the deadline they set and the earliest reminder in the system; board inspections whose observations become findings; environmental clearance with its approved-capacity check; and the public liability policy with its Environment Relief Fund contribution.
	Waste Management	The Schedule I catalogue keyed by category code, and a dated movement log covering generation, dispatch, in-house use, landfill, incineration and the operator and recycler movements — with the Form 10 manifest lifecycle tracked to the copies that come back, storage aged against the permitted period, and the receiving facility's authorisation checked on the day the waste left.
	Resource & Utility Consumption	Water by process, cooling and domestic; effluent; fuel, raw material and power; production and by-product — recorded by period, matched to the consent condition each is measured against, and divided into the per-unit-of-product ratios the environmental statement asks for rather than having them typed.
	Statutory Environmental Returns	MPCB Form IV and Form V as versioned formats whose fixed cells are configuration, derived from the four registers above; an override that keeps the derived figure beside the declared one and demands a reason; filing as a permission separate from preparing; immutability once filed; a portal-ordered export for keying; and filing reminders driven from the formats, so a return nobody raised still appears.
Behaviour & participation	**Safety Observations & BBS**	Versioned observation checklists, contributing factors, actions that force an explicit hierarchy-of-controls choice, and coverage and trend reporting that always states its denominator.
	Worker Participation	Hazard reports, suggestions, safety-committee input and risk-assessment involvement — the ISO 45001 §5.4 clause auditors most often find unsupported.

Domain	Module	What it holds and enforces
	Safety Meetings	Toolbox talks and safety committee meetings with participants and action items that survive the meeting.
	Award & Reward	Formal recognition with a nomination and approval trail.
Quality operations	**Nonconforming Output**	Detection stage, containment, disposition with mandatory approval for “use as is”, verification and closure.
	Design & Development	Inputs, outputs, review, verification, validation and approval; a design change routes through Management of Change rather than a parallel mechanism.
	Suppliers	Approval status, risk rating and periodic evaluation; a poor result can raise a finding.
	Customer Satisfaction	Survey, direct feedback, repeat business, complaint and warranty-claim log with satisfaction trends.
GMP manufacturing	**Materials & Lots**	One master covering raw material through finished product, with shelf life, retest period, storage and hazard attributes; goods receipt with transport condition; and a lot register where quarantine, release, rejection and hold are quality-unit decisions under electronic signature, enforced where material is issued rather than on a label.
	Batch Manufacturing Records	A structured, versioned Master Batch Record — bill of materials, process steps, enforceable in-process limits, yield range — independently checked by the quality unit and immutable once effective; batch execution with first-expiry-first dispensing, lot genealogy, second-person checks the database itself enforces, blocking limits and yield reconciliation; quality-unit review and release under signature; and the printable batch record an inspector asks for by name.
	Deviations & Recall	Deviations that name the batch, step or lot they departed from, carry the quality unit's batch-impact determination, escalate their systemic half into the existing CAPA engine, and block release until dispositioned. Recall, market action and *timed mock recall* resolving affected lots by walking the genealogy chain and building the consignee list from despatch records.
Resources & access	**Competency & Training**	Competency master with renewal periods, sessions, validated attendance, optional assessments with frozen scores, auto-issued certificates, expiring-competence dashboard, gaps report — and role assignment blocked where a required competency is not held.
	Assets	Monitoring and measuring equipment with calibration and maintenance history and overdue visibility.
	Visitor Management & Emergency	Visitor approval levels, configurable fields, pass design with QR, induction; emergency scenarios, response teams, drills with timings and effectiveness, and plan reviews.

Modules are licensed individually or in packs and editions. Every module inherits search, filter, sort, pagination, CSV export, comments, attachments, notifications, reminders and audit history without being built again — which is why adding a module to an existing deployment is a configuration exercise rather than a project.

Two screens sit in the platform base rather than in any pack, because they read *across* modules and are worth more with each one added: the **compliance dashboard**, which resolves ten weighted dimensions into a score per site, ranks what would move it, and reports register gaps

between sites; and **audit readiness**, which lists what each kind of inspector asks and the screen that answers it. A dimension whose module is switched off drops out of the weighting rather than scoring zero — so the score never penalises a site for something it has not licensed.

SECTION 6

ISO 9001, ISO 14001 and ISO 45001 — clause by clause

This is the framework family the platform was designed around, and coverage is close to complete. The tables below are condensed from the product's maintained clause mapping; the declared gaps are stated at the end of the section rather than omitted from it.

ISO 9001:2015 — Quality management

Clause	Requirement	Where it lives
4.1 / 4.2	Context; interested parties	Issue register and interested-party register with needs, expectations, owner and review date — shared across all three standards rather than duplicated per system.
4.3 / 4.4	Scope; the QMS and its processes	Organisation profile and site model, so scope can be stated and evidenced per site.
5.1–5.3	Leadership, policy, responsibilities	Roles and department heads assignable per user; management review agenda maps to the §9.3 inputs.
6.1	Risks and opportunities	Scored register with treatment actions and review history.
6.2	Quality objectives and planning	Target, comparator and frequency per departmental objective; periodic results with evidence; achievement calculation.
6.3	Planning of changes	Management of Change — impact and risk assessment, approvals, closure requiring verification.
7.1.5	Monitoring and measuring resources	Assets with calibration and maintenance records; overdue equipment is visible and cannot be marked compliant without a record.
7.2	Competence	Competence is **enforced**, not merely recorded: a blocking requirement refuses a role assignment while the person does not hold the competency; completing training confers the competencies it declares, dated and expiring on the strictest renewal period.
7.4	Communication	One notification and email pipeline across every assignment, approval and due-date event.
7.5	Documented information	Sequential approvals, effective version, immutable approved revisions, controlled distribution and acknowledgement — plus Read & Understood assessments pinned to a specific revision, so a pass is evidence about the text the person actually read.
8.1	Operational planning and control	Management of Change, PSSR and HAZOP for planned and modified operations.
8.3	Design and development	Inputs, outputs, review, verification, validation and approval; design changes route through MOC.
8.4	Externally provided processes and services	Supplier approval status, risk rating, periodic evaluation; poor results raise findings.
8.6 / 8.7	Release; control of nonconforming output	Detection stage, containment, disposition with mandatory approval for release on concession, verification and closure.

Clause	Requirement	Where it lives
9.1.1	Monitoring, measurement, analysis	Organisation and “My Work” dashboards, objective results, trend reports, CSV export, printable reports — all authorisation-scoped.
9.1.2	Customer satisfaction	Feedback, survey, complaint and warranty log with trends; a formally investigated complaint references the incident rather than duplicating it.
9.2.2 a)	Audit programme at planned intervals	The programme as a record distinct from the audits: period, owner, approved schedule, per-clause criteria and scope, coverage percentage, and frequencies that expand into dated audits on approval — so “at planned intervals” is enforced by the schedule, not by memory.
9.2	Internal audit	Schedule, execute, report, approve; team roles; findings raised from checklist items.
9.3	Management review	Sixteen standard agenda points covering the §9.3.2 inputs, with decisions and trackable actions.
10.2	Nonconformity and corrective action	Minor and major NCs require an approved root cause analysis and an approved CAPA before closure — enforced, not advisory.
10.3	Continual improvement	Recognition programme plus the management-review decision and action loop.

