

Pharma & biotech

From production to patient. Built for GxP.

XILTRIX | Nothing left to chance.

	 1. Manufacturing GMP EU Annex 1	 2. Quality control GMP	 3. Storage GMP GDP	 4. Distribution & transport GDP	 5. Hospitals & pharmacies GDP GPP	 6. Clinical use & research GCP GLP
	- Production & filling - Aseptic environments - Process equipment - In-process monitoring	- QC laboratories - Stability testing - Environmental rooms - Sample storage, incl. LN₂	- Warehouses - Cold & frozen storage - Cryogenic storage (LN₂) - Quarantine & release	- Temperature-controlled - Road, air & sea - Passive & active packaging - In-transit monitoring (via partners)	- Hospital pharmacies - Receiving & storage - Reconstitution & compounding - Distribution to wards	- Clinical trials - Research laboratories - Cell & gene therapy - Patient administration
 Key processes	- Production & process control - Filling & packaging - Aseptic operations - Release & storage	- QC testing - Stability testing - Method validation - Sample storage	- Inbound, storage & picking - Quarantine & release - LN₂ auto-fill & supply - Returns & recalls	- Loading & shipment - In-transit monitoring (via partners) - Delivery & receipt - Excursion investigation	- Receiving & acceptance - Compounding & reconstitution - Distribution to wards - Returns & waste management	- Clinical trial operations - Sample handling - Research & development - Long-term storage & follow-up
 Locations	- Manufacturing sites - Cleanrooms - Production areas - Utility rooms (HVAC)	- QC laboratories - Microbiology labs - Stability chambers - Environmental rooms	- Warehouses & cold rooms - Freezer, ULT & LN₂ storage 3PL facilities - Cross-dock areas	- Trucks, vans, air cargo - Sea freight containers - Transfer hubs - Last-mile delivery	- Hospital pharmacies - Receiving areas - Medication storage rooms - Compounding rooms	- Clinical research units - Research laboratories - Biobanks & cryo storage - Procedure rooms
 Assets to monitor	- Cleanrooms (T/RH/particles) - Critical process equipment - Incubators & bioreactors - Cryogenic vessels	- Refrigerators & freezers - Stability chambers - Incubators (CO₂/O₂) - LN₂ sample storage	- Cold rooms (2–8°C) - Ultra-low freezers (≤ -80°C) - LN₂ tanks & auto-fill supply - Dock doors & backup power	- Refrigerated trucks/containers - Passive/active shippers - Temp & location loggers - Lid/box opening & shock	- Medication fridges/freezers - Compounding environments - Controlled drug cabinets - Backup power & alarms	- Incubators (CO₂/O₂) - LN₂ tanks & cryogenic storage - Sample storage freezers - Lab & procedure room environment
 Environmental parameters	- Temperature - Humidity - Differential pressure - Particles (non-viable & viable)	- Temperature - Humidity - CO₂ / O₂ - LN₂ level	- Temperature - Humidity - LN₂ level, pressure & fill cycles - Door status	- Temperature - Location (GPS, via partners) - Shock / impact (via partners) - Lid/box opening	- Temperature - Humidity - CO₂ (for compounding) - Differential pressure	- Temperature - Humidity - CO₂ / O₂ - LN₂ level & pressure
 GxP requirements	GMP (EU Annex 1) - EM programme (viable/non-viable) - Qualification & mapping - Data integrity (ALCOA+)	GMP - Validated monitoring - Calibration - Deviation & CAPA	GDP - Qualified storage - Temperature mapping - Deviation & CAPA	GDP - Qualified transport - Route/lane validation - Excursion investigation	GDP GPP - Qualified storage - Continuous monitoring - Audit & traceability	GCP GLP - Sample integrity - Environmental control - Deviation management
XILTRIX value	- Validated monitoring at scale - Real-time alarms & workflows - Integration with BMS/EMS - Supports audits & inspections	- Supports sample integrity - Automated reporting - Calibration services - Risk reduction & compliance	- Auto-fill: level, pressure, fill cycles - Early sight of upstream issues (closed valves) - Unattended storage covered - Multi-site visibility	- In-transit monitoring via logistics partners - Excursion alerts - Monitored handover into facilities - End-to-end visibility	- Early warning for medication quality - Actionable alarms - Audit-ready evidence - Multi-site control	- Early warning for valuable samples - Supports clinical research - Long-term stability monitoring - Audit-ready documentation
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.	



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Built for GxP

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