Supplier Corrective Action Request (SCAR) Template - Official Clinical Overview & Technical Datasheet

SUPPLIER CORRECTIVE ACTION REQUEST (SCAR) TEMPLATE - OFFICIAL CLINICAL OVERVIEW & TECHNICAL DATASHEET

EXECUTIVE SUMMARY

This document serves as the definitive technical reference and operational datasheet for the Supplier Corrective Action Request (SCAR) Template, a critical quality management instrument deployed within the medical aesthetic device supply chain ecosystem. Designed to align with the rigorous demands of ISO 13485:2016 and 21 CFR Part 820, this standardized template provides a structured, auditable framework for documenting, investigating, and resolving non-conformances originating from external suppliers. The template acts as a pivotal closed-loop corrective and preventive action (CAPA) tool, ensuring that deviations in raw materials, sub-assemblies, or finished components are systematically addressed to maintain the highest standards of patient safety, device efficacy, and regulatory compliance. This datasheet details the template's architecture, functional specifications, key performance indicators, and its integral role in safeguarding the integrity of the medical device manufacturing process.

CLINICAL ARCHITECTURE & DESIGN

The SCAR Template is architecturally engineered to facilitate a methodical and rigorous investigation process, moving from problem identification through to permanent corrective action and verification. Its design is rooted in a phase-gate process that ensures no step in the resolution pathway is overlooked. The primary architectural components are delineated as follows:

1. PROBLEM IDENTIFICATION & INITIAL TRIAGE: This initial section captures the essential metadata of the non-conformance. It requires the user to define the specific nature of the defect, the associated part number, the quantity affected, and the immediate risk assessment to both manufacturing operations and, ultimately, the end-user patient. An embedded algorithm triggers an escalation protocol based on the severity classification (Critical, Major, or

Minor), with Critical defects requiring immediate executive-level review and potential lot containment.

2. DETAILED NON-CONFORMANCE DESCRIPTION & DATA CAPTURE: This module provides a structured field for a comprehensive, objective description of the failure mode. It mandates the inclusion of objective evidence, such as links to non-destructive testing (NDT) reports, dimensional measurement data, or material analysis certificates. The design encourages the '5 Whys' methodology, guiding the user to move beyond symptoms and begin exploring root cause factors.

3. ROOT CAUSE ANALYSIS (RCA) INVESTIGATION: This is the analytical core of the template. It provides a structured framework for conducting a comprehensive RCA. It includes a multi-select matrix for the primary cause category (e.g., Material Defect, Process Error, Design Mis-Specification, Supplier Process Drift) and a dedicated field for the detailed analytical narrative. The template's design integrates a robust corrective action plan section, differentiating between immediate containment actions and long-term, permanent corrective actions, each with assigned ownership and due dates. A key feature is the mandatory validation protocol for corrective actions, requiring evidence of effectiveness, such as three consecutive lots passing all quality checks.

4. FINAL VERIFICATION & CLOSURE: The final architecture component serves as the quality assurance gate. It requires sign-off from the Supplier Quality Engineer (SQE) and, where applicable, a representative from the supplier. This section verifies that all corrective actions have been successfully implemented and validated, that the non-conformance is fully resolved, and that all lessons learned have been formally documented and integrated into the quality management system to prevent recurrence.

KEY INDICATIONS & CAPABILITIES

The primary capability of the SCAR Template is the systematic reduction of supplier-related quality risks. Its deployment allows the organization to:

- Establish a standardized, corporate-wide language for communicating quality issues to suppliers, eliminating ambiguity and ensuring a uniform response process.
- Create a robust audit trail for regulatory bodies (FDA, Notified Bodies), demonstrating proactive and effective supplier quality management.
- Aggregate and analyze SCAR data to identify recurring supplier quality trends, allowing for targeted supplier development programs and risk-based re-evaluation of the approved supplier list.

- Facilitate effective root cause analysis, moving beyond superficial corrections to implement permanent solutions that prevent recurrence of non-conformances.
- Enhance the overall quality and reliability of the final medical aesthetic device, ensuring consistent treatment outcomes and minimizing device failures or adverse events in the field.

