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STANDARDS & GUIDANCE BRIEF · UNITED STATES · REGULATION

# 21 CFR Part 803

Medical Device Reporting

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| DOCUMENT | QES-WP-107, 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-803.html |

**IN FORCE** In force and unchanged by the QMSR. Manufacturers and importers file reports electronically (eMDR).

## What It Covers

When device manufacturers, importers and user facilities must tell FDA about deaths, serious injuries and malfunctions, and what they must keep on file.

## Who It Applies To

Manufacturers and importers of devices marketed in the US, and device user facilities such as hospitals and nursing homes, each with their own duties.

## Key Requirements

- Manufacturers report deaths and serious injuries within 30 calendar days of becoming aware.
- Malfunctions that would be likely to cause or contribute to death or serious injury if they recurred are also reported within 30 days.
- Five-work-day reports where remedial action is needed to prevent an unreasonable risk of substantial harm, or when FDA asks.
- Written MDR procedures (§803.17) and MDR event files (§803.18).

## What an Auditor Asks to See

- The MDR procedure and who decides reportability.
- Complaint files showing the date of awareness and the reportability decision with its reasoning.
- Submitted eMDRs and evidence they were on time.

## Where Systems Fall Short

- The "became aware" date never recorded, so timeliness cannot be shown.
- Malfunction reportability judged differently from one complaint to the next.

**How QES helps.** Complaint and MDR procedures rebuilt so every decision is dated, reasoned, and trended. 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 803 — www.ecfr.gov/current/title-21/part-803.

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