

Ohio Site Maturity Assessment — NC Rate Benchmarking

AMGEN — DEVIATION TREND INTELLIGENCE

Site Maturity Assessment

Generated by: Pace AI Agent

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Site: New Albany, Ohio (OH)

Maturity: 6 months (opened February 2024)

NC RATE ANALYSIS

Ohio NC rate: 2.4 NCs/batch

Network average (24-month maturity): 1.7 NCs/batch

Deviation from average: +40%

MATURITY-ADJUSTED BENCHMARK

Expected range at 6-month maturity: 2.0-2.5 NCs/batch

Assessment: WITHIN NORMAL RANGE for new site commissioning

NC BREAKDOWN (past 6 months)

Total NCs: 67

Equipment qualification: 42 (62%) — Expected for new facility

Cleaning validation: 12 (18%) — ELEVATED for cleaning specifically

Process deviations: 13 (20%) — Normal range

FOCUS AREA: CLEANING VALIDATION

Cleaning NCs are concentrated on CS-series chromatography skids (new to Amgen fleet).

Root cause: Valve dead-leg at V-204 documented in OQ but not in cleaning protocol.

This is a design-level gap, not an operator or procedure execution issue.

RECOMMENDATION

Overall site health is commissioning-normal. Focus corrective action narrowly on cleaning validation protocol for CS-series equipment. Do not treat elevated NC rate as a broad site quality concern.

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