



Complaint Handling & MDR Kit

Log, investigate, decide reportability and trend complaints.

What's inside

File	What it is / how to use it
01_Complaint_Intake_and_Investigation_Forms.docx	Intake with aware date, screening questions, investigation and closure.
02_MDR_Reportability_Decision_Tree.docx	4-step 21 CFR 803 decision tree, clocks, decision record.
03_Complaint_Log_and_Trending.xlsx	Log with automatic 30-day / 5-workday due dates and overdue flags; monthly category trending per 1,000 units with alert rule.

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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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Complaint Intake & Investigation

Complaint Handling & MDR Kit - Document 01 - Rev A (2026-10)

Complaint intake

A complaint is any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device after it is released for distribution (21 CFR 820.3 / ISO 13485 definition, summarized).

Complaint #		Date received / aware date (day 0)	
Received by / channel		Complainant name & contact	
Facility / user facility?		Device, model, catalog #	
Lot / serial / UDI-PI		Date of event	
Patient involved? Injury? Death?		Device available for return?	

Event description (complainant's words)

Initial screening (within 1 business day)

Question	Y / N
Possible death or serious injury?	
Malfunction that could cause death/serious injury if it recurred?	
Possible 5-day report trigger (remedial action needed to prevent unreasonable risk / FDA request)?	
Other markets affected (EU vigilance etc.)?	

Any Y: go to 02_MDR_Reportability_Decision_Tree immediately; start the clock from the aware date.