ISO 14001:2015 — Environmental management

Clause	Requirement	Where it lives
6.1.2	Environmental aspects and impacts	Likelihood × severity scoring with computed significance — automatically significant where a legal requirement is linked — a justified override, control measures and periodic review that can raise a finding when controls prove inadequate.
6.1.3	Compliance obligations	Shared statutory register: consents, authorisations, EPR obligations, waste rules and sector requirements each held as an obligation with owner, frequency and evidence trail.
6.2	Environmental objectives	The objective engine is not standard-specific; an environmental KPI is an objective with an environmental metric.
8.1	Operational control	Change management for planned changes with environmental impact; control measures recorded on the significant aspect itself.
8.2	Emergency preparedness and response	Scenario register with scored risk, planned response, resources, external agencies and named response team; announced and unannounced drills with response and evacuation timings and effectiveness evaluation; and the review-and-revise loop, with a plan held under review until it is actually revised.
9.1 / 9.2 / 9.3	Evaluation, internal audit, management review	Same audit engine, same programme, same review meeting — an EMS audit is an audit tagged to the relevant clauses; environmental performance is a standing agenda category.
10.2	Nonconformity and corrective action	The same findings and CAPA workflow as quality and safety.

ISO 45001:2018 — Occupational health & safety

Clause	Requirement	Where it lives
5.4	Consultation and participation of workers	A participation register — hazard reports, suggestions, safety-committee input, risk-assessment involvement — plus BBS observations as a second structured channel. This is the clause most often found unsupported, and it is a record here rather than an assertion.
6.1.2	Hazard identification and risk assessment	HAZOP for structured process hazards; the risk register for OH&S risk; BBS for behaviour and condition-level hazards.
6.1.3	Legal and other requirements	Shared compliance register — Factories Act, state rules and the OSH Code as it commences.
7.2 / 7.3	Competence and awareness	Awareness is evidenced by assessment, not assumed from attendance; BBS shows observer competency as of the observation's own date, not today's.
8.1.2	Eliminating hazards, reducing risk	BBS actions force an explicit hierarchy-of-controls choice — elimination, substitution, engineering, administrative, PPE — rather than defaulting to retraining. Permit to Work is the administrative control for non-routine work itself.
8.1.4	Contractors on site	**COVERED.** On-site work control is real: a permit names its acceptor, contractor supervisor, fire watcher, stand-by and crew, and issue is refused where roster-linked crew do not hold a valid gate pass. Pre-qualification now carries the four 1910.119(h)(2)(i) criteria with a re-qualification clock and a report naming which one is missing.
8.1	Health surveillance	Pre-employment and periodic examinations, hazard-based surveillance programmes with independent clocks, exposure history, trend analysis, fitness certificates, vaccination tracking and contractor clearance.
8.2	Emergency preparedness and response	The proactive half shared with ISO 14001; the reactive half is the incident and medical-treatment workflow plus first aid registers and kit readiness.
9.1	Monitoring and measurement	Coverage and trend reporting designed never to rank individuals or read a quiet department as a safe one — every rate states its denominator.
10.2	Incident investigation and corrective action	Investigation with team, process safety event tiering, medical workflow, and the shared findings and CAPA engine.

THE GAPS WE DECLARE IN THIS FAMILY

- **ISO 9001 §8.2 — Requirements for products and services.** There is no dedicated contract or order review module. Design & Development covers requirements for something being designed, not every order taken against an existing catalogue. Sites typically hold this in their ERP; where it is needed here, it is quotable development.
- **ISO 14001 §6.1.4 — Planning action.** Environmental aspects, compliance obligations and risks each track their own treatment actions with owners and dates. What there is no single view of is all three presented together as one environmental action plan; the registers are shown separately, or exported and combined.
- **ISO 45001 §8.1.4 — Contractor pre-qualification.** *Closed since the previous edition of this paper.* A contractor is now flagged as such and carries the four criteria 29 CFR 1910.119(h)(2)(i) names — injury and illness rates, safety programme review, insurance currency and statutory registration — with a re-qualification clock and a report that names *which* criterion is missing rather than returning a bare pass or fail. On-site control remains the permit regime and gate-pass-checked crews.

SECTION 7

Statutory occupational safety — Factories Act, OSH Code, OSHA

A statute imposes duties on an occupier, and many of them are physical: fence the machine, guard the hoist, provide the canteen. No application discharges those. What an application does is hold the register, the inspection record, the test certificate, the training evidence and the corrective action that prove the physical duty was discharged and is being maintained. Read every row below in that light.

> **ON THE OSH CODE 2020**
>
> The Occupational Safety, Health and Working Conditions Code consolidates the Factories Act 1948 with twelve other central labour laws and is commencing alongside state rules on a staggered timetable. Its substantive duties — health, safety, welfare, hazardous process controls, annual health examinations, safety committees, accident notification — carry forward, with changes to thresholds, definitions and form numbers rather than to the underlying obligations. Everything described here survives the transition; the section numbers do not. Note too that the Act itself prescribes almost none of the actual forms — the *state* Factory Rules do, and they differ, which is why registers in this system are configured rather than hard-coded.

29 CFR 1910.119 — Process Safety Management

PSM is where the platform is strongest. Ten of the fourteen elements are covered by modules built for the purpose rather than adapted to it.

Element	Requirement	Status	Module
(c)	Employee participation	COVERED	Worker participation register and safety committees
(e)	Process hazard analysis, with findings resolved and tracked to completion	COVERED	HAZOP with guide words, parameters, scored deviations and recommendations; a study cannot close while a deviation has an open action — the governance gate §1910.119(e)(5) asks for. The five-year revalidation clock is not tracked.
(f)	Operating procedures	COVERED	Controlled documents with effective versions and acknowledgement
(g)	Training, refreshed at least every three years, with the means used to verify understanding	COVERED	Training with validated attendance, optional assessment whose score is frozen at submission, certificates requiring both presence and a pass, and competency renewal periods
(h)	Contractors	PARTIAL	Gate-pass-checked crew and medical clearance; contractor injury log and pre-qualification outstanding
(i)	Pre-startup safety review	COVERED	PSSR checklists with an authorisation gate that refuses on an outstanding “No”
(j)	Mechanical integrity	PARTIAL	Asset calibration and maintenance records; inspection and testing programmes against written

Element	Requirement	Status	Module
			procedures are not modelled as a discipline of their own
(k)	Hot work permit	**COVERED**	Permit to Work, including §1910.252 fire prevention and the fire watch
(l)	Management of change	**COVERED**	MOC with impact and risk assessment, approvals and verified closure
(m)	Incident investigation	**COVERED**	Investigation with team, process safety event tiering and chemical release detail
(n)	Emergency planning and response	**COVERED**	Scenarios, response teams, drills with timings, plan reviews
(o)	Compliance audits, at least every three years	**COVERED**	Audit programme with frequency expansion, plus findings and CAPA

Factories Act 1948 — the record layer

Duty	Status	How it is evidenced
§41C — periodic medical examination of workers in hazardous processes	**COVERED**	Configurable examination frequency by hazard category driving each worker's due date, structured test protocols (spirometry, audiometry, vision, ECG, chest X-ray, laboratory), fitness certificates, two-tier reminders to the worker and the health centre, and a printable examination register calling out overdue and never-examined workers separately.
§45 — first aid appliances and the first aid register	**COVERED**	First aid case register covering employees, contractors and visitors alike with response time, ambulance and hospital referral; first aid box register with periodic inspections, an overdue report and a daily reminder.
Accident and dangerous occurrence notification	**COVERED**	Incidents with investigation, statutory medical forms and notification tracked as part of the record — deliberately configured rather than hard-coded, because state rules differ.
Safety committee and worker consultation	**COVERED**	Safety meetings with participants and action items; the worker participation register.
Contract labour medical fitness	**COVERED**	Per-firm worker roster, dated clearances with certificates, revocation and computed gate-pass status with expiry reminders.
Calibration and verification of weighing and measuring instruments	**COVERED**	Tracked as calibration records against the asset, alongside ordinary calibration.
§41F & Second Schedule — permissible limits of exposure to chemical and toxic substances	**COVERED**	An exposure limit register carrying the statutory value, averaging period and citation; personal and area sampling with duration, method and instrument; and a verdict computed against the limit *in force when the sample was taken* and stored on the sample, so revising a limit cannot retrospectively turn a past exceedance into a pass. An exceedance raises a major nonconformity without asking and enrols the worker for medical examination.
§35 — protective equipment; 29 CFR 1910.132–138	**COVERED**	A written hazard assessment carrying all four fields 1910.132(d)(2) names, with a database constraint refusing a certified assessment missing any of them; issue and return per named person; and respirator fit testing on the annual clock with the minimum fit factor enforced — a failed or revoked test withdraws that respirator from its wearer automatically.

