REPORT

Risk Assessment Report for Biospecimen Management Compliance with ICH E6(R3)

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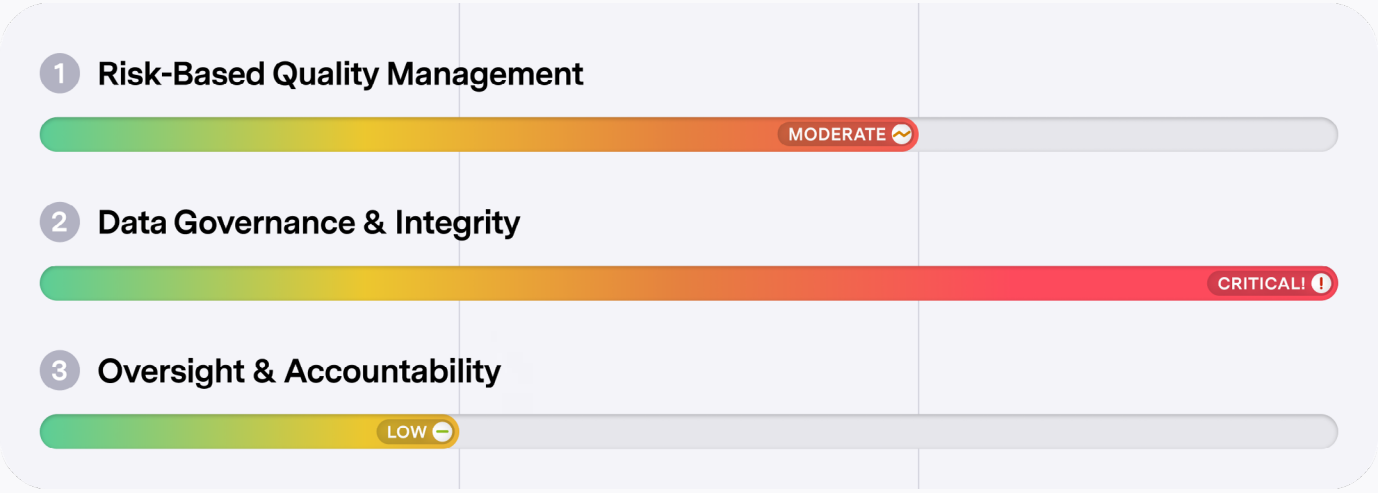
Executive Summary

This report presents a comprehensive risk assessment for Lumon's biospecimen management practices in light of the upcoming ICH E6(R3) guidelines. Based on the self-assessment scorecard and our detailed analysis, we have identified several areas of concern that require immediate attention to ensure compliance by the EMA's July 23rd deadline for ICH E6(R3) adoption.



MODERATE

1 Risk-Based Quality Management

This section focuses on proactive risk identification and mitigation across the biospecimen lifecycle. ICH E6(R3) mandates a risk-based approach to quality management, making it crucial for sponsors to implement robust controls and monitoring systems. To ensure compliance, it's important to consider adopting tech-enabled solutions that provide real-time sample tracking, automated inventory management, and standardized metadata capture processes.

RISK AREA	FINDING	RECOMMENDATION
Sample Integrity Controls	CRITICAL Manual process… lab manuals	
Controls for Sample Metadata Capture	MODERATE Lab-specific e-… forms with limita…	
Essential Record Documentation	LOW Tracking samp… spreadsheets, … CTMS	
Sample Tracking & Monitoring	MODERATE Manual spreads… with periodic sa…	
Inventory Management	MODERATE Automated resu… with some inacc…	

CRITICAL

2 Data Governance

This section addresses the enhanced data governance rules that now apply to biospecimens, elevating their status to that of clinical data. ICH E6(R3) emphasizes the importance of maintaining data integrity and complete audit trails throughout the biospecimen lifecycle. To meet these requirements, consider implementing validated systems with robust security measures, ensuring quick retrieval of sample histories and comprehensive data access controls.

RISK AREA	FINDING	RECOMMENDATION

LOW

3 Sponsor Oversight & Accountability

This section highlights the sponsor's ultimate responsibility for delegated biospecimen activities under ICH E6(R3)'s enhanced oversight rules. The new guidelines place increased emphasis on sponsor accountability, making it essential to have clear processes for assessing fit-for-purpose tools, training stakeholders, and monitoring stakeholder performance. To achieve compliance, sponsors should consider implementing comprehensive training programs, establishing robust communication channels with stakeholders, and leveraging analytics tools for real-time performance monitoring.

RISK AREA	FINDING	RECOMMENDATION

What's Next?

Lumon Industries faces significant risks in several critical areas of biospecimen management as defined by ICH E6(R3). Immediate action is required to address high-risk areas and ensure compliance by the EMA's July deadline.

Don't know your risk level?

Complete our free self-assessment to determine where your biospecimen operations may be at risk for non-compliance

Take assessment >

Get a custom report

Book a free risk consultation with one of our experts and receive a custom risk report like this one, with recommendations tailored to your organization

Schedule a meeting >