

Corrective Action

ISO 9001:2026 Edition

SAMPLE

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- 4. Pharmaceutical, biotech, and combination products: GMP/GxP CAPA programme; deviations log; data integrity (ALCOA+) for CAR records; Qualified Person oversight; periodic Quality Reviews trend the CAR data.
- 5. Connected-product cybersecurity: EU Cyber Resilience Act vulnerability remediation; PSTI Act 2022 for consumer connectable products; ISO/SAE 21434 cybersecurity corrective action for road vehicles.
- 6. Consumer products: UK GPSR/EU GPSR safe-product obligations; OPSS/RAPEX notification; Consumer Rights Act 2015 remedies; Consumer Protection Act 1987 product-liability defence — complete CAR records support the defence.
- 7. Customer-flowed-down corrective-action obligations: Customer Quality Agreements that mandate notification cadence, format, and channel; customer-portals (automotive supplier portals, aerospace prime portals); shared-CAR commercial regimes.
- 8. Public-sector: Procurement Act 2023/PCR 2015 corrective-action obligations under public-contract terms; FOI-compatible CAR records where applicable; ICO/regulator engagement records.
- 9. Climate-related corrective action (ISO 9001:2026 Clause 4.1): where climate change is determined relevant per F0410-01, energy/carbon/resource-efficiency deviations are eligible CAR triggers; disposition decisions consider end-of-life and circular-economy implications (re-manufacture preferred over scrap where feasible).

1.3 Roles, Responsibilities & Authorities

Regardless of organisational structure or corrective-action scope, the roles below are agreed by Top Management and incorporated into existing job descriptions. The Authority Matrix (F0530-02) records the named individual holding each role at any point in time; the RACI Matrix (F0530-03) records the activity-level responsibility allocation across the corrective-action process.

Sectoral mandated roles, including Qualified Persons in pharmaceutical contexts, the Person Responsible for Regulatory Compliance (PRRC) under EU MDR, ITAR Empowered Officials, customer-mandated quality representatives, and Notified-Body liaison contacts, are appointed alongside these roles where corrective action falls within a regulated sector, and act through the appropriate role below.

1.3.1 Top Management

Top Management are accountable for the corrective-action programme and are responsible for:

- Approving QMS changes arising from corrective action under P0630-01;
- Approving resource allocation to address systemic root causes;
- Authorising regulator-facing corrective-action submissions where required;
- Reviewing corrective-action KPIs at management review under P0930-01;
- Acting on adverse trends and approving escalations to deeper RCA;
- Approving corrective actions for safety-critical, regulated, or recall-driven CARs above the documented threshold.

1.3.2 Process Owner

The Process Owner (typically the Quality Director or Head of Quality) is accountable for the corrective-action process as a whole, and is responsible for:

- Maintaining this procedure and ensuring it remains aligned with ISO 9001:2026 (as amended), customer-flowed-down requirements, and applicable sectoral regulation;
- Owning the CAR-category taxonomy in §1.2 and updating it when the QMS scope or regulatory context changes;
- Resolving cross-functional process issues raised by the Quality Manager, Initiators, Process Owners, Operations Manager, Supervisors, Customer Services, Internal Audit, or Information Security;
- Reviewing the KPIs in §1.5 and proposing changes to thresholds, frequency, or KPI selection at management review.

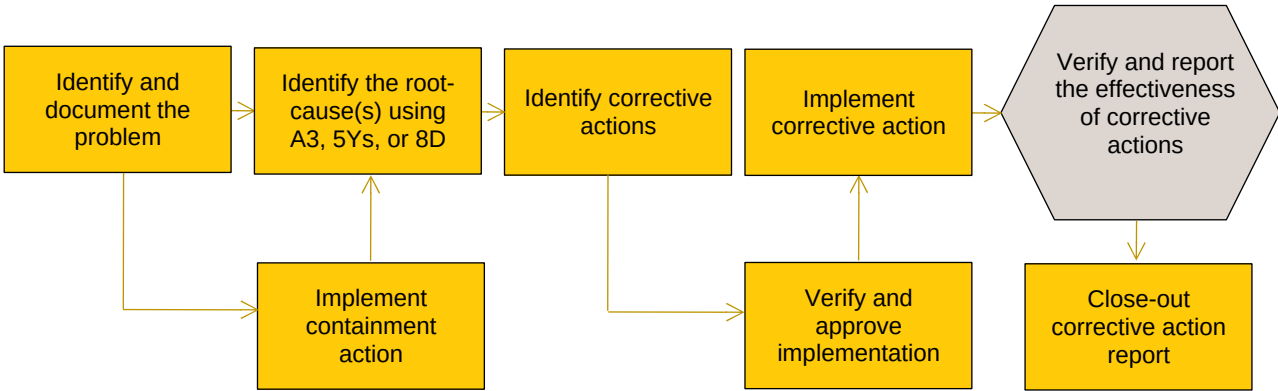
1.3.3 Quality Manager

The Quality Manager is responsible for the day-to-day operation of the corrective-action process:

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Based upon the information captured from the *Corrective Action Report*, the *Corrective Action Tracker* prompts the user to use 1 of 4 increasingly detailed problem-solving methods (e.g., OFI improvement form, A3, 5-whys, or 8D), depending on the severity or complexity of the nonconformity.

This ensures that the appropriate tools and techniques are applied for problem-solving and formulating corrective action.

1.4.2 Define the Problem

Senior Management will be actively involved in any major corrective actions, ensuring that all actions agreed by any multi-functional teams are carried out entirely. Major corrective actions and improvements are placed on the continual improvement programme and reported at Top Management review meetings.

A corrective action report form is issued for repetitive, ongoing problems during our production processes and issues that majorly impact customer end product delivery and quality management system noncompliances. Other nonconformities outside these criteria are controlled through the remedial action system. All corrective action reports raised are categorized as follows:

High - A problem that results in major/significant impact or is repetitive. Requires a root-cause analysis, corrective and preventative action(s)
Medium - A problem that results in moderate impact. Requires containment and root-cause analysis, and corrective actions when appropriate
Low - A low-level problem requiring cause analysis, containment, and a structured action plan
OFI - Improvement opportunity that does not need correction but instead can be enhanced, improved, or made more efficient

The Quality Manager will review any issues raised and update the nonconformity report to identify the cause and the level of action required. Repeated nonconformities of the same nature or significant deviations from procedures or policies are reported to Top management for action and resolution. The Quality Manager is responsible for:

- 1. Identifying the root cause(s) of the nonconformity;
- 2. Identifying appropriate corrective actions (including modifying or creating new work practices);
- 3. Planning and implementing corrective actions;
- 4. Verifying the close-out and effectiveness of corrective actions;
- 5. The Quality Manager verifies the implementation of corrective actions;
- 6. Where noncompliances are identified outside the audit process, the Quality Manager or designee documents this using the *Corrective Action Report* form as appropriate.

Where applicable, any corrective action taken and controls implemented to eliminate the cause of nonconformity are applied to other similar processes and are controlled by the Quality Manager in liaison with affected process owners. Significant actions are entered into the *Corrective Action Tracker*.