Duty	Status	How it is evidenced
§§28, 29, 31 — examination of hoists, lifting machinery and pressure vessels by a competent person	COVERED	The examination recorded against the equipment with the competent person's name, qualification and agency, the acceptance criteria, the certificate number, and a verdict of fit, fit with conditions or unfit — on a statutory frequency separate from ordinary preventive maintenance. An overdue or unfit examination *refuses a work permit* on that equipment, which is the difference between a register and a control.
§11(2), §§17–19, §§42–48 — cleanliness, lighting, drinking water, sanitation, welfare	COVERED	Versioned inspection forms that are immutable once published, the Factories Act standard question set added in one action, and an inspection round register per area with its own frequency where a never-inspected area counts as overdue rather than as compliant. The §11(2) whitewashing question requires a date. A critical item answered “No” raises a nonconformity automatically.
§7, §40B, §49 — appointment of the occupier, manager, Safety Officer and Welfare Officer	COVERED	The appointment as a dated record with the qualification it rests on — and, for the four posts that require it, the date the notice went to the Chief Inspector with its reference. The register flags an unsent notice, because an appointment nobody notified is not a valid appointment however well qualified the person is, and reports posts with nobody appointed at all.
§§51–62 — weekly and daily hours, spread-over, weekly holiday, register of adult workers	COVERED	A shift roster from which the §62 register of adult workers and the §61 notice of periods of work both print. The 48-hour week, nine-hour day, ten-and-a-half-hour spread-over and weekly-holiday limits are computed and shown against every roster row. Breaches are recorded and made loud rather than refused — a register that will not record a 50-hour week does not prevent the week, only the evidence of it.
§§66–71 — employment of women, adolescents and children	PARTIAL	The statutory category is derived from the date of birth rather than trusted from a typed field, and the register of young persons prints from it. Where no date of birth is on file the register reports “not known” rather than defaulting to “adult”. Date of birth sits behind the occupational health confidentiality boundary by design, so the register is only as complete as the medical profiles.
§41B — compulsory disclosure of hazards; MSIHC Rules 1989 threshold quantities	COVERED	A chemical register with GHS classification, signal word, hazard and precautionary statements, incompatibilities and the safety data sheet itself — readable by *every* signed-in user, because §41B and 29 CFR 1910.1200(g)(8) both require the information to reach the worker. Site holdings are summed across locations against the threshold quantity for the Major Accident Hazard determination; a substance with no threshold recorded reports “not determined” rather than reading as safe.
§§88, 88A, 89 — notice of accidents, dangerous occurrences and notifiable diseases	PARTIAL	The notification clock is derived from the injury classifications recorded on the incident rather than typed by hand, running from when the employer knew, and a reminder chases *hourly* — because 29 CFR 1904.39 allows eight hours for a fatality and a next-morning reminder arrives after the deadline. The §89 occupational disease notice has its fields and its clock but nothing derives one, because that needs a diagnosis recorded against the Third Schedule.
§110 — prescribed forms, annual and half-yearly returns	PARTIAL	The engine is built and it is configuration, not code: a form's number, title, statutory citation and column layout are designed in the application by your compliance team and print from live data, and every seeded format ships marked *unverified* until somebody has checked it against the published Rules. What is deliberately *not* shipped is a pre-configured set of per-state form numbers — a wrong form number that looks authoritative is worse than an empty register. The annual and half-yearly returns are not yet register kinds.

Duty	Status	How it is evidenced
Overtime, leave with wages and payroll registers	NOT COVERED	Deliberately out of scope. This belongs to your HR or time-office system, and a half-built payroll is worse than none. The roster records *planned* shifts; it is not an attendance system.
Guarding, ventilation, welfare facilities	N/A — PHYSICAL	No software discharges these. The inspection records and corrective actions that evidence them do live here.

The platform does not encode any statute in application code, and deliberately so: obligations differ by state, sector and site, and belong in data your compliance team configures and owns. What it provides is the register, the evaluation cycle, the evidence trail and the nonconformity path — the same machinery every other module uses.

SECTION 8

Pollution control board compliance — consents, returns and the regulator

A state pollution control board is a different regulator from a labour inspector, asking for different things on a different timetable. It grants the consent that permits the plant to operate at all, attaches dozens of conditions to it, sends a notice when something is wrong, and takes two annual returns that between them describe a whole year of waste, water, fuel, production and emissions. Almost every manufacturer in India is inside this regime, and it is the one most often run on spreadsheets.

THE OBSERVATION THIS SECTION IS BUILT ON

The annual returns are not a form to fill in. They are a year of records you either kept or did not. Form IV asks for waste by category and by movement — generated, dispatched, utilised, landfilled, incinerated, and what is left in store. Form V asks for water and fuel by category, raw material and process water *per unit of product*, production against consented quantity, and stack and effluent results against prescribed limits — each against the previous financial year. All of it for a period that has already ended.

The normal way this is done is a fortnight in June, reconstructing the year from weighbridge slips, meter books and laboratory reports. The figures that result are not wrong so much as *undefendable*: when a board officer asks where one came from, the honest answer is that somebody added it up at the time.

Four registers, kept as the year happens

The returns derive from records the plant keeps anyway, if it keeps them somewhere a query can reach. That is the whole design: four registers, and the returns become a query over them rather than a compilation.

Register	What it holds	What it answers on the returns
Consents and their conditions	The consent or combined authorisation, its validity, the authorised signatory, and every consented quantity and prescribed concentration limit as a condition in its own right	Every “Consented Quantity” and “Prescribed Limit” cell on both forms, and both header blocks
The waste log	One row per waste event, with the Form 10 manifest, transporter, vehicle and receiving facility as first-class columns	Form IV Parts A to C in full; Form V Parts D, E and F
Consumption and production	Water by process, cooling and domestic; effluent; fuel; raw material; power; production and by-product, by period	Form V Part B, including the per-unit-of-product ratios and every previous-year column
Monitoring	Stack, effluent, ambient and noise results, judged against the consent's own limit, with the analysing laboratory and its recognition	Form V Part C, with the percentage variation computed rather than typed

WHY THE PRESCRIBED FORMAT IS DATA, NOT CODE

Both forms are held as versioned configuration — parts, sections, row labels, columns, units, order, and which parts a generator sees as against a disposal facility operator. Adding another state board's version of Form V is copying a format and editing labels, not a code change. A published format is immutable and a revision is a new version, so a return filed four years ago still prints in the format it was filed under.

Every format ships marked unverified, and the return says so on its face. A board revises its portal without revising a gazette. A format that looks authoritative while carrying a column the portal dropped last year is worse than one that admits it has not been checked; somebody with the current portal in front of them marks it verified and their name is recorded against it.

The return derives itself, and then a person reviews it

Raise a return for a period and every derivable cell fills from those four registers. Parts A to F of both MPCB forms derive. What remains is review rather than archaeology — and the review is where the real control sits.

