

Cross-Site Trend Alert — Filter Integrity Cluster

AMGEN — DEVIATION TREND INTELLIGENCE

Cross-Site Trend Alert Report

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Alert Level: HIGH

SUMMARY

A cluster of 10 filter integrity test failures has been identified across 4 Amgen manufacturing sites within a 3-month period. Semantic analysis reveals all 10 NCs share a common root cause: a formulation change by filter vendor Millipore (Vendor Z) effective November 2025.

CLUSTER COMPOSITION

ATO: 3 NCs (Equipment Malfunction category)

IRE: 2 NCs (Process Deviation category)

PR: 3 NCs (Filtration Failure category)

OH: 1 NC (Equipment Qualification category)

Note: Same failure mode filed under 4 different TrackWise dropdown categories.

ROOT CAUSE ANALYSIS

Vendor Z (Millipore) issued Formulation Change Notification FCN-VZ-2025-0892 in October 2025, modifying the membrane formulation of Durapore CVGL 0.22um filters. All 10 NCs occurred after the FCN effective date. 8 of 10 NCs trace to Lot VZ-2025-1847 (post-change lot).

EXISTING CAPA STATUS

CAPA-ATO-2025-0445: Partially effective (40% reduction, not eliminated)

CAPA-PR-2025-0892: OPEN — 33 DAYS OVERDUE

Neither CAPA addresses vendor formulation change as root cause.

RECOMMENDED ACTIONS

1. Place Vendor Z on qualification hold pending formulation review
2. Qualify alternative filter supplier (Sartorius or Pall)

3. Close overdue CAPA-PR-2025-0892 or escalate
4. Issue vendor audit request per SOP-VND-004

EVIDENCE PACKAGE

Attached: All 10 NC initiation forms, SAP MM procurement timeline, vendor FCN document, CAPA effectiveness data.

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