

NICHE-SEARCH

WORKSHEET 5 OF 9

ISO 9001 Readiness Gap Analysis

Not a certification checklist. A practical audit of which Level 3 elements are already running and which are not. Run once per year or before any external audit or due diligence.



Complementary worksheet for
Quality Control Systems
by Ibrahim Anwar

What This Is For

ISO 9001:2015 certification costs money and takes time, but the largest share of that cost is not the audit fee — it is closing gaps that have existed for years and were never documented. This worksheet maps which clauses are already running with verifiable evidence, which are partially in place, and which have not started. Running this analysis once surfaces the low-hanging fruit that can be closed in under 20 hours each, clearing a significant portion of audit findings before the auditor arrives.

The operator who needs this sheet is considering certification within the next 12–18 months, or has a due diligence inquiry from an investor or corporate buyer that requires quality system evidence. They do not need to know ISO 9001 clause numbering — this sheet supplies the clause reference alongside a plain-language summary of what each clause actually requires in practice.

Benefits

What you get when you actually run this worksheet on a real situation:

- Converts an abstract standard into twelve concrete yes/no/partial questions grounded in what the business already does, removing the intimidation factor from a 9001 gap analysis.
- The 'Evidence Available?' column separates 'we do this' from 'we can show this to an auditor within one hour' — the only distinction that matters in a third-party audit.
- Identifies which gaps require under 20 hours to close, so the pre-certification investment can be sequenced from cheapest-and-fastest to longest-and-costliest.
- Provides a year-on-year comparison point: run it in 2025, run it again in 2026, and the delta shows what the team actually closed versus what stayed on the list.
- Gives a concrete answer to an investor's due diligence question about quality system maturity without requiring a full certification to exist.

Framework To Use

— Gap-to-Hours Prioritization

For each 'Partial' or 'Not Started' gap, estimate closure in person-hours — the threshold is 20 hours, not months. Under 20 hours is low-hanging fruit regardless of clause complexity.

RUNNING + EVIDENCE	PARTIAL	NOT STARTED
<p>Clause is implemented AND a physical document or record can be shown to an auditor today. No action required — just maintain.</p>	<p>Clause is implemented in practice but not documented, or documented but not consistently followed. Estimate hours to close. Under 20 hours = do it this quarter.</p>	<p>Neither implementation nor documentation exists. Estimate hours to build the minimum viable version. Sequence after all Partial gaps are closed.</p>

How To Use

Follow these steps in order. Each one builds on the previous.

- 1** Read the Requirement Summary for each clause before assessing status. The summary is written in operational language, not ISO clause language — use it to assess what actually exists in the business today.
- 2** For Status: mark Running only if the requirement is consistently followed in practice. Partial means it runs sometimes, or was implemented once but has drifted. Not Started means it does not exist in any functional form.
- 3** For Evidence Available: mark Yes only if a physical document or record can be retrieved and shown to an external auditor within one hour without searching. 'We did train people but there are no records' = No.
- 4** For each Partial or Not Started row: write the Gap Description in one sentence, then estimate the hours required to close the gap to Running + Evidence status. Be specific: 'write calibration log template + backfill last 3 months = 6 hours' is more useful than 'need to document.'
- 5** Sort your filled-in rows by estimated hours, ascending. The rows at the top are this quarter's action list. The rows at the bottom are next quarter's, after you have built momentum from the easy wins.
- 6** Run the same sheet again 6 months later. Any row that is still Partial or Not Started after being on the action list for two consecutive periods has a structural obstacle — find it and name it, do not just re-list it.

Example Use

A mid-sized garment manufacturer with 85 employees is 18 months from a planned ISO 9001 certification. The owner runs this gap analysis for the first time before commissioning a consultancy.

Cl.8.5 (Production and service provision) is assessed as Running — IPQC checklists exist, SOPs are posted, shift records are maintained. Evidence: yes. No gap action needed.

Cl.7.2 (Competence and training records) is assessed as Partial. Operators are trained, but the only records are handwritten notes in a desk drawer with no dates or signatures. Gap: training register does not exist in an auditable format. Estimated hours to close: 8 hours (design simple register template, enter names and dates from memory for the last 12 months, get operators to sign). Low-hanging fruit — added to this quarter's action list.

Cl.9.1 (Monitoring, measurement, and analysis) is assessed as Not Started in terms of the formal KQI monthly report. FPY and defect rate are tracked but never compiled into a monthly summary that management formally reviews. Gap: no documented management review meeting. Estimated hours: 15 hours to design the report template, run first review meeting, and document the meeting minutes. Still under the 20-hour threshold.

Cl.8.3 (Design and development) — marked N/A with a note: the business manufactures to client specifications only. No in-house product design occurs. This clause is documented as not applicable with a one-paragraph rationale, which is itself an auditable record.

After filling all 12 rows: 4 rows are Running + Evidence, 5 are Partial, 2 are Not Started, 1 is N/A. Total estimated hours for all Partial + Not Started gaps: 94 hours. Consultancy quote comes in at \$3,200 for gap closure assistance. The owner closes the 5 Partial gaps independently (estimated 37 hours) before engaging the consultancy for the more complex Not Started items. Consultancy scope is reduced and quoted lower as a result.