Design decision	Why it is that way
An override keeps what the records said	Change a derived figure and the system stores your declared value *beside* the derived one, marks the row as a variance and asks for a written reason. A form that quietly accepted the edit would be a spreadsheet with extra steps. Re-typing the same figure is not an override, and does not demand a justification for changing nothing.
Re-deriving never discards a declaration	Refresh the return after correcting the underlying records and untouched rows update, while overridden rows keep the figures you declared — only the comparison behind them is refreshed, so the variance is measured against today's records rather than against a stale derivation.
Filing is a separate permission from preparing	Compiling a return is day-to-day work for the EHS team. Declaring its figures to a regulator is not, and the two are granted separately.
A filed return is immutable	After filing, the figures are what the site has told a regulator. The record locks, and a correction is a revised filing rather than an edit. The portal acknowledgement can still be recorded when it arrives, because that completes the same act rather than revising it.
Submission is refused only for an empty required cell	Not for an override, an exceedance, or a consent that lapsed during the period. Those are the facts a return exists to disclose, and a system that blocked submission over them would teach people to adjust figures until it let them through.

Nothing submits to the board. Neither the Maharashtra portal nor Gujarat's XGN offers a submission interface. The platform prepares, reviews, approves and records the filing, and produces an export ordered to match the portal's own field sequence so the keying is mechanical rather than error-prone. The UAN and the acknowledgement come back from the portal and are recorded against the return. A vendor claiming to file on your behalf is describing something that does not exist.

The rest of the relationship with the board

A consent used to appear in a compliance system the moment it was granted and vanish from view until it expired. Everything in between lived in somebody's inbox.

Record	Status	What it changes
Consent, including a combined CAC or CC&A	COVERED	Maharashtra and Gujarat issue one instrument covering the water consent, the air consent and the waste authorisation together. It is recorded once, covering every regime it carries — one number, one validity, one renewal clock — and it answers both returns. A 180-day renewal clock escalates daily once lapsed, because a renewal application, its inspection and the board's decision take months.
Conditions of the consent	COVERED	The quantitative conditions drive the returns. The numbered narrative ones — green belt, zero liquid discharge, DG-set hours, flow meters, bank guarantees — become tracked obligations with an owner, an evaluation cycle and evidence. The compliance report prints them worst-first, in the order an inspection visit follows.
The application that produced it	COVERED	Fees, the board's query, your reply, the decision, and the consent it granted. Without it, a renewal that went in four months ago and has heard nothing looks exactly like one nobody has started — and only one of those is normal.
Directions and show-cause notices	COVERED	With the deadline the notice sets, an owner, and a reminder that runs earlier than every other clock in the system. Every other reminder here chases paperwork; this one chases the thing that can close a plant. A notice cannot be recorded without its reply period, because that period is the whole point of it.
Board inspections	COVERED	The visit, the officer, the outcome, and each observation — which can be raised as a finding and run through the same assignment and closure route as any other nonconformity, and tied to the consent condition it bears on.
Environmental clearance	COVERED	A different instrument from a different authority, attached to a project rather than an operating unit. Its conditions share the same register, and the half-yearly compliance report derives from them. The approved capacity is compared against recorded production — producing above it is the commonest clearance violation there is, and one a site walks into by growing.
Public liability insurance	COVERED	The policy, the sum insured, the renewal clock and the Environment Relief Fund contribution the Act ties to the premium. Sites holding hazardous substances *with no policy in force* are read from the chemical register, because the evidence of a missing policy is the absence of a row.
Notification to the board on a release	COVERED	A release to air, water or land raises its own clock to the board, beside the labour-department one. A spill contained in a bund and recovered raises none — and where nobody recorded where it went, the platform declines to assert a discharge rather than inventing one.

Four findings an inspector produces that a spreadsheet cannot

These are the questions that turn a routine visit into a notice, and each of them is a query the records can answer only if the records were designed for it.

The question	How it is answered
Where is the Form 10 copy for this consignment?	The manifest is a six-copy document, and the copies that come back prove the waste arrived. Their return is tracked, and a dispatch still missing them after thirty days is surfaced — stated as the platform's own prompt to chase, since the Rules set no period for a copy's return.
How long has this waste been in store?	Aged from the date it arrived. A holding with no arrival date recorded is reported as *unanswerable* rather than as compliant: the failure mode here is a wrong answer confidently given.
Was that facility authorised when you sent it?	Checked on the day the waste left, not today. Sending waste to a facility whose authorisation had lapsed is the generator's breach, not only the operator's. A facility recorded only as free text yields no answer rather than a pass.
Is this consent limit laxer than the notified standard?	The notified standards are held as a catalogue and put side by side with the consent condition — as a question, never asserted as a finding. A consent may lawfully be stricter; it may not be laxer, and a site working to it in good faith has no way of noticing.

WHAT IS DELIBERATELY NOT BUILT

A producer's extended producer responsibility ledger. Under the plastic, e-waste and battery rules a producer, importer or brand owner carries registration, category-wise targets, procured certificates and a shortfall exposure — a target-and-credit ledger. Most manufacturing sites are in scope as *bulk consumers* instead, whose duty is to channel end-of-life items to a registered recycler and keep the record, which the waste log already discharges in full. The platform says which of the two applies on the screen, so a site does not go looking for machinery it does not need.

A meter as a record. Flow meters at the effluent outlet and on the water draw are read into the consumption register, but a reading does not yet point at a meter with its own serial number and calibration clock.

Gujarat formats. The seeded returns are Maharashtra's. The engine is state-agnostic and adding GPCB's variants is configuration, but nothing here should be read as “works for Gujarat” until somebody has checked the column sets against XGN.

SECTION 9

21 CFR Part 11 — the position, stated plainly

READ THIS BEFORE THE TABLES

This application is not, today, a fully 21 CFR Part 11 compliant system — and no software product is, because roughly half of Part 11 is procedural and belongs to you. What it has is the core: two-component electronic signing with declared signature meaning, access control, enforced sequencing, segregation of duties and a versioned audit trail. What remains, and is on the roadmap, is record retention and protection, an inspection-ready complete-record export, audit-trail review tooling, and the validation package. We state this in writing because you will discover it during qualification, and a vendor who let you find it then does not deserve the next contract.

First, scope: Part 11 does not reach everything

Part 11 applies only to records that a *predicate rule* — 21 CFR 210 and 211 for drug GMP, 820 for device QSR, 58 for GLP, 606 for blood — already requires you to keep. Deciding which records those are is a regulatory judgement made by your organisation, not a property of the software. It also has a direct cost: every record type you put in scope gains a signing challenge for its approvers and a row in your validation traceability matrix. **Putting everything in scope by default is the commonest and most expensive mistake in a Part 11 programme.**

The platform therefore ships an explicit in-scope registry — nine record types, each declared against the predicate rule that put it there — and leaves everything else approving the way it always has. A BBS observation or a visitor pass does not prompt anyone for a password, because nothing requires it to.

Record type in scope today	Predicate rule that puts it there
Document version	21 CFR 211.100 / 211.180; 820.40 — document controls
Finding	21 CFR 211.192; 820.100 — nonconformity and corrective action
Root cause analysis	21 CFR 820.100(a)(2) — investigating the cause of nonconformities
CAPA plan	21 CFR 820.100 — corrective and preventive action
Nonconforming output	21 CFR 820.90; 211.192 — control of nonconforming product
Change request (MOC)	21 CFR 211.100(b); 820.30(i), 820.70(b) — change control
Design project	21 CFR 820.30 — design controls
Audit / audit programme	21 CFR 820.22 — quality audits and the schedule they run against

