Elexes

POST-MARKET REVIEW / 18 CHECKS

# Complaint and Post-Market Quality Checklist

Connect feedback, investigation, surveillance and follow-up.

Device / markets: _____ Reviewer / date: _____

Tick when verified. Reference the evidence and assign the highest-priority action.

## 01 Intake and identification

- ☐ Capture source, receipt date and device identifiers.
- ☐ Assess feedback against the complaint definition.
- ☐ Define intake routes, owners and escalation responsibilities.

## 02 Assessment and reporting

- ☐ Assess safety concerns, affected scope and markets.
- ☐ Document reportability decisions and applicable due dates.
- ☐ Escalate urgent issues without waiting for case closure.

## 03 Investigation and records

- ☐ Collect relevant evidence and technical inputs.
- ☐ Justify any decision not to investigate as applicable.
- ☐ Retain findings, communications and closure approvals.

## 04 Surveillance planning

- ☐ Define device scope, data sources and responsible roles.
- ☐ Plan proactive and reactive collection and review methods.
- ☐ Link findings to risk, clinical evidence and required outputs.

## 05 Trending and review

- ☐ Use consistent codes and verify data completeness.
- ☐ Define indicators, thresholds and review intervals.
- ☐ Evaluate signals with relevant use or exposure context.

## 06 Actions and follow-up

- ☐ Assess CAPA, risk-update and field-action needs.
- ☐ Track actions, communication and effectiveness as needed.
- ☐ Feed outcomes into surveillance and management review.

**Priority gap / evidence reference:**

**Action / owner / due date:**