# Change Control Request

## Section 1 – Initiation Phase

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| **Change Title:** | Update RMS-3333 Endotoxin Specification for QY-GEL Antifoam |
| **Change Control Champion** | Project Manager |
| **Department** | Manufacturing Science and Technology |
| **Date Initiated** | 18 Jun 2026 |
| **Completion Required** | 25 Jun 2026 |
| **Product Description and Item Code** | QY-GEL Antifoam (Material Code: 123) |
| **Site Affected by Change** | Manufacturing Facility |
| **Department/s Affected by Change** | QA, Manufacturing, Supply Chain |
| **Regulatory Change** | N/A |

### *Detailing of Change / Justification and strategy*

**Current Situation**
Current Situation: The internal Raw Material Specification (RMS-3333) specifies "Endotoxin Level: < 1 EU/ml" as a release criterion for QY-GEL Antifoam. However, the vendor Certificate of Analysis (COA) for received lot 00004515 states "Endotoxin Level: Report Result" with an actual measured value of "< 5 EU/ml". This discrepancy has caused QA to flag the material as non-conforming, putting manufacturing timelines at risk.

**Proposed Situation**
Proposed Situation: Update RMS-3333 to align with vendor's current specification approach, changing the endotoxin requirement from a pass/fail criterion ("< 1 EU/ml") to a "report only" requirement, while maintaining appropriate risk controls.

**Change Justification**
Change Justification: CompCello has formally changed their endotoxin reporting approach two months ago, but the notification was sent to a former employee without a centralized process to capture such communications. The actual endotoxin level in the received lot (< 5 EU/ml) is still within acceptable limits for our manufacturing process based on historical data and risk assessment. Updating our RMS will prevent future supply chain disruptions while maintaining product quality.

## 2. Products Impacted By Change

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| **Product Name / Description** | QY-GEL Antifoam |
| **Product Item Code** | 123 |
| **Market impacted** | All |
| **Registered** | YES |

## 3. Risk Assessment

Temporary Controls: - Material lot 00004515 has been quarantined pending resolution - Manufacturing timeline adjusted to accommodate potential delay Proposed Follow-up Actions: - Update RMS-3333 to reflect vendor's current endotoxin reporting approach - Implement centralized vendor communication tracking system - Review and update SOP for handling vendor specification changes Risk Assessment: The change represents a minor risk as the actual endotoxin levels remain within acceptable process limits. Historical data shows that endotoxin levels up to 5 EU/ml have not impacted final product quality or patient safety.