Header

Project Name: CAPA Ageing Reduction Initiative
Product Line: Sleep Therapy Devices
Platform: Respironics Platform A
Primary Team: Quality
Supporting Teams: R&D, Post Market Surveillance, Regulatory Affairs
Project Phase: Post-Market

Timeline:
- Diagnostic Phase: Q1 2022 – Q2 2022

- Process Redesign: Q3 2022 – Q4 2022

- Dashboard Implementation: Q1 2023

- Stabilisation & Monitoring: Q2 2023 – Q3 2023

Document Type: Project History
Keywords: CAPA ageing, complaint backlog, workflow optimisation, dashboard implementation, cross-functional coordination

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Section 1 – Objective

Reduce average CAPA ageing time by improving investigation workflows, clarifying ownership, and increasing visibility into complaint trends and action status.

Section 2 – Current Status

CAPA ageing reduced by 32% compared to baseline.
Complaint-to-investigation transition time reduced.
Dashboard monitoring integrated into weekly Quality review meetings.

Section 3 – What Went Well

- Clear definition of ageing metrics (from CAPA open date to closure).
- Implementation of a centralised dashboard improved transparency.
- Weekly cross-functional review cadence improved accountability.

- Early identification of stalled investigations.

Section 4 – What Went Wrong

- Initial data inconsistencies across complaint and CAPA systems.
- Incomplete or delayed data entry from responsible parties during investigation updates.
- Ownership of investigations was unclear for cross-platform issues.
- Some corrective actions were delayed due to incomplete documentation.

Section 5 – Approaches Attempted

1. Manual backlog clearing by assigning temporary task force.
2. Automated ageing dashboard linked to TrackWise.
3. Revised escalation protocol for high-severity CAPAs.
4. Standardised investigation checklist to reduce rework.

Manual backlog clearing produced short-term improvement but was not sustainable.
Dashboard + escalation protocol produced sustained improvement.

Section 6 – Outcome

Average CAPA ageing reduced from 118 days to 80 days.
High-severity CAPAs now flagged automatically after 45 days.
Escalation ownership formalised within Quality governance.

Section 7 – Key Lessons

- Visibility drives accountability more effectively than manual intervention.
- Data standardisation must precede workflow optimisation.
- Cross-functional governance structures are critical in post-market processes.
- Temporary resource allocation does not solve systemic inefficiencies.