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Pharmaceutical Facility Decommissioning & Exit Strategy Checklist

A high-rigor framework for managing regulatory, safety, financial & legal liabilities.

Phase 1: Strategic Planning (T-Minus 6–12 Months)

Establishing the governance and legal "Safe Harbor" for the transition.

- [ ] **Appoint Decommissioning Lead:** Establish a cross-functional team (EHS, QA, HR, Facilities).
- [ ] **Review Lease & Legal Obligations:** Identify "Warm Shell" vs. "Broom Clean" requirements.
- [ ] **Stakeholder Communications:** Draft internal/external messaging to manage market perception.
- [ ] **Retention Strategy:** Finalize "Stay-Packages" for key technical staff required for the wind-down.
- [ ] **Regulatory Impact Assessment:** Evaluate the effect on active IND/NDA/MAA filings.

Phase 2: Asset & Material Reconciliation (T-Minus 3–6 Months)

Ensuring 100% accountability for regulated materials and clinical assets.

- [ ] **Controlled Substances Audit:** Perform 100% reconciliation of DEA-regulated materials; initiate Form 222 for transfers or schedule witnessed destruction.
- [ ] **Clinical Manufacturing Equipment:** Identify all assets used for Clinical Trial Materials (CTM); ensure cleaning validation and maintenance logs are audit-ready.
- [ ] **Wall-to-Wall Inventory:** Categorize every asset as *Redeploy, Sell, or Scrap*.
- [ ] **Data & Metadata Migration:** Extract raw data from standalone instrument PCs (HPLC, MS, LIMS); move to GxP-compliant archives.

Phase 3: Technical Wind-Down (T-Minus 1–3 Months)

Managing the physical removal of hazards and bio-containment systems.

- [ ] **Biosafety Cabinet (BSC) & Isolator Sterilization:** Execute VHP (Vaporized Hydrogen Peroxide) or gas-phase decontamination; provide certificates for relocation or disposal.

- [ ] **Chemical & Biological Waste Manifesting:** Execute bulk removal of all reagents, solvents, and biohazards.
- [ ] **Sample & Stability Transfer:** Coordinate cold-chain logistics for the transfer of cell banks and stability samples.
- [ ] **Clinical Quality Closeout:** Finalize all open Deviations, CAPAs, and Change Controls related to site assets.
- [ ] **Radiation Safety Survey:** (If applicable) Perform final decommissioning survey with a Radiation Safety Officer (RSO).

Phase 4: Final Facility Closeout (T-Zero)

Final transition to "Safe-State" for property handover.

- [ ] **HEPA & Ductwork Remediation:** Professional cleaning of fume hoods and certified abatement of contaminated HEPA systems.
- [ ] **Utility "Safe-Off":** Cap specialty gasses (Argon, N2, CO2) and neutralize AWN (Acid Waste Neutralization) tanks.
- [ ] **Final EHS Clearance:** Obtain a formal "Safe for Unrestricted Use" certificate for the property.
- [ ] **Security & IT Handover:** Revoke badge access, wipe biometric databases, and secure the perimeter.
- [ ] **Archival Handover:** Final transfer of all GxP records, maintenance logs, and decommissioning certificates to the corporate repository.

Phase 5: Personnel Transition & Support (T-Minus 6 Months to Exit)

Ensuring that the human element of restructuring is managed with the same regulatory rigor and professional dignity as the physical assets.

- [ ] **Critical Role Assessment:** Map every role against the decommissioning timeline; identify "Phase 4" essential staff.
- [ ] **Retention Bonus Design:** Finalize stay-bonus structures (usually 10%–30% of base) for personnel required through the T-Zero date.
- [ ] **Severance Modeling:** Calculate liability for various tiers of tenure and level; ensure compliance with the WARN Act (60-day notice requirements).
- [ ] **Outplacement Services:** Contract with life-science-specific career firms to provide onsite resume workshops and interview prep.
- [ ] **COBRA & Benefits Continuity:** Prepare detailed "Transition Folders" for every employee explaining health insurance, 401k vesting, and unemployment filing.
- [ ] **Knowledge Retention Sessions:** Conduct "Exit Interviews 2.0"—recorded deep-dives with lead scientists to document unwritten process parameters.

Need a Strategic Partner for Your Transition?

Complex exits don't have to be chaotic. The presence of controlled substances, biosafety requirements, and clinical manufacturing assets requires more than a simple move—it requires a qualified shutdown.

Cachet Pharma Consulting specializes in the heavy lifting of pharmaceutical restructuring.

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