FORM-920 - CHANGE CONTROL TRACKING FORM

SECTION 1 – INITIATION PHASE

1. CHANGE DETAILS

Change Title:	Endotoxin Specification Discrepancy - QY-GEL Antifoam RMS-3333
Change Control Champion:	Project Manager
Department:	Manufacturing Science and Technology
Date Initiated:	24 March 2026
Completion Required:	TBD (pending QA review)
Product Description and Item Code:	QY-GEL Antifoam (Material Code: 123)
Site Affected by Change:	GMP Manufacturing Site
Department/s Affected by Change:	Manufacturing, QA, Supply Chain, MSAT
Regulatory Change:	No - Internal specification alignment only
Details completed by:	Project Manager
Date:	24 March 2026
Comments:	Material lot 00004515 on hold pending resolution

DETAILING OF CHANGE / JUSTIFICATION AND STRATEGY

Current Situation:
Internal Raw Material Specification RMS-3333 for QY-GEL Antifoam specifies 'Endotoxin Level: < 1 EU/ml' as a release criterion. The received vendor COA for batch 00004515 states 'Endotoxin Level: < 5 EU/ml - Report Result', indicating a different specification limit and that the test is informational only, not a release criterion. This discrepancy has caused QA to flag the material as non-conforming, placing the lot on hold.

Proposed Situation:
Resolution through one of two pathways: (1) Accept the vendor COA with current result under a deviation, pending RMS update to align with vendor specification; or (2) Require full requalification if QA deems specification change unacceptable. Material will remain quarantined until resolution is approved.

Change Justification:
The discrepancy was discovered during routine QA review prior to GMP manufacturing run. Timely resolution is critical to avoid production delays. The vendor has indicated a formal change notification was issued 2 months ago, but communication breakdown prevented internal update of RMS. This change control addresses immediate material release while establishing process improvements to prevent recurrence.

2. PRODUCTS IMPACTED BY CHANGE

Product Name / Description	Product Item Code	Market Impacted	Registered
QY-GEL Antifoam (Raw Material)	123	Internal Use	YES

Client Plasmid Production (Upstream)	N/A - Project Specific	Client Market	YES

3. RISK ASSESSMENT - AS PER COMPANY RISK ASSESSMENT PROCEDURE

Outcome of Change Control Risk Assessment:

Risk Category: MINOR Quality Risk: - Material specification change may impact product quality if endotoxin levels are critical - Current lot shows result of < 5 EU/ml (actual value not specified on COA) - Historical data suggests vendor material has consistently met < 1 EU/ml limit - Risk to final product considered LOW based on historical performance **Regulatory Risk:** - No regulatory filing required (internal specification alignment) - Deviation documentation will maintain audit trail - Risk: MINIMAL **Supply Chain Risk:** - Current lot on hold - production timeline at risk - Alternative sourcing may be required if specification unacceptable - Risk: MODERATE (mitigated by current alternative vendors listed in RMS) **Operational Risk:** - Communication breakdown in vendor notification process identified - Risk to future material qualifications without process improvement - Risk: MODERATE (requires SOP update and process enhancement)

Date of Assessment:	24 March 2026
Champion (initial/date):	PM/24-Mar-2026
Major / Minor:	MINOR
Comments:	See attached Risk Mitigation Strategy document for detailed assessment and re

SECTION 2 - CHANGE CONTROL PACKAGE REVIEW

Department	Signature	Date
Quality		
QA		
Manufacturing		
Supply Chain		
MSAT		
Regulatory		

SECTION 3 – REVIEW AND CLOSURE

Information Provided for Change Closure:
- Completed Change Control Request
- Vendor COA (batch 00004515)
- Internal RMS-3333
- QA deviation record (if applicable)
- Updated RMS document (post-approval)

First batch where change will occur: TBD (pending resolution)

Quality Assurance Associate reviews package:	_____ YES / _____ NO	Sign & Date:
Quality Assurance Associate closes change control:	_____ YES / _____ NO	Sign & Date:
Quality Assurance Associate distributes closure notice:	_____ YES / _____ NO	Sign & Date:

Change Control file marked as closed and archived:	_____ YES / _____ NO	Sign & Date:

Comments: Attach vendor communication confirming change notification, updated SOPs, and process improvement documentation.