What ships today

Section	Control	Status	Implementation
§11.10(d)	Limiting system access to authorised individuals	COVERED	Thirty-minute session timeout, ten-attempt lockout with a one-hour unlock, active-user checks, forced password change, per-site isolation enforced by registry and regression-tested, and authorisation applied to the administration console as well as the application.
§11.10(f)	Operational system checks enforcing permitted sequencing	COVERED	Every transition is a transactional service with explicit guards. An approval on a step that is not the current pending step is refused, with a stated error.
§11.10(g)	Authority checks — who may use, sign, or perform	COVERED	Per-module abilities, refusal of self-approval, and an approval chain that declines to route rather than auto-approve when its authority matrix is unconfigured.
§11.50(a)	Signature manifestations — printed name, date and time, meaning	COVERED	Name and title snapshotted at signing; server-set timestamp, never client-supplied; one of five declared meanings resolved per model and stage, rendered into a declaration and frozen onto the signature. A rejection is signed with withheld wording rather than treated as a non-event.
§11.50(b)	Manifestations included in displayed and printed copies	COVERED	The name, timestamp, meaning and declaration render wherever approval history renders — on screen and in every report PDF.
§11.200(a)(1)	At least two distinct identification components	COVERED	An in-scope approval requires re-entry of user ID and password, enforced inside the approval service rather than the controller — an unsigned decision is unreachable regardless of caller.
§11.200(a)(1)(i)–(ii)	Continuous-period signing rules	COVERED	The first signature of a period demands both components; within a fifteen-minute period the password alone completes a signature. The window is deliberately shorter than the session timeout, lapses on idle and sign-out, and only an executed signature opens one.
§11.300(d)	Detecting and reviewing attempted unauthorised use	PARTIAL	Every signature and every failed attempt is logged with outcome, record and IP address, searchable and exportable; failed signing attempts count toward account lockout. Push alerting at the moment of a lockout is not yet wired — the regulation's wording is “immediate and urgent”.
§11.10(e)	Secure, time-stamped audit trail that does not obscure prior values	PARTIAL	Versioning with prior values and the acting user is in place across the record set. Missing: an in-application audit-trail viewer, a reason-for-change field, and versioning on a remaining set of configuration and detail models.
§11.10(b)	Accurate and complete copies for inspection	PARTIAL	Human-readable PDFs and CSV exports exist for the major modules. A single “this CAPA and everything that ever happened to it” artefact, and a structured electronic export, are not yet available.

Section	Control	Status	Implementation
§11.10(c)	Protection of records through the retention period	PARTIAL	Controlled-document immutability is genuinely strong. A general retention model with enforced holds, soft deletion across in-scope records, and tested restore procedures are outstanding.
§11.70	Signature-to-record linking	PARTIAL	Relational linking with referential integrity, which is broadly accepted for closed systems. Content binding — a hash proving the signature covered the record as it then stood — is roadmap, except for document versions, whose files are immutable once approved.
§11.10(a)	Validation of the system	NOT COVERED	An extensive automated test suite exists and is excellent raw material for operational qualification — but a test suite is evidence a validation effort cites, not validation. See the programme below.

What only you can supply

These will never become "covered" by shipping code, and any vendor claiming otherwise is describing something they cannot deliver.

- **§11.100(b) — Identity verification.** Your HR or IT procedure for verifying an individual's identity before an electronic signature is assigned to them, and a record that it happened.
- **§11.100(c) — Certification to the FDA.** A one-time letter, on paper, signed by hand, stating that your electronic signatures are the legally binding equivalent of handwritten ones. Nothing to build; nothing to skip either.
- **§11.10(j) — The accountability policy.** A written policy holding individuals accountable for actions taken under their signature. It fits neatly as a controlled document in this system with a mandatory acknowledgement and a Read & Understood assessment — but you must write it and make acknowledgement a precondition of account activation.
- **§11.10(i) — System-specific training.** The competency machinery is built and gates role assignment; the curriculum that says "trained on this application" is yours to define.

The remediation programme, in priority order

#	Work item	Sections	Why it is where it is in the order
G2	Record protection, retention and soft deletion	§11.10(c), (e)	Blocking. For a predicate-rule record, a deletion must itself be recorded and the data retained. Includes tested backup and restore — an untested backup is not coverage.
G7	Validation package	§11.10(a)	Blocking, and almost entirely documentation: validation plan, user/functional/design specifications, risk assessment, IQ/OQ/PQ protocols with executed evidence, and a traceability matrix from each clause to the test that demonstrates it.
G3	Inspection-ready complete-record export	§11.10(b)	An investigator asks for one CAPA and everything that ever happened to it, as one artefact, in both human-readable and structured form — with the export itself logged.

#	Work item	Sections	Why it is where it is in the order
G4	Audit-trail completeness and review tooling	§11.10(e)	A per-record trail viewer, a reason-for-change captured at edit time on records in an approved state, and a periodic audit-trail *review* record. Audit-trail review is the observation both FDA and CDSCO inspectors are currently writing most often.
G8	Credential lifecycle and security-event alerting	§11.300(b), (d)	Password ageing and history, periodic access review with a recorded decision, and security events routed into the existing notification pipeline.
G5	Signature-to-content binding	§11.70	A hash of the signed payload, surfaced as a “this signature covers the record as it stood” check in the record view and the complete-record export.
G6	Closed versus open system posture	§11.30	A deployment decision, not a code one. Behind your own network with access controlled by you, an installation is a closed system and §11.30 does not apply. Reachable from the public internet, it is not, and needs documented encryption in transit and at rest.

ALSO RELEVANT IF YOU ARE AN INDIAN SITE EXPORTING TO THE US

An Indian site becomes subject to Part 11 when it manufactures, tests or holds product for the US market and its electronic records support that product — the FDA's jurisdiction runs to the records, wherever the server sits. Read alongside it: **Schedule M** of the Drugs and Cosmetics Rules as revised in 2024, which now carries explicit computerised system and data-integrity expectations; **EU GMP Annex 11** and the **MHRA** data-integrity guidance, which are stricter than Part 11 on risk assessment, supplier assessment and periodic review; and **PIC/S PI 041** and **WHO TRS 1033 Annex 4**, which are what a CDSCO inspector or a customer audit will most likely cite. A site that satisfies Part 11 will generally satisfy revised Schedule M. The reverse is not reliably true.

Stated so nobody goes looking: there is no batch record, no electronic batch record review, no LIMS, no instrument interface and no production execution in this system. Part 11 applies here to the QMS records it holds — documents, CAPA, change control, calibration, training, complaints, supplier controls. Your manufacturing and laboratory records are a different system's Part 11 problem, and we will say so in front of your auditor.

SECTION 10

ISO/IEC 17025 and the limits of scope

A short section, and the most useful one in a competitive evaluation. Every claim above is worth exactly as much as the honesty of this page.

ISO/IEC 17025:2017 — covered in half, and it is the predictable half

ISO 17025 is an accreditation standard for a laboratory rather than a management system for an organisation, and it splits cleanly in two.

- **Clause 8 — management system requirements: largely covered.** Document control, records, risk and opportunity, improvement, corrective action, internal audit and management review are the same engines described throughout this paper. Equipment records, calibration traceability and environmental condition monitoring are built.
- **Clause 7 — process requirements: not covered, and will not be by configuration.** Methods, sample handling, test results, measurement uncertainty, reporting and proficiency testing are a laboratory information management system. This is not one. A laboratory running this platform gets its Clause 8 management system; it still needs a LIMS for Clause 7.

ICH Q7 and Schedule M — the batch record, built; the laboratory, not

These regulate a *product*: a batch of active pharmaceutical ingredient, a lot of food. Until August 2026 there was no product, batch or recall record here at all, and this page said so. That has changed, and it is worth being precise about what did and did not.

Built. A material master covering raw material through finished product; goods receipt with quarantine and quality-unit lot release; a structured, versioned Master Batch Record — bill of materials, process steps, in-process limits, yield range — that becomes immutable once effective; batch execution with first-expiry-first dispensing, lot genealogy, second-person checks the database itself enforces, blocking in-process limits and yield reconciliation; deviations that name the batch they affected and prevent its release; quality-unit batch record review and release under 21 CFR Part 11 electronic signature; the printable batch manufacturing record; and recall, market action and *timed mock recall* resolving affected lots by walking the genealogy chain. This closes ICH Q7 §6.3–6.7, §8.1, §10.2 and §15, and 21 CFR 211.184–211.192.

