Header

Title: Improving CAPA Efficiency Through Data Governance and Workflow Visibility
Product Line: Cross-Portfolio
Related Project: CAPA Ageing Reduction Initiative
Primary Teams: Quality, Post Market Surveillance
Document Type: Lessons Learned
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Context

A post-market initiative aimed to reduce CAPA ageing revealed systemic inefficiencies in workflow visibility, ownership clarity, and data integrity across complaint and investigation processes.

Observed Patterns

- High CAPA ageing was correlated with incomplete or inconsistent data entry.
- Manual backlog reduction created temporary improvement but did not address root causes.
- Cross-functional ownership gaps increased investigation cycle time.
- Lack of real-time visibility delayed escalation of high-severity issues.

Root Causes Identified

- No standardised data entry enforcement across teams.
- Ageing metrics were not uniformly defined.
- Escalation thresholds were informal and inconsistently applied.
- Investigations relied on reactive monitoring rather than proactive dashboards.

Effective Interventions

- Centralised ageing dashboard integrated with TrackWise.
- Standardised investigation checklist to reduce documentation rework.
- Formalised escalation protocol for high-severity CAPAs.

- Governance cadence (weekly review meetings with clear accountability).

Generalised Lessons

1. Data quality is a prerequisite for process optimisation.
2. Visibility mechanisms reduce ageing more sustainably than manual task forces.
3. Cross-functional governance must be formalised early.
4. Metrics must be clearly defined before improvement initiatives begin.
5. Reactive backlog clearing is not a substitute for systemic redesign.

Applicability to Future Projects

These lessons are applicable to:

- Complaint handling improvements
- Investigation workflow redesign
- Dashboard or reporting initiatives
- Cross-functional post-market processes
- Any initiative involving distributed data ownership