

Non-Conformance Initiation Form — NC-OH-2026-0088

AMGEN — TRACKWISE QMS

Non-Conformance Initiation Form

NC Number: NC-OH-2026-0088

Site: New Albany, Ohio (OH) — New facility, opened February 2024

Date Filed: 2026-02-19

Classification: Major

Product: Lumakras (sotorasib)

Equipment: Chromatography Skid CS-OH-002

Event Description:

Cleaning validation failure on chromatography skid CS-OH-002. Post-cleaning rinse sample showed residual protein at 847 ppm vs acceptance limit of 500 ppm (69% above limit). Swab sample from valve V-204 junction showed highest concentration (1,240 ppm), suggesting dead-leg in flow path at this location.

Cleaning Protocol: VP-OH-CL-012

Rinse Sample Result: 847 ppm (limit: 500 ppm)

Swab V-204: 1,240 ppm

Swab V-201: 180 ppm (within spec)

Swab V-207: 95 ppm (within spec)

Immediate Actions:

1. CS-OH-002 removed from service pending investigation
2. Re-cleaning initiated with extended rinse cycle
3. Manufacturing scheduled on backup chromatography train
4. Engineering review of V-204 valve configuration requested