Reflection Prompts

After filling in the worksheet on the previous page, work through these.

1. Clause rows to fill: Cl.4.1 Understanding the organization. Cl.4.2 Understanding interested parties. Cl.5.1 Leadership commitment. Cl.6.1 Risk and opportunity planning. Cl.7.1 Resources (people, infrastructure, environment). Cl.7.2 Competence and training records. Cl.8.1 Operational planning and control. Cl.8.3 Design and development (if applicable). Cl.8.4 Control of external providers (IQC + vendor scorecard). Cl.8.5 Production and service provision (IPQC + SOPs). Cl.10.2 Nonconformance and corrective action (NCR + CAPA). Cl.9.1 Monitoring, measurement, analysis (KQI monthly reports).

2. For every row marked Partial or Not Started: estimate the time to close the gap in person-hours, not months. Gaps that take under 20 hours are low-hanging fruit regardless of complexity. Prioritize those first — they clear audit findings cheaply and build momentum for the harder ones.

3. Column 4 check: 'Evidence Available?' means a document or record that exists right now and can be shown to an auditor within one hour. If the answer is 'we do this but haven't written it down,' that is the same as Not Started for audit purposes.

Tips and Traps

TIPS

- Run this analysis before calling a consultancy. The consultancy's opening question is this exact assessment — doing it yourself first reduces billable hours and gives you negotiating clarity on scope.
- Mark N/A explicitly for clauses that genuinely do not apply to your business model. A blank row looks like a gap. An N/A with a one-sentence rationale is an auditable record.
- The 20-hour threshold is not arbitrary. Gaps under 20 hours can typically be closed by one person in one concentrated work week. Gaps over 20 hours need scheduling, resourcing, and a plan. Sequencing the under-20s first builds momentum.
- If 'Evidence Available?' is consistently No across all Running rows, the quality system exists but is not documented. That is a Level 2 condition, not a Level 3 readiness — the priority is documentation, not new implementation.

TRAPS

- Marking a clause Running because someone on the team says 'we do that.' Running means it is done consistently, by everyone who should do it, with a record that proves it. One person's practice is not a system.
- Estimating gap closure in months rather than hours. Months are a planning unit, not a work unit. Hours can be scheduled on a calendar. 'Three months to close this gap' means it will not happen unless hours are explicitly allocated.
- Using this worksheet to check certification readiness rather than readiness to run a better system. Certification is a byproduct of a system that actually works. A business that builds the system to pass the audit will pass the audit and then watch the system erode.

Appendixes

Appendix A – Clause Quick Reference (Plain Language)

- Cl.4.1 : Do you know what internal and external factors affect your QMS?
- Cl.4.2 : Do you know who has a stake in your quality (customers, regulators, suppliers) and what they need from you?
- Cl.5.1 : Does leadership actively drive the quality system, or just authorize it?
- Cl.6.1 : Have you identified risks and opportunities for the QMS?
- Cl.7.1 : Do you have adequate people, infrastructure, and environment to run QC?
- Cl.7.2 : Are operator competencies defined and training records maintained?
- Cl.8.1 : Are operations planned and controlled with documented criteria?
- Cl.8.3 : If you design products: is design review, verification, validation documented?
- Cl.8.4 : Do you control external providers (IQC, supplier scorecard, approved lists)?
- Cl.8.5 : Are production/service processes controlled with SOPs, IPQC, traceability?
- Cl.9.1 : Do you monitor KQIs and analyze them at regular management reviews?
- Cl.10.2 : Are nonconformances (NCRs, complaints) logged with CAPA and closure?

Appendix B – Minimum Evidence per Clause

- Cl.4.1 : One-page context analysis document, dated and signed.
- Cl.4.2 : Stakeholder register or equivalent list with needs mapped.
- Cl.5.1 : Signed quality policy; meeting minutes from at least one management review.
- Cl.6.1 : Risk register with at least 5 entries, owner, and planned response.
- Cl.7.1 : Resource list with maintenance and calibration records for critical tools.
- Cl.7.2 : Training register with dates, topics, and operator signatures.
- Cl.8.1 : SOPs for critical process stages + production records showing compliance.
- Cl.8.3 : Design review records (if applicable); N/A rationale if not.
- Cl.8.4 : Approved supplier list + IQC receiving records + vendor scorecard.
- Cl.8.5 : IPQC records + lot traceability from IQC through final inspection.
- Cl.9.1 : Monthly KQI report (at least 3 months) + management review meeting minutes.
- Cl.10.2 : NCR log + CAPA log with closure dates and effectiveness verification.



CONFIRMATION

WHERE THIS WORKSHEET COMES FROM

Quality Control Systems

Consistent Quality Is the Result of a System, Not Inspection

by Ibrahim Anwar

This worksheet is one of nine in the *Quality Control Systems* companion worksheet pack. The full pack is grouped into three categories: high-volume worksheets you can run weekly, niche-search worksheets for rare but high-value situations, and specific-case worksheets that walk you through a single concrete scenario.

Every framework, decision filter, and figure used in these worksheets is drawn from the chapters of the source book. The book sets the diagnosis, the worksheets give you the form to act on it.

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