Form-920: Change Control Tracking Form

Section 1 – Initiation Phase

1. Change Details	
Change Title:	Update to RMS-3333 Endotoxin Specification for QY-GEL Antifoam
Change Control Champion:	Project Manager – GMP Manufacturing
Date Initiated:	24 July 2026
Completion Required:	15 August 2026
Product Description:	QY-GEL Antifoam (Material Code: 123) for GMP Plasmid Production
Site Affected:	GMP Manufacturing Facility
Department(s) Affected:	Quality Assurance, Manufacturing, Supply Chain, Regulatory
Regulatory Change:	No
Details completed by:	Project Manager, 24 July 2026

Comments:

A discrepancy has been identified between the internal RMS-3333 specification and the CompCello vendor COA for Lot 00004515 of QY-GEL Antifoam. The RMS specifies endotoxin level < 1 EU/ml as a release criterion, while the COA reports endotoxin as 'Report Result' with measured value < 5 EU/ml. This change is required to align internal documentation with the vendor's current 'report only' reporting format for endotoxin levels.

Section 2 – Detailing of Change / Justification and Strategy

Current Situation:

The internal RMS-3333 (dated 12 April 2024) specifies 'Endotoxin Level: < 1 EU/ml' as a pass/fail release criterion for QY-GEL Antifoam. However, the CompCello COA for Lot 00004515 (Date of Manufacture: 01 May 2025) lists endotoxin as 'Report Result' with a measured value of < 5 EU/ml, indicating the vendor no longer applies a pass/fail specification.

Proposed Situation:

Update RMS-3333 to change endotoxin specification from '< 1 EU/ml' to 'Report Result' format, aligning with vendor COA reporting. The material release decision will be based on review of reported values rather than a pass/fail threshold.

Change Justification:

The vendor has changed their reporting format from specification-based to report-only for endotoxin levels. The current discrepancy prevents material release and puts GMP manufacturing timelines at risk. CompCello notified of this change two months ago, but the communication was not captured due to employee departure.

2. Products Impacted By Change

Product Name / Description	Product Item Code	Market Impacted	Registered
GMP Plasmid Production Run	N/A	Clinical/Commercial	YES

Section 3 – Risk Assessment

Outcome of Change Control Risk Assessment:	Minor
Champion (initial/date):	Project Manager / 24 July 2026
Comments:	Risk is assessed as Minor. The change affects documentation only and does not i

Attached Risk Assessment:

• Risk Mitigation Strategy Document attached separately

Section 4 – Change Control Package Review

Department	Sign Required	Department	Sign Required
Quality Assurance	[ ]	Business Development	[ ]
QC	[ ]	Engineering	[ ]
Logistics	[ ]	Warehouse	[ ]
Process Development	[ ]	Manufacturing	[ ]
Supply Chain	[ ]		
Regulatory	[ ]		
Validation	[ ]		

Temporary Controls Implemented:

• Material Lot 00004515 has been placed on quarantine hold pending resolution of this change control
• Manufacturing run is on hold pending QA approval of material release or deviation

Proposed Follow-up Actions:

1. Update RMS-3333 specification document to reflect 'Report Result' format for endotoxin
2. Obtain QA approval for updated RMS and release of current material lot
3. Implement centralized vendor communication tracking process (see Risk Assessment)
4. Review other raw material specifications for similar discrepancies
5. Update SOPs to include vendor change notification review procedures