Title21 CGT Platform

An end-to-end digital orchestration platform for Cell and Gene Therapy (CGT) workflows, compliance, and quality management.

https://www.title21.com/cell-and-gene-therapy-orchestration-platform/

Overview

The Title21 CGT Platform is a comprehensive, end-to-end digital orchestration solution designed for the complex, highly-regulated workflows of the Cell and Gene Therapy (CGT) industry. It is specifically built to empower cell therapy labs, biotherapeutic manufacturers, and blood and marrow transplant (BMT) centers to transition from paper-based and disjointed systems to a single, integrated platform.

Key Benefits and Value Proposition:

Accelerated Time-to-Patient: Streamlines documentation and quality processes, eliminating bottlenecks and manual errors to speed up the delivery of life-saving therapies.
Enhanced Compliance: Ensures adherence to stringent regulatory and accreditation frameworks, including FDA 21 CFR Part 11, HIPAA, GxP, FACT/JACIE, and AABB, by providing auditable, electronic records.
Operational Efficiency: Consolidates all aspects of quality, manufacturing, and patient management into one system, breaking down data silos and reducing the paperwork burden.
Data-Driven Insights: Provides real-time, 360-degree visibility and customizable dashboards for proactive decision-making and continuous quality improvement.
Main Features and Capabilities:

Manufacturing Execution System (MES): Features fully Electronic Batch Records (EBR) designed to ensure the safety, efficacy, and traceability of manufactured products.
Enterprise Quality Management System (EQMS): Automates and streamlines quality processes, including Document Control, Error Management, Learning and Competency Management (staff training), Audit, Corrective and Preventive Action (CAPA), and Equipment Maintenance/Calibration.
End-to-End Traceability: Tracks all three supply chains (custody, identity, and condition) for biological materials like donor samples and cell lines throughout the entire process, from patient evaluation

through to product infusion and long-term follow-up (LTFU).
Interoperability and Integration: Eliminates manual data entry by connecting with existing systems, devices, suppliers, partners, registries, and Electronic Medical Records (EMR) like Epic, Cerner, and SAP.
Workflow Automation: Provides easy-to-follow, intuitive, and automated workflows that conform to the facility's standards and accommodate complex treatment protocols (HCT, HPC, BMT, MNC, CAR-T, IEC).
Target Users and Use Cases:

Cell Therapy Laboratories
Biotherapeutic Manufacturers (cGMP manufacturing programs)
Blood and Marrow Transplant (BMT) Centers and Programs
Healthcare and Life Sciences Organizations subject to FDA-regulated domains.

Key Features

- Electronic Batch Records (EBR)
- Enterprise Quality Management System (EQMS)
- Manufacturing Execution System (MES)
- End-to-End Traceability (Chain of Custody/Identity)
- EMR/External System Integration (Epic, Cerner, SAP)
- Automated and Customizable Workflows
- Real-Time Data-Driven Insights and Analytics
- Staff Training and Competency Management

Pricing

Model: enterprise

Pricing is not publicly disclosed and is available upon request via a scheduled demo. The platform is an enterprise-grade solution tailored for large healthcare and life sciences organizations.

Target Company Size: medium, enterprise

Integrations

Epic, Cerner, SAP, External Systems/Devices/Registries

Compliance & Certifications

FDA 21 CFR Part 11, HIPAA, GxP, FACT/JACIE, AABB