Biopharma Storage Planning Aid

For storage of biological materials, drug substances, raw materials, cell banks, finished goods, and more.

This planning aid and checklist is available to help SciSafe customers identify and complete the necessary steps to set up storage for biopharma materials. Your situation may require more or fewer actions, but this template can serve as a baseline for your planning.

Start planning at least 6-8 weeks before the first shipment.

Planning Actions:

A. Inventory Preparation and Organization ☐

- Create a detailed inventory spreadsheet:
  - Unique IDs for each material (lot number, sample ID)
  - Container types (vial size, box dimensions, pallet size)
  - Quantity per item
  - Storage condition requirements
  - Expiration dates (if applicable)

B. Define Materials and Storage Conditions ☐

- List all materials requiring storage
- Specify exact storage conditions
  - Liquid nitrogen (LN2) tanks (-196°C to -150°C)
  - Ultra-low temperature freezers (-100°C to -70°C)
  - Walk-in freezers (-40°C to -20°C)
  - Refrigerated storage (2°C to 8°C)
  - Controlled room temperature storage or pallets (15°C to 30°C)
- Indicate if the material requires special handling or storage
  - Hazardous
  - Toxic
  - Physical isolation

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C. Documentation Requirements

- Safety Data Sheets (SDS) for materials
- Certificate of Analysis (COA) for GMP/regulated materials
- Material transfer agreements (if needed)
- Maintain full audit trails for all shipments and storage activities

D. Shipping and Logistics Coordination

- Choose transportation method: validated dry shippers, frozen couriers, temperature-controlled trucking
- Confirm pick-up/drop-off date and time window
- Use shipping containers qualified for the required temperatures
- Pre-arrange temperature monitoring devices for shipping
- Share tracking information with SciSafe's Biorepository Manager or Operations Manager

E. Inventory Access Requirements

- Frequency
- Turn-around time
- Return

F. Storage Facility Certifications

- Review storage facilities' compliance
  - FDA
  - cGMP
- Review storage facilities' certifications
  - ISO 9001
  - ISO 20387
  - College of American Pathologists Biorepository Accreditation Program (CAP- BAP)
- Assess facilities certification requirements based on risk assessment

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G. Quality and Regulatory Compliance

- Execute a Quality/Service Agreement outlining storage expectations
- Define chain of custody procedures (hand-off documentation)
- Schedule a risk-based quality review or site audit (if required)
- Prepare validation documentation if the material is used for future GMP use
- Identify required monitoring or access reports
- Review Quality Management System
  - Manuals
  - Process
  - Structure

H. Contingency Planning

- Discuss backup power, generator, and LN2 supply coverage
- Set up contact points for emergency notifications (temperature excursions, alarms).
- Review of the storage facilities' disaster preparedness plan and historical real-world responses

I. Audit Readiness

- Schedule quality audits and/or remote qualification tours
- Establish document access plan for inspections (e.g., batch records, validation reports)
- Review storage partner's external audit process
- Review storage partner's last internal audit process, schedule, and results