QUALITY EXCELLENCE SERVICES

Quality Excellence Services
18 Maple Avenue, Ste. 148
Barrington, RI 02806
United States of America
+1 (401) 246-3204 · +1 (401) 252-9653
mweeden@qesisbest.com · https://QESisBest.com

STANDARDS & GUIDANCE BRIEF · UNITED STATES · REGULATION

21 CFR Part 806

Medical Devices; Reports of Corrections and Removals

DOCUMENT	QES-WP-108, Rev B	DATE	November 7, 2026
ISSUED BY	US Food and Drug Administration	PREPARED BY	Conner Davidson
EDITION	Current as published in the eCFR	STATUS CHECKED	October 24, 2026
INDUSTRIES	Medical Devices	ONLINE	qesisbest.com/standard-21-cfr-806.html

IN FORCE In force and unchanged by the QMSR.

What It Covers

What must be reported to FDA when a manufacturer or importer corrects or removes devices already in the field, and what must be recorded when no report is required.

Who It Applies To

Device manufacturers and importers.

Key Requirements

- A written report within 10 working days of starting a correction or removal made to reduce a risk to health, or to remedy a violation that may present a risk to health (§806.10).
- A record kept for corrections and removals that do not need reporting, with the reason (§806.20).
- Routine servicing, stock recoveries and market withdrawals are outside the reporting duty, but should be documented as such.

What an Auditor Asks to See

- The decision record for each field action: reportable or not, and why.
- Reports filed within 10 working days, with their content.
- Links between the field action, the CAPA, and the complaint trend that triggered it.

Where Systems Fall Short

- Field actions labeled "market withdrawal" without a documented health-risk assessment.
- No record kept for the actions that were judged not reportable.

How QES helps. A field-action procedure that forces the health-risk decision and records it either way. See the gap assessment: qesisbest.com/services.html#gap-assessment · +1 (401) 246-3204 · mweeden@qesisbest.com

Sources, checked October 24, 2026. eCFR — 21 CFR Part 806 — www.ecfr.gov/current/title-21/part-806.

A summary for orientation, prepared by Quality Excellence Services. It does not reproduce or replace the standard or regulation: read the official text, which governs. Not legal advice.