



Medical Device Supplier Quality Kit

Risk-based supplier qualification, quality agreements, monitoring and SCARs.

What's inside

File	What it is / how to use it
01_Medical_Supplier_Quality_Workbook.xlsx	Approved supplier list with risk-based audit intervals, scorecard and SCAR log.
02_Supplier_Control_Procedure.docx	Risk-based purchasing procedure.
03_Quality_Agreement_Template.docx	Quality agreement template.
04_SCAR_Form.docx	SCAR form.

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About the author

Built by Matt Norman, US Navy veteran and former SpaceX Falcon 9 quality inspector and QA supervisor. (Not affiliated with or endorsed by SpaceX.) Norman Quality Tools is Veteran-Owned & Operated. Contains no SpaceX, government, or customer proprietary information; all example data is made up.

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Supplier Control Procedure

Medical Device Supplier Quality Kit - Document 02 - Rev A (2026-10)

1. Purpose and scope

Control suppliers in proportion to the risk their product or service poses to device safety and performance (ISO 13485 clause 7.4; 21 CFR 820 via QMSR).

2. Responsibilities

Role	Responsibility
Quality manager	[Define]
Approver	[Define]

3. Procedure

1. Classify supplier risk (High/Medium/Low) from product criticality.
2. Qualify: questionnaire, certificates, audit (High), first article.
3. Sign a quality agreement for critical suppliers.
4. Monitor with the scorecard quarterly; issue SCARs as needed.
5. Re-evaluate on the interval in the ASL; disqualify when needed.

4. Records

- ASL
- Qualification records
- Quality agreements
- Scorecards
- SCARs

5. Revision history

Rev	Date	Change	Approved

Role	Name	Signature	Date
Prepared by			
Approved by			

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