

CAPA Propagation Recommendation — Ireland Gowning Protocol

AMGEN — DEVIATION TREND INTELLIGENCE

CAPA Propagation Recommendation

Generated by: Pace AI Agent

Date: 2026-02-17

Priority: HIGH

SOURCE CAPA

CAPA-ATO-2025-0445: Revised gowning protocol with secondary glove change

Effectiveness: 83% reduction in Micrococcus counts ($p=0.001$)

Site: Thousand Oaks (ATO)

TARGET SITE: IRELAND (IRE)

Trigger NC: NC-IRE-2026-1103 (Micrococcus excursion, Grade B Room 204)

Evidence: 12-month upward trend at VA-204-03 matching pre-CAPA ATO pattern

GAP ANALYSIS

1. SOP Gap: IRE SOP-IRE-GWN-014 Rev 3 (March 2024) vs ATO SOP-ATO-GWN-014 Rev 5 (July 2025)

Missing: Secondary glove change at B/C transition

2. Training Gap: Ireland gowning training last completed March 2024 (11 months overdue)

3. ComplianceWire: Training curriculum does not include updated protocol

RECOMMENDED ACTIONS

1. Update SOP-IRE-GWN-014 from Rev 3 to incorporate secondary glove change (from ATO Rev 5)

2. Schedule retraining of all Ireland gowning-qualified personnel via ComplianceWire

3. Increase EM monitoring at VA-204-03 to daily for 90-day verification period

4. Track effectiveness using same metrics as ATO (Micrococcus CFU trend)

ESTIMATED TIMELINE: 2-3 weeks implementation

COST AVOIDANCE: Prevents escalation to Grade A contamination event (estimated \$5-15M risk)

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