

Non-Conformance Initiation Form — NC-IRE-2026-1103

AMGEN — TRACKWISE QMS

Non-Conformance Initiation Form

NC Number: NC-IRE-2026-1103

Site: Dun Laoghaire, Ireland (IRE)

Date Filed: 2026-02-17

Classification: Major

Product: Enbrel (etanercept)

Area: Grade B Cleanroom, Room 204

Monitoring Point: VA-204-03

Event Description:

Routine environmental monitoring detected *Micrococcus luteus* at 12 CFU on viable air sample at monitoring point VA-204-03, Grade B corridor adjacent to gowning Room 203 airlock. Action limit is 10 CFU per EU GMP Annex 1. Alert limit of 8 CFU was breached 4 times in the previous 3 months at this same location.

Organism: *Micrococcus luteus* (skin-associated flora)

Count: 12 CFU (vs action limit 10 CFU)

Sample Method: Active air sampling, 1000L volume

Immediate Actions:

1. Room 204 Grade B area placed under enhanced monitoring (daily vs weekly)
2. Gowning practices audit initiated for personnel accessing Room 203/204
3. HVAC filter inspection scheduled
4. Adjacent Grade A areas confirmed unaffected