SOP-CAL-018 Revision Recommendation — DO Probe Calibration

AMGEN — DEVIATION TREND INTELLIGENCE

SOP Revision Recommendation

Generated by: Pace AI Agent

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Priority: HIGH

TARGET SOP: SOP-CAL-018 Rev 4 (DO Probe Calibration Procedure)

Applicable Sites: ATO, IRE, PR

FINDING

7 dissolved oxygen excursion NCs across 3 sites in 4 weeks, all occurring on Days 12-16 of culture (peak cell density phase). All batches showed titer >10% above historical average (4.8 g/L vs 4.2 g/L). Current SOP-CAL-018 calibration was validated for titer up to 4.5 g/L.

ROOT CAUSE

Media optimization has increased average titer from 4.2 to 4.8 g/L. Higher titer = higher cell density = higher oxygen demand. DO probes calibrated per current SOP are accurate but response is insufficient for the increased demand profile. The probes are operating beyond their validated range.

HISTORICAL PRECEDENT

In Q3 2024, an identical pattern (5 minor DO NCs over 6 weeks) preceded 2 batch failures at ATO, costing $3.2M. Current trajectory (7 NCs in 4 weeks) is more aggressive.

RECOMMENDED REVISIONS

1. IMMEDIATE: Increase DO probe calibration frequency from quarterly to monthly

2. SHORT-TERM: Expand validation range in SOP-CAL-018 Rev 5 to cover titer up to 5.5 g/L

3. LONG-TERM: Evaluate optical DO sensors (e.g., Hamilton VisiFerm) for high-titer applications

Change control to be initiated in TrackWise.