

Non-Conformance Initiation Form — NC-PR-2026-0447

AMGEN — TRACKWISE QMS

Non-Conformance Initiation Form

NC Number: NC-PR-2026-0447

Site: Juncos, Puerto Rico (PR)

Date Filed: 2026-02-18

Classification: Minor

Product: Prolia (denosumab)

Equipment: Bioreactor BR-PR-005 (2000L)

Event Description:

Dissolved oxygen (DO) dropped below validated range from 40% setpoint to 28% for approximately 12 minutes on Day 14 of cell culture. Recovery achieved after manual increase of sparging rate. No batch impact confirmed — titer results pending from LIMS.

Process Parameters:

DO Setpoint: 40%

Minimum Observed: 28%

Excursion Duration: 12 minutes

Culture Day: 14 (peak cell density phase)

Recovery Method: Manual sparging adjustment

Immediate Actions:

1. DO probe recalibrated — passed per SOP-CAL-018
2. Batch RPR-2026-0118 continued under enhanced monitoring
3. Additional DO samples collected for offline verification