Not built. There is no *specification* with numeric acceptance criteria, no sample or test result, no generated certificate of analysis and no out-of-specification investigation. A CoA is a file attached to a lot. Nor is there equipment qualification, process validation, cleaning and changeover records, warehouse bin management, or label reconciliation.

The honest summary is therefore: **this platform now holds the batch record and the quality system around it, but not the laboratory that decides whether a batch meets its specification.** A site running a LIMS has the complementary half and the two fit together. A site without one still needs to buy that capability elsewhere.

The complete list of what this platform will not do

Not in the product	What we recommend instead
Specifications with numeric limits, samples, test results, certificates of analysis, out-of-specification investigations	A LIMS. Batch records, lot genealogy and recall *are* built (Section 10); the laboratory verdict is what is not

Not in the product	What we recommend instead
Laboratory methods, samples, results, uncertainty, reporting	A LIMS
Contract and order review (ISO 9001 §8.2)	Usually already in your ERP; quotable as development where it is not
Overtime, leave with wages and payroll	Your HR or time-office system. The *roster* and the §62 register of adult workers are built; attendance and wages are deliberately not, because a half-built payroll is worse than none
Days-away-from-work counts on an injury case (29 CFR 1904.32)	Your payroll or HR system. The case is classified as lost-time, but the *number of days* is not held, and the OSHA 300A prints “Not recorded” rather than a false zero
Lockout/tagout energy control procedures per machine (29 CFR 1910.147)	Declared gap. Energy isolation points and authorised employees are registered; the written procedure per machine and its annual periodic inspection certification are not
Audiometric standard threshold shift determination (29 CFR 1910.95)	Declared gap. Noise dosimetry and automatic enrolment into audiometric surveillance are built; comparing successive audiograms is not, because audiogram results are stored as free text rather than frequency by frequency
Pre-configured Factory Rules forms for each Indian state	Deliberately not shipped. The form designer, the register engine and the printing are built, and your compliance team configures your state's formats from its published Rules — a wrong form number that looks authoritative is worse than an empty register. The two OSHA 1904 formats ship verified because 1904 specifies them column by column
Filing a return on the board's portal	Not possible for anyone. Neither the Maharashtra portal nor Gujarat's XGN offers a submission interface. The return is prepared, reviewed, approved and recorded here, and exported in the portal's own field order for keying. A vendor claiming to file on your behalf is describing something that does not exist
A producer's extended producer responsibility ledger (plastic, e-waste, battery)	Deliberately not built. Most manufacturing sites are in scope as *bulk consumers*, whose duty is to channel end-of-life items to a registered recycler and keep the record — which the waste log discharges in full, and the screen says so. Targets, procured certificates and shortfall belong to a producer, importer or brand owner, and would be a separate ledger
Continuous emission monitoring telemetry to the board's server	Belongs to the instrument and the board's endpoint, not to a compliance system. What is built is the part a board asks about: the *exceptions* — when the analyser was down, why, for how long, and whether the board was told
Pre-configured pollution control board formats for each state	Maharashtra's Form IV and Form V ship, marked unverified. Gujarat and the rest are configuration rather than code, for the same reason as the Factory Rules forms above: a wrong column set that looks authoritative is worse than none
A flow meter as a record with its own calibration clock	Declared gap. Meter readings are held in the consumption register, but a reading does not yet point at a meter with a serial number and a calibration due date
Equipment cleaning records, clean/dirty status and equipment use logs (ICH Q7 §5.2)	Declared gap. Line clearance is captured per batch step, and maintenance and statutory examination are held against the asset; cleaning as its own record is not built
Production execution, MES, maintenance planning as a discipline	Your MES or CMMS; asset calibration, maintenance and statutory examination *records* live here
Instrument and device data interfaces	Not built. Note that if instrument data is ever imported, 21 CFR §11.10(h) source-device checks become live and would need designing

Five rows left this list in the previous edition of this paper: measured workplace exposure against permissible limits, the PPE and respiratory protection programme, contractor pre-qualification scoring, the prescribed statutory registers, and working-hours records. This edition adds five more rows than it removes — all of them from the pollution control board work in Section 8, where building the returns and the consent register made the boundaries of that regime specific enough to state. A list that only ever gets shorter is a list nobody is checking.

WHY THIS PAGE EXISTS IN A SALES DOCUMENT

Because the alternative is discovering it in month four, when the implementation is half-paid and the certification audit is booked. Every gap named here is named in our internal engineering documents in the same words, and those documents are available to your evaluation team. A vendor whose gap analysis and whose sales deck say the same thing is telling the truth in both.

SECTION 11

The benefit case

Three layers of benefit, each of which lands with a different person on your evaluation committee. The numbers in the model below are deliberately left as your inputs — a benefit case built from someone else's benchmarks does not survive contact with your CFO.

Operational — what changes for the people doing the work

Today	With the platform
Findings tracked in a spreadsheet, chased by email	Assignment, due date, escalation and reminder are the workflow. Aging is a report, not an exercise. Nothing closes without the evidence its severity requires.
Permits approved by phone and papered afterwards	Approval routed by permit type and shift, gas tests that block issue outside limits, crew checked against gate-pass validity, four-signature closure with the fire watch recorded.
SOP revisions emailed as attachments	Sequential approval, one effective version, controlled distribution with acknowledgement, and a Read & Understood assessment pinned to the revision the person actually read.
Training attendance sheets in a folder	Self check-in, trainer validation, assessment with a frozen score, auto-issued certificates, and a role assignment that is refused when a required competency is not held.
Management review minutes typed up and filed	Sixteen standard agenda inputs, decisions recorded, actions with owners and due dates that appear in each owner's “My Work” the same day.

Managerial — what changes for the person accountable

- **One definition of everything.** One severity scale, one aging clock, one closure rule, one meaning of “verified” — across every module and every plant. Comparison between sites becomes possible because the definitions are shared, not normalised afterwards.
- **Corporate visibility without local duplication.** Corporate sees every site and drills into one at a time; a plant sees its own. No plant maintains a second report for head office, which is where most group-level reporting effort actually goes.
- **A compliance score per site, and the ranked reason for it.** Ten weighted dimensions — findings, CAPA effectiveness, statutory examinations, exposure, inspections, training, calibration, obligations and the rest — resolve to one number per site, with the contribution of each dimension shown so the number can be argued with rather than merely reported. A dimension whose module is switched off drops out of the weighting instead of scoring zero, so the score never punishes a site for something it does not run. It also detects *register gaps*: a hazard one plant has assessed and another has not is reported as a gap relative to its peers, which is the finding a site-by-site review structurally cannot produce.
- **Audit preparation becomes retrieval.** The evidence exists in the shape an auditor asks for, with approval history embedded in the printed report, because it was created that way.
- **The pre-visit briefing is in the product.** An *Audit Readiness* screen lists, for each of six kinds of visitor, the questions they typically ask, the screen that answers each one, and what that screen proves — with each answer linking straight to the record, filterable by framework, and exportable as a list to hand to whoever has to close

something before the visit. The known gaps are marked in it as plainly as the strengths, for the reason given in Section 10.

- **Key-person risk removed.** The management system stops being the person who knows where everything is.

Commercial — the cost model

Populate the middle column from your own records. The right column is the mechanism by which the platform changes the number — stated so you can challenge each one individually rather than accepting a single headline figure.

