CS-Series Fleet Impact Assessment

AMGEN — DEVIATION TREND INTELLIGENCE

Fleet Impact Assessment

Generated by: Pace AI Agent

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Equipment: CS-Series Chromatography Skids

Priority: HIGH — Fleet-wide impact

AFFECTED EQUIPMENT

1. CS-OH-002 (Ohio) — Installed, AFFECTED by cleaning failure

2. CS-OH-003 (Ohio) — Installed, not yet validated, SAME DESIGN

3. CS-IRE-001 (Ireland) — On order, delivery Q3 2026

4. CS-PR-001 (Puerto Rico) — On order, delivery Q4 2026

DESIGN ISSUE

All CS-series units share identical valve manifold design with ~15cm dead-leg at V-204 junction. This dead-leg was documented in Operational Qualification (OQ-OH-CS-002, Section 4.3.2) but was not addressed in the cleaning validation protocol (VP-OH-CL-012).

IMPACT WITHOUT CORRECTION

• CS-OH-003: Will fail cleaning validation when qualified

• CS-IRE-001: Will fail cleaning validation after installation

• CS-PR-001: Will fail cleaning validation after installation

• Estimated rework per site: 3-6 months of validation activities

• Estimated cost per site: $200K-$500K in validation rework + production delays

PROACTIVE FIX

1. Update CS-series cleaning protocol template to include dead-leg flush at V-204

2. Issue Engineering Change Notice (ECN) to all receiving sites

3. Revalidate CS-OH-002 with updated protocol

4. Pre-qualify CS-OH-003 with corrected protocol before production use

5. Ensure CS-IRE-001 and CS-PR-001 receive corrected protocol at installation

COST AVOIDANCE: $600K-$1.5M across fleet (3 sites x $200-500K each)

TIME SAVINGS: 9-18 months of cumulative validation rework avoided