

CRO / CMO

Operational resilience for every study. Built for GxP.

XILTRIX | Nothing left to chance.

	 1. Study setup GxP GLP GCP	 2. Sample handling GMP GLP GCP	 3. Storage & stability GMP GLP GCP	 4. Distribution GDP GCP	 5. Study execution GCP GLP	 6. Close-out & archiving GCP GLP
	- Facility qualification - Environment mapping - Sensor installation - Validation & calibration	- Sample intake & registration - Processing & aliquoting - In-process monitoring - Chain of custody	- Short- & long-term storage - LN₂ storage with auto-fill - Stability studies - Inventory management	- Packout & shipment - Temp-controlled transport - In-transit (via partners) - Excursion alerts	- Environment control - Equipment monitoring - Deviation management - Audit-ready documentation	- Sample archiving - Long-term storage - Data retention & reporting - Site decommissioning
	 Key processes	- Study & protocol setup - Facility qualification - Method validation - Supplier approval	- Receipt & accessioning - Processing & preparation - QC testing - Chain of custody	- Storage & inventory - LN₂ auto-fill & supply - Retention & retrieval - Temperature mapping	- Packaging & shipment - Cold chain logistics - In-transit (via partners) - Customs & regulatory	- Study execution - Ongoing monitoring - Deviation & CAPA - Client & regulator audits
	 Locations	- R&D labs - Process development - Analytical laboratories - Stability chambers	- Sample processing labs - QC/analytical labs - Cleanrooms (where relevant) - Production suites (CMO)	- Cold & ultra-low rooms - LN₂ storage areas - Quarantine & release areas - Warehouse / 3PL facilities	- Packaging areas - Shipping & logistics hubs 3PL partner sites - Airports & hubs	- Clinical research units - Bioanalytical laboratories - Patient sample storage - Investigator site depots
	 Assets to monitor	- Cleanrooms (T/RH/particles) - Lab & process equipment - Incubators (CO₂/O₂) - HVAC & utility systems	- Refrigerators & freezers - Incubators & shakers - Centrifuges & analysers - Critical lab equipment	- Ultra-low freezers (≤ -80°C) - LN₂ tanks & auto-fill supply - Cold rooms (2–8°C) - Stability chambers	- Dry ice/LN₂ shippers - Active & passive packaging - Temperature/shock loggers - Dock doors & loading areas	- Lab fridges/freezers - Controlled storage cabinets - Clinical site equipment - Backup power & alarms
	 Environmental parameters	- Temperature - Humidity - Differential pressure - Particles (non-viable & viable)	- Temperature - Humidity - CO₂ / O₂ - Vibration / shock	- Temperature (to -196°C) - LN₂ level, pressure, fills - Humidity - Door status	- Temperature - Location (GPS, via partners) - Shock (via partners) - Lid/box opening	- Temperature - Humidity - CO₂ / O₂ - Room T/RH/pressure
	 GxP requirements	GMP GLP GCP - Qualification (DQ/IQ/OQ) - Calibration & validation - Data integrity (ALCOA+)	GMP GLP GCP - Validated monitoring - Audit trail & documentation - Deviation & CAPA	GMP GLP GCP - Mapping & qualification - Continuous monitoring - Data integrity (ALCOA+)	GDP GCP IATA - Qualified transport - Excursion management - Chain of custody records	GCP GLP - Site compliance & audits - Continuous monitoring - Traceability & documentation
	XILTRIX value	- Fast, validated deployment - Supports method validation - Audit-ready documentation - Scales to global networks	- Real-time monitoring & alerts - LIMS link via REST API - Less sample loss & rework - Supports client audits	- Auto-fill: level & pressure - Closed valves flagged early - Multi-site visibility - Early warning for samples	- In transit (via partners) - Excursion alerts - Monitored handover - End-to-end chain of custody	- Continuous compliance - Actionable alarms - Audit-ready evidence - LIMS/CTMS link via REST API

Beyond monitoring



IT expertise

In-house IT know-how: SSO with Active Directory, ISO 27001, full encryption, REST API to LIMS, BMS and EMS.



Consultancy & validation

Risk inventory, URS and validation support (IQ/OQ), from design to inspection.



Visualisation, built in

Zoomable floor plans and live dashboards on any device; wall screens built into your lab.



Proven since 1987

No customer has lost irreplaceable material because our monitoring failed



24/7 technical support

Monitoring chain watched around the clock; alarms escalate to your own on-call team



Built for GxP

GMP | GLP | GCP | GDP: validated monitoring, audit-ready, data integrity