

# CAPA Effectiveness Report — CAPA-ATO-2025-0445

AMGEN — TRACKWISE QMS

CAPA Effectiveness Verification Report

CAPA Number: CAPA-ATO-2025-0445

Site: Thousand Oaks (ATO)

Title: Revised Gowning Protocol — Secondary Glove Change at Grade B/C Transition

Implementation Date: July 2025

## CAPA DESCRIPTION

Added mandatory secondary glove change step at Grade B/C gowning transition to reduce skin flora transfer into Grade B areas. Updated SOP-ATO-GWN-014 from Rev 4 to Rev 5.

## EFFECTIVENESS DATA (from LIMS)

Pre-CAPA (Jan-Jun 2025):

- Avg Micrococcus counts at Grade B monitoring points: 6.2 CFU
- Action limit exceedances: 14 events
- NCs filed: 14

Post-CAPA (Jul 2025-Feb 2026):

- Avg Micrococcus counts: 1.1 CFU
- Action limit exceedances: 0 events
- NCs filed: 0

Reduction: 83% (statistically significant,  $p=0.001$ )

Verdict: EFFECTIVE

Note: This CAPA has NOT been propagated to other Amgen sites. Ireland and Puerto Rico gowning SOPs remain on older revisions.