

Cell & gene therapy

Protecting sensitive therapies. Built for GxP.

XILTRIX | Nothing left to chance.

	 1. Process development GLP GMP	 2. Manufacturing GMP EU Annex 1	 3. Storage GMP	 4. Distribution & transport GDP GMP	 5. Clinical sites GCP GMP	 6. Post-treatment & follow-up GCP
	- Cell line development - Vector production - Process optimisation - Environmental control	- Cell & vector production - Aseptic processing - In-process monitoring - Controlled environments	- LN₂ storage with auto-fill - Ultra-low freezers - Stability storage - Inventory management	- Temperature-controlled - Chain of custody - In-transit (via partners) - Excursion alerts	- Receiving & thawing - Preparation & administration - Controlled storage - Patient-linked material	- Long-term sample storage - Biomarker analysis - Patient follow-up samples - Data & traceability
 Key processes	- Cell line development - Process development - Method validation - Quality control	- Aseptic manufacturing - Cell expansion & harvest - Vector production - In-process control	- Short- and long-term storage - LN₂ auto-fill & supply - Sample tracking & traceability - Stability testing	- Packaging & shipment - In-transit (via partners) - Excursion management - Chain of custody	- Receiving & acceptance - Thawing & preparation - Patient administration - Documentation & reporting	- Long-term follow-up storage - Sample analysis - Registry & data management - Audit & compliance
 Locations	- R&D laboratories - Process development suites - QC labs - Cleanrooms (research)	- GMP cleanrooms (EU Annex 1) - Production suites - Fill & finish areas - QC & release labs	- Cryogenic storage rooms - Ultra-low freezer rooms - Secure sample storage (LN₂) - Stability chambers	- Packaging areas - Shipping & logistics hubs 3PL facilities - Air/ground transport routes	- Hospital pharmacies - Cell therapy prep rooms - ATMP treatment wards - Cryogenic storage at site	- Clinical research units - Long-term storage facilities - Biobanks (patient samples) - Academic research centres
 Assets to monitor	- Incubators (CO₂/O₂) - Bioreactors - Cleanroom environments - Critical research equipment	- Bioreactors & fermenters - Incubators - Freezers & refrigerators - HVAC & cleanroom systems	- Ultra-low freezers (≤ -80°C) - LN₂ tanks & cryogenic vessels - LN₂ supply tanks & auto-fill - Backup power & alarms	- Dry ice/LN₂ shippers - Temperature & shock loggers - Active vs passive packaging - Lid/box sensors & GPS	- Cryo freezers & LN₂ tanks - Thawing equipment - Medication fridges - Room environment sensors	- Ultra-low freezers - LN₂ storage tanks - Sample storage systems - Lab & analysis equipment
 Environmental parameters	- Temperature - Humidity - CO₂ / O₂ - Particles (non-viable & viable)	- Temperature - Humidity - Differential pressure - Particles & room status	- Temperature (to -196°C) - LN₂ level, pressure & fill cycles - Humidity - Door & power status	- Temperature - Location (GPS, via partners) - Shock (via partners) - Lid/box opening	- Temperature - Humidity - CO₂ / O₂ - Differential pressure	- Temperature - Humidity - LN₂ level & pressure - CO₂ / O₂ (where relevant)
 GxP requirements	GLP (research phase) - Data integrity (ALCOA+) - Environmental control - Audit & documentation	GMP (EU Annex 1) - Validated monitoring - Calibration & qualification - Audit trail & deviations	GMP GCP - Validated storage - Mapping & qualification - Data integrity (ALCOA+)	GDP GMP - Qualified transport routes - Excursion investigation - Chain of custody records	GCP GMP - Controlled storage & handling - Patient safety & traceability - Excursion management	GCP - Long-term stability - Sample integrity & traceability - Data & audit readiness
XILTRIX value	- Real-time monitoring in R&D - Early warning for research material - Supports method validation - Audit-ready data & reporting	- Validated monitoring for GMP - Integration with BMS/EMS - Early-warning alerts - Less downtime & product loss	- Auto-fill: level & pressure - Closed valves flagged early - Unattended storage covered - Audit-ready documentation	- In-transit visibility (via partners) - Excursion alerts & intervention - Monitored handover - End-to-end chain of custody	- Early warning for patient material - Actionable alarms - Audit-ready evidence - REST API to hospital systems	- Long-term sample integrity - Continuous monitoring - Supports clinical research - Audit-ready data
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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Monitoring chain watched around the clock; alarms escalate to your own on-call team



Built for GxP

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