Cost line	Your figure	What changes it
Person-days spent preparing for each certification and surveillance audit × audits per year	— — —	Evidence is retrieved rather than reconstructed; reports print with approval history attached
Person-days spent per internal audit cycle on scheduling, packs and report chasing	— — —	Programme expands into dated audits automatically; checklists are templates; findings raise from checklist items
Hours per month reconciling registers across departments and sites	— — —	There is one register; reconciliation ceases to be an activity
Corrective actions overdue beyond target, and average days past due	— — —	Reminders, escalation and aging dashboards make overdue visible before an auditor makes it visible for you
Repeat findings per year at surveillance audit	— — —	Closure requires verified effectiveness rather than a date; repeats are judged far more harshly than first findings
Cost of a single major nonconformity: re-audit fees, remediation, certificate risk, customer audit exposure	— — —	Sequencing and authority checks prevent the categories of finding that arise from process, not from performance
Customer and second-party audits per year × days of preparation each	— — —	The same evidence base serves every audience; no per-customer evidence pack is assembled from scratch
Cost of a lost-time incident, and of a statutory notification filed late	— — —	Permit, HAZOP, MOC and PSSR controls act before the event; incident workflow tracks notification deadlines after it

WHERE THE CASE IS USUALLY STRONGEST

In our experience the decisive lines are rarely the licence-versus-spreadsheet comparison. They are: **(a)** audit and customer-audit preparation days, which are large, recurring and easy for your own team to count; **(b)** the second and subsequent sites, where the marginal cost of another plant is a fraction of the first and the alternative is another parallel set of registers; and **(c)** the avoided cost of one major nonconformity or one late statutory notification, which is a low-probability, high-severity line that your risk register almost certainly already carries a number for.

Commercial model

Modules are licensed individually, in functional packs, or as editions sized to a buyer profile — from a single-plant organisation pursuing first certification through to a multi-plant group with a corporate HSE function. Both a subscription and a perpetual licence are available, the latter because many process plants and public-sector undertakings can commit

capital budget far more readily than recurring revenue budget, and because an on-premise buyer reasonably wants the licence to survive the relationship. Additional sites are charged at a fraction of the first. Implementation is milestone-linked so that payment tracks delivery rather than the calendar. Current figures are in the accompanying proposal, which is generated against the exact module scope quoted — the scope document and the price come from the same source, so a proposal cannot describe one scope and price another.

SECTION 12

Deployment, security and data ownership

Deployment

A single web application and a single PostgreSQL database per organisation. It deploys on your own servers, in your own private cloud, or hosted — the same build in each case. There is no shared multi-tenant database: one organisation, one database, one upgrade cycle you control.

Access

Browser-based, responsive, and usable on a tablet at the gate or in the control room. No client installation. Sessions time out after thirty minutes; accounts lock after ten failed attempts and unlock after an hour or by an administrator.

Data ownership

Your data is yours, in a standard PostgreSQL database with a documented schema. Every list in the application exports to CSV within the exporting user's own authorisation. There is no proprietary storage format and no exit toll.

Security posture

- Authorisation enforced at the query layer, so no export, report or API path can widen what a user may see
- Site isolation enforced in one place across a registry of every operational model, with a regression test that fails the build if a new module is not registered
- Password reset by emailed token to the account owner — no administrator path that sets a known password
- Signature and failed-attempt logging with IP address
- Static security scanning and dependency vulnerability auditing in the build pipeline
- File attachments handled through a policy layer rather than raw uploads

Continuity

Standard PostgreSQL backup and point-in-time recovery, plus object storage for attachments. For regulated deployments, restore must be *exercised*, not merely configured — that is part of the retention work in Section 9 and part of your qualification, and we will run it with you.

Configuration ownership

The intent throughout is that your administrators own the configuration and we own the software. Permit forms, approval matrices, check sheets, checklist templates, risk matrices, examination protocols, email templates, module switches, roles and the access-control matrix are all edited from within the application. This matters for three reasons: your procedures change faster than any vendor's release cycle; a change you make yourself does not carry a change request and a bill; and a configuration that is versioned inside the system is auditable, whereas one that lives in a vendor's ticket queue is not.

> **A NOTE FOR YOUR IT FUNCTION**
>
> Conventional, boring, well-understood technology: Ruby on Rails 8, PostgreSQL, server-rendered HTML with progressive enhancement, background jobs in the same database, containerised deployment. No exotic runtime, no per-seat client, no dependency on a single cloud vendor's proprietary services. That is a deliberate choice for a system a plant will run for a decade.

SECTION 13

Implementation — the first ninety days

Implementations fail when everything is configured before anything is used. The sequence below produces usable evidence inside the first month and complete evidence within one audit cycle, because each phase is a vertical slice that goes live rather than a layer that waits.

Phase	Scope	What exists at the end of it
Weeks 1–2 **Foundation**	Organisation, sites, departments, locations, users, roles, access matrix	Everyone can sign in and sees exactly what they should. The site boundary is real from day one, so a later plant rollout is an addition rather than a migration.
Weeks 3–5 **First live module**	The module with the sharpest daily pain — usually Permit to Work, Findings or Documents	One workflow is genuinely in production with real users. This is the phase that decides whether the rollout succeeds; everything after it is easier because people have already changed how they work once.
Weeks 5–8 **The improvement loop**	Findings, root cause, CAPA, effectiveness verification, notifications	Every other module now has somewhere to send a problem. Findings raised from audits, aspect reviews, supplier evaluations, incidents and observations all land in one register with one aging clock.
Weeks 7–10 **Governance**	Controlled documents, audit programme, objectives, management review	The certification-facing spine. The year's audit programme is approved and expands itself into dated audits; document control is live with effective versions and acknowledgement.
Weeks 9–12 **Domain modules**	Incidents, MOC, HAZOP, PSSR, occupational health, BBS, emergency — as licensed	Domain workflows go live against a foundation that already works, with historical data migrated where it is worth migrating and archived where it is not.
Ongoing **Cycle one**	First full internal audit and first management review inside the system	The management system's own evidence of itself, produced end to end by the platform — which is what the certification body reads.

IF YOU ARE PURSUING A PART 11 POSITION

Run qualification in parallel from week one rather than after go-live. The in-scope record registry (Section 9) is a decision your QA function makes early, because it determines the size of the traceability matrix, the number of approvers who will meet a signing challenge, and therefore the cost of the whole programme. We will supply the requirements and design inputs the validation package traces to, and the existing automated test suite as raw material for operational qualification. **The validation package is a joint deliverable with a named owner on each side — not a document we hand over and not one you write alone.**

What we need from you

- **A named process owner per module**, empowered to decide how the workflow should run. Not a committee — the single most reliable predictor of a slow implementation is a configuration decision that needs four signatures.

- **Your existing forms and matrices as they actually are**, not as the manual describes them. The system is configured to your real practice; where the real practice is wrong, that is a finding worth having early.
- **A decision on historical data**: what is migrated, what is archived as attachments, what stays where it is. Migrating everything is usually the wrong answer.
- **Two hours per week of leadership attention** for the first six weeks. This is the whole of the change-management requirement, and skipping it is the only failure mode we have not been able to engineer around.

SECTION 14

Twelve questions to ask any IMS vendor

Use these on us and on everyone else you are evaluating. Ask for the answers in writing. The last four are the ones that most vendors will not put in writing at all.

