

Non-Conformance Initiation Form — NC-ATO-2026-0915

AMGEN — TRACKWISE QMS

Non-Conformance Initiation Form

NC Number: NC-ATO-2026-0915

Site: Thousand Oaks (ATO)

Date Filed: 2026-02-18

Classification: Minor

Product: Aimovig (erenumab-aooe)

Equipment: Bioreactor BR-030-003, Suite 3

Event Description:

Temperature increased from 37.0C setpoint to 37.8C (+0.8C) over a 23-minute period during Night Shift B (02:15 to 02:38). Alarm was acknowledged by Operator EMP-4521 at 02:18 but response was delayed due to concurrent activity on adjacent reactor. Temperature returned to setpoint after manual cooling water valve adjustment.

This is the 3rd temperature NC in Bioreactor Suite 3 in 6 weeks:

NC-ATO-2026-0847: +0.5C (Jan 05)

NC-ATO-2026-0873: +0.6C (Jan 19)

NC-ATO-2026-0915: +0.8C (Feb 18) — THIS NC

Severity trend: INCREASING

Immediate Actions:

1. Manual cooling water valve override applied
2. Temperature returned to setpoint at 02:38
3. Batch AMV-2026-0089 continued under enhanced monitoring
4. Suite 3 escalated to enhanced surveillance