1 Introduction

Everything you need to demonstrate systematic context analysis, stakeholder management, and risk-based thinking. Built around ISO 9001:2026, each register maps directly to a specific clause, with scoring methodologies aligned to ISO 31000:2018 risk management guidelines. Formula-driven analysis, power scores, influence bands, suggested strategies, risk movement, days open, and review due dates are all automatically calculated, with no manual lookups required.

2 What's in the Toolkit

The compliance toolkit provides everything you need to implement a scored, traceable approach to ISO 9001:2026 Clauses 4.1 (Organisational Context), 4.2 (Interested Parties), and 6.1 (Risks and Opportunities). It consists of three register workbooks, three guidance documents, three procedure documents, three analysis form templates, and an interactive HTML dashboard that brings Excel spreadsheet data to life.

3 How the Registers Connect

Three linked registers create one unified framework. Internal and external context issues and stakeholder expectations flow into risk and opportunity identification and assessment. The linked registers provide full traceability from Clause 4.1 through to Clause 6.1, with outputs to management review. The three registers form a linked chain. Understanding this flow is key to getting the most from the toolkit:

1. Context Register	→	2. Interested Parties	→	3. Risk Register
Identify internal and external issues that affect your quality management system (QMS). 19-column scored register for internal and external issues. Auto-routes to SWOT, PESTLE, or competitor analysis based on issue source. Includes Scoring Matrix worksheet. **Clause 4.1**		Identify stakeholders whose needs and expectations affect your QMS. 22-column scored register for stakeholder assessment. Auto-populates strategy and objectives based on Priority × Relevance scoring. Includes Scoring Matrix worksheet. **Clause 4.2**		Assess risks and opportunities arising from contextual issues and stakeholder requirements. 33-column register with pre/post-control scoring, automated exposure analysis, risk movement tracking, and seven analysis worksheets, including Dashboard and Risk Distribution. **Clause 6.1**

The linkage mechanism: Each register has a "Linked Risk Ref" column. When a context issue or interested party scores 13 or above (High or Very High), it should be formally assessed in the Risk Register. The Linked Risk Ref column records the cross-reference (e.g., RO17, RO32), creating full traceability from context through stakeholders to risk treatment.

4 Quick Start — Setup in 5 Steps

Follow these steps to configure the toolkit for your organisation. You can complete this initial setup in a single session. Read the guides, adopt and deploy the procedures, and customise the registers before populating any data.

Step 1: Customize Your Process Names

All three registers use a shared process/department list. Edit the process names to match your organisation's structure:

- **Context Analysis Register:** Cell B89 in the Context Register sheet

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- **Inputs:** Context Register (Phase 1 outputs), IP Register (Phase 2 outputs), incident reports, customer complaints, audit findings, process performance data.
- **Outputs:** Populated F0611-01 Risk Register with pre/post-control scoring. Treatment plans with owners and timescales. Cross-references back to source registers.

Seq	Type	Component	Action/Purpose
3.1	Form	**F0611-02 Opportunity Evaluation Form**	Formally evaluate identified opportunities before adding them to the register (Clause 6.1.3). Assess feasibility, required resources, expected benefits (the desired effect), and alignment with quality objectives.
3.2	Register	**F0611-01 Risk & Opportunity Register**	Enter all risks and opportunities. Include escalated items from Context (score 13+) and IP (score 13+) registers, plus additional risks from brainstorming, incident review, and customer feedback. Complete identification columns (A–K), score pre-control Likelihood (M), and Impact (N). Define Actual Control (R), Mitigation Response (S), Mitigation Plan (T), Objectives (U), Opportunities (V), Owner (W). After implementation, score Post-Control Likelihood (X) and Post-Control Impact (Y). Enter cross-reference back to Context Column S and IP Column V.
3.3	Dashboard	**Risk_and_Opportunity_Dashboard.html (R&O Metrics tab)**	Upload the XLSX file. Review all 16 charts: pre/post heat maps, exposure doughnuts, risk score movement butterfly, control effectiveness, by-process analysis, type and source distribution, top 10 residual risks, and status breakdown.
3.4	Gantt	**Risk_and_Opportunity_Dashboard.html (Gantt tab)**	Upload the XLSX file. Review the timeline: status-coloured bars (green=Closed, blue=Monitoring, amber=In Treatment, red=Open), TODAY line, review due markers (purple diamonds), overdue indicators. Sort by the date raised, reference, pre-score, residual score, status, process, or days open.
3.5	Table	**Risk_and_Opportunity_Dashboard.html (Register tab)**	Upload the XLSX file. Share the 21-column sortable, filterable table. Filter by Type (Risk/Opportunity), Status, Process, or Exposure. Use free-text search to find specific entries.

1. **Review context and the interested parties register outputs.** Any context issue or interested party scoring 13+ must be entered in the F0611-01 Risk Register.
2. **Identify additional risks and opportunities** through brainstorming, process analysis, incident review, past audit results, and customer feedback.
3. **For each risk, complete identification columns (A–K), then score pre-control Likelihood (M) and Impact (N). Include risks to the provision of conforming products during and after a disruption, and keep treatment proportionate to the potential impact (Clause 6.1.2). Include risks to the provision of conforming products during and after a disruption, and keep treatment proportionate to the potential impact (Clause 6.1.2).**
4. **Define treatment:** Actual Control Measure (R), Mitigation Response (S), Mitigation Plan with timescales (T), Objectives (U), and Opportunities (V). Assign an Owner (W).
5. **After implementing controls,** score post-control Post-Control Likelihood (X) and Post-Control Impact (Y) to confirm the residual risk is acceptable.

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