#	The question	Our answer
1	Show me a finding raised from an audit checklist item, one from a supplier evaluation and one from an environmental aspect review, in a single aging report.	Yes — one register, one severity scale, one aging clock, one closure rule. Findings raise from every module through the same path.
2	Can one person raise, investigate and close the same major nonconformity?	No. Self-approval is refused in the service layer, and a major NC requires an approved root cause and an approved CAPA before it can close.
3	Show me the SOP revision that was effective on the date of an incident three years ago.	Yes. Approved revisions are immutable and every historical version stays retrievable, with its approval history.
4	What happens if the authority matrix has no approver configured for this permit type on night shift?	The system refuses to route the approval and says so. It does not auto-approve and it does not pick a default.
5	Can a plant see another plant's records? Prove it, and show me the test.	No. The boundary is enforced in one place across a registry of every operational model, with a regression test that fails the build if a module is added without registering.
6	Who configures a new permit form or approval matrix, and what does it cost?	Your administrators, from inside the application, at no cost. Configurations are versioned, so a permit already issued still shows the form it was issued against.
7	Can I export everything, and what happens to my data if we part ways?	Standard PostgreSQL with a documented schema, CSV export on every list within the user's own authorisation, and no proprietary storage format.
8	Does an approval record what the approver was attesting to, or just that they clicked?	For regulated records, one of five declared meanings, rendered into a declaration and frozen onto the signature at signing time.
9	**Are you 21 CFR Part 11 compliant? Answer in writing, clause by clause.**	**No — and neither is any product, because half of Part 11 is procedural.** Section 9 states what ships, what is yours, and what is still being built. We will hand your QA team the full internal gap analysis.
10	**Show me your clause mapping including the rows where you fall short.**	Seventeen frameworks across nine mapping documents, maintained against the current code as working gap analyses, with declared gaps in each. Available to your evaluation team on request.
11	**What does your product deliberately not do?**	Section 10 is a complete list, with what we recommend instead for each item.
12	**Who owns the validation package, and what exactly will you deliver into it?**	A joint deliverable with a named owner on each side. We supply requirements and design inputs, the automated test suite as OQ raw material, and support through execution. We do not claim to hand you a validated system.

WHY WE PUBLISHED QUESTIONS 9 TO 12

Because they are the questions we are most confident answering, and because a vendor who answers “yes, we are Part 11 compliant” to question 9 has told you something important about every other answer they gave you.

APPENDIX A

Clause-to-module index

A one-page reference for your certification body, your consultant and your internal audit team. Full clause-by-clause mappings for all nine frameworks — including the rows marked partial and not covered — are maintained with the product and available on request.

Module	Clauses and sections it evidences
Audit Programme	ISO 9001 §9.2.2 a) · ISO 14001 §9.2 · ISO 45001 §9.2 · ISO 19011 §5 · 29 CFR 1910.119(o) · 21 CFR 820.22
Audits	ISO 9001 §9.2 · ISO 14001 §9.2 · ISO 45001 §9.2 · ISO 17025 §8.8 · 21 CFR 820.22
Findings & CAPA	ISO 9001 §10.2 · ISO 14001 §10.2 · ISO 45001 §10.2 · ISO 17025 §8.7 · 21 CFR 211.192, 820.100
Controlled Documents	ISO 9001 §7.5 · ISO 17025 §8.3 · 29 CFR 1910.119(f) · 21 CFR 211.100, 211.180, 820.40, Part 11 §11.10(c)
Management Review	ISO 9001 §9.3 · ISO 14001 §9.3 · ISO 45001 §9.3 · ISO 17025 §8.9
Quality Objectives	ISO 9001 §6.2 · ISO 14001 §6.2 · ISO 45001 §6.2
Context & Interested Parties	ISO 9001 §4.1–4.2 · ISO 14001 §4.1–4.2 · ISO 45001 §4.1–4.2
Risks & Opportunities	ISO 9001 §6.1 · ISO 14001 §6.1.1 · ISO 45001 §6.1.1 · ISO 17025 §8.5
Compliance Obligations	ISO 14001 §6.1.3, §9.1.2 · ISO 45001 §6.1.3 · Factories Act & state rules · OSH Code 2020
Environmental Aspects	ISO 14001 §6.1.2, §8.1, §9.1
Permit to Work	ISO 45001 §8.1.2, §8.1.4 · 29 CFR 1910.119(k), 1910.252 · Factories Act hazardous operations
Management of Change	ISO 9001 §6.3, §8.1 · ISO 45001 §8.1.3 · 29 CFR 1910.119(l) · 21 CFR 211.100(b), 820.30(i), 820.70(b)
HAZOP	ISO 45001 §6.1.2 · IEC 61882 · 29 CFR 1910.119(e)
PSSR	ISO 45001 §8.1.1 · 29 CFR 1910.119(i)
Incidents	ISO 45001 §10.2 · ISO 14001 §8.2 · 29 CFR 1904, 1910.119(m) · Factories Act notification · 21 CFR 820.198
Emergency Preparedness	ISO 14001 §8.2 · ISO 45001 §8.2 · 29 CFR 1910.119(n), 1910.38
Occupational Health	ISO 45001 §8.1 · Factories Act §41C, §45 · OSH Code 2020 · Contract Labour Act
Workplace Exposure Monitoring	ISO 45001 §8.1.2, §9.1 · Factories Act §41F & Second Schedule · 29 CFR 1910.95, 1910.1000, 1910.1020, Subpart Z
PPE & Respiratory Protection	ISO 45001 §8.1.2 · Factories Act §35 · 29 CFR 1910.132–138, 1910.134(f)
Workplace Inspections	ISO 45001 §8.1.1, §9.1.1 · Factories Act §11, §§17–19, §§42–48
Statutory Registers & Formats	Factories Act §7, §36, §40B, §49, §§66–71, §110 · 29 CFR 1904.29, 1904.32, 1910.146(c), 1910.147(c)
Shift Roster	Factories Act §§51–62 · OSH Code 2020

Module	Clauses and sections it evidences
Chemical Register & SDS	ISO 45001 §8.1.2 · Factories Act §41B, §§88, 88A, 89 · MSIHC Rules 1989 · 29 CFR 1910.119(d), 1910.1200, 1904.39
Competency & Training	ISO 9001 §7.2 · ISO 14001 §7.2–7.3 · ISO 45001 §7.2–7.3 · ISO 17025 §6.2 · 29 CFR 1910.119(g) · 21 CFR 211.25, 820.25, Part 11 §11.10(i)
Assets & Calibration	ISO 9001 §7.1.5 · ISO 17025 §6.4–6.5 · 29 CFR 1910.119(j) · 21 CFR 211.68, 820.72
Suppliers	ISO 9001 §8.4 · 21 CFR 820.50
Nonconforming Output	ISO 9001 §8.6, §8.7 · 21 CFR 820.90, 211.192
Design & Development	ISO 9001 §8.3 · 21 CFR 820.30
Customer Satisfaction	ISO 9001 §9.1.2 · 21 CFR 820.198 (complaints, by reference to Incidents)
BBS & Worker Participation	ISO 45001 §5.4, §6.1.2, §8.1.2, §9.1 · 29 CFR 1910.119(c)
Safety Meetings & Recognition	ISO 45001 §5.4, §7.4, §10.3 · Factories Act safety committee
Visitor Management	ISO 45001 §8.1.4, §8.2
Platform — access, approvals, audit trail	ISO 9001 §7.5.3 · ISO 17025 §8.4 · 21 CFR Part 11 §11.10(d), (e), (f), (g), §11.50, §11.200(a)(1)
Platform — compliance dashboard & audit readiness	ISO 9001 §9.1.1, §9.3.2 · ISO 14001 §9.1.2 · ISO 45001 §9.1.1, §9.3 · Factories Act inspection readiness

NEXT STEPS

The most useful next hour is not a slide deck. It is a working session against your own material: bring one real permit, one real finding with its CAPA, and one real SOP revision, and we will run them end to end in the system and show you the evidence trail each one produces.

For an evaluation committee, we will also provide the full clause-by-clause mapping documents for all nine frameworks — gaps included — and a proposal generated against the exact module scope you select.

DEEPAK CYBIT

Software development and industry-specific applications since 2016. Teams in Vadodara, Pune and Mumbai. Products include CompliHub, Sampliefy LIMS, Athena Suite (Idea to Plant), OccuSafe and Minits.ai.

CompliHub — one web application running quality, environmental and occupational health & safety management together, with one authorisation model, one approval engine and one audit trail across all of it.