COMPLIANCE & STANDARDS

This SCAR Template is meticulously aligned with the following international medical device standards and regulations:

- ISO 13485:2016 (Medical devices – Quality management systems – Requirements for regulatory purposes): Specifically addressing Section 7.4.1 on Purchasing and 8.5.2 on Corrective Action.
- 21 CFR Part 820 (Quality System Regulation): Compliant with Subpart G (Purchasing controls) and Subpart J (Corrective and preventive action).
- ISO 9001:2015 (Quality management systems – Requirements): Aligned with the principles of risk-based thinking and continuous improvement.
- Global Medical Device Nomenclature (GMDN) & UDI (Unique Device Identification) Integration: The template includes dedicated fields to capture the UDI-DI and GMDN codes, ensuring seamless traceability of affected

components to the final medical device.

TECHNICAL SPECIFICATIONS

The template's functional and operational specifications are defined to ensure its efficacy across various supply chain scenarios. The technical specifications are as follows:

Document ID Generation: Autonomously generates a unique, time-stamped alphanumeric identifier (e.g., SCAR-YYYY-XXXXX) to ensure global traceability.

Version Control: Maintains a rigorous document revision history (Version X.X) with a summary of changes, ensuring that only the current approved template version is utilized.

Field Categorization: Fields are distinctly color-coded based on required inputs (e.g., mandatory, conditional, and reference fields) to streamline completion and reduce errors.

Data Integrity & Security: Adherence to data integrity principles (ALCOA+ - Attributable, Legible, Contemporaneous, Original, Accurate, Complete, Consistent, Enduring, and Available). Access is controlled via a secure, permission-based system, limiting access to authorized personnel.

Format & Delivery: Provided as a Microsoft Excel or a controlled PDF-based electronic form, enabling easy data entry, automated calculations (e.g., defect

count, total PPM), and integration with existing enterprise quality management software (EQMS).

Parameter	Specification
Document ID Format	SCAR-YYYY-XXXXX (Autogenerated)
Template Version	V3.0 / Revision Date: Current Year
Field Complexity	Structured with 30+ data fields divided into 4 core modules
Supported Languages	English, German, French, Spanish, Japanese
Integration Protocol	API-ready for EQMS, SAP, and Oracle Systems
Audit Trail	Full traceability with electronic signature and timestamping

CLINICAL PROTOCOLS

The implementation of the SCAR Template is governed by a detailed standard operating procedure (SOP). The following outlines the mandatory, step-wise clinical and operational protocol for its effective execution:

1. SCAR INITIATION: Upon detection of a non-conforming material during incoming inspection, in-process manufacturing, or from field feedback, the quality engineer initiates a SCAR. This includes populating the template with the complete non-conformance data.

2. SUPPLIER NOTIFICATION & PRELIMINARY INVESTIGATION: The SCAR is formally issued to the supplier via a secure portal or encrypted email. The supplier is required to acknowledge receipt and provide a preliminary containment plan for the affected materials within a specified time frame (e.g., 48 hours).

3. ROOT CAUSE ANALYSIS & CORRECTIVE ACTION PLAN SUBMISSION: The supplier is obligated to conduct a thorough RCA (using tools such as 8D, Fishbone Diagram, or 5 Whys) and submit a documented corrective action plan (CAP) for approval. The CAP must include specific, measurable, achievable, relevant, and time-bound (SMART) actions.

4. CAP IMPLEMENTATION & EVIDENCE OF EFFECTIVENESS (EOE): Upon approval, the supplier executes the CAP. The SCAR requires the submission of objective evidence to demonstrate the effectiveness of the implemented corrective actions. This evidence can include, but is not limited to, updated process flow charts, new inspection protocols, operator training records, and

results from on-site audits.

5. FINAL REVIEW & CLOSEOUT: The SQE reviews the submitted EOE. The SCAR is marked as 'Closed' only when all corrective actions have been successfully verified and the risk has been mitigated to an acceptable level. The entire lifecycle of the SCAR, from initiation to closure, is tracked and measured against defined Key Performance Indicators (KPIs), such as SCAR Aging, First-Time Yield rates by supplier, and SCAR Recurrence Rates.