

Medical Device Complaint Trend Review Checklist

Complaint Pattern

- Are the complaints describing the same or related failure?
- Are they consistently coded and grouped?
- Has the complaint count changed from the historical baseline?

Exposure & Severity

- Has the complaint rate changed?
- Has product exposure changed?
- Has severity increased?
- Is there a lot, supplier, market or user pattern?

Cross-Functional Review

- Do service, manufacturing, supplier or PMS records show a similar pattern?
- Has the issue occurred after corrective action?
- Are existing risk controls still effective?

Escalation

- Does the pattern require additional investigation?
- Should CAPA or risk management be considered?
- Is supplier, engineering or PMS involvement needed?
- Is regulatory or field-action assessment required?
- Is the decision documented and assigned?