

De-Risking Sample Management

Pharma and biotech organisations outsourcing to CROs, face risks if sample management is inadequate. We consolidate best practices, risk mitigation strategies, and a compliance checklist with audit timelines to ensure regulatory adherence and research integrity.

Introduction

A comprehensive sample management policy is not merely a regulatory obligation; it is a critical component of risk mitigation. Effective protocols ensure that unforeseen events—such as equipment failure—do not compromise research or sample integrity or regulatory non-compliance or result in significant financial and time-based losses.



Risk Considerations for Key Biological Sample Types

- Clinical Trial Samples: With average per-patient trial costs exceeding \$120,000, these samples are irreplaceable. Implement redundancy through aliquoting and separate storage.
- FFPE Blocks and Slides: Used in histology and biomarker studies; finite and irreplaceable. Require controlled temperature and humidity.
- High-Risk or High-Value Samples: Rare tumor types, rare disease samples, high-containment pathogens, or ethically sensitive materials demand stringent handling.
- Nucleic Acids (DNA, RNA, cDNA Libraries): Highly sensitive to degradation; maintain RNase-free conditions and -80°C storage.



Master Stocks

- Cell Banks: Track freeze—thaw cycles, passage numbers, and perform authentication checks (e.g., mycoplasma).
- Pathogen Banks: Ensure compliance with biosafety level standards and robust tracking.
- Drug Candidates: Maintain detailed records and secure storage for IP protection.
- Proteins and Antibodies: Preserve stability and batch consistency to avoid costly errors.



Risk Mitigation Strategies

- Implement redundancy strategies (e.g., aliquoting, separate storage).
- Use validated monitoring systems for temperature and humidity with alarms.
- Maintain robust and secure documentation and chain-of-custody records.
- Ensure disaster recovery and backup power systems are tested regularly.



Key Recommendations

- Regularly review and update sample management policies.
- Audit CRO compliance with contractual obligations and regulatory standards.
- Invest in secure, validated storage and tracking systems.



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Suggested compliance Checklist for Pharma/Biotech Outsourcing to CROs:

Category	Checklist Items	Audit Timeline Examples
Governance & Documentation	<ul style="list-style-type: none"> ✓ Documented policies and processes aligned with international standards such as, OECD GLP principles, ICH E6 Guidelines and relevant local regulations ✓ SOPs reviewed and approved by QA ✓ Staff trained on the relevant requirements and SOPs ✓ Chain-of-custody maintained for all samples 	Initial Qualification Audit: Prior to contract execution <i>Sponsor responsibility</i>
#Study Protocol & Records	<ul style="list-style-type: none"> ✓ Approved study protocols and amendments ✓ Raw data archived securely ✓ Electronic systems validated for GxP compliance 	Routine Audit: Every 12—18 months <i>Sponsor responsibility</i>
Storage & Redundancy	<ul style="list-style-type: none"> ✓ Validated storage conditions (temperature, humidity) ✓ Aliquoting for critical samples ✓ Backup power and disaster recovery plans 	Triggered Audit: Within 30 days of major deviation <i>CRO or Sponsor responsibility</i>
Quality Assurance	<ul style="list-style-type: none"> ✓ Robust Quality Management System and Independent QA unit oversight ✓ Periodic inspections of CRO facilities ✓ Retention of reference samples for retrospective analysis as applicable 	Ongoing Oversight: During study lifecycle <i>CRO responsibility</i>
Security & Compliance	<ul style="list-style-type: none"> ✓ Restricted access to sample storage ✓ Biosafety compliance for hazardous materials ✓ Ethical and IP clauses in contracts 	Close-Out Audit: At study completion <i>Sponsor responsibility</i>
Data Integrity	<ul style="list-style-type: none"> ✓ GxP-compliant electronic systems (audit trails) ✓ Version control for SOPs and protocols ✓ Secure archiving for minimum retention period 	Archival Review: Post-study data storage verification <i>CRO responsibility</i>

