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Choosing a LIMS for Cell and Gene Therapy

2026 Buyer's Guide

With dozens of LIMS on the market, it can be difficult to know how to select a solution that is best suited for the unique requirements of cell and gene therapy (CGT). CGT is one of the most complex fields within the biotech industry. This complexity stems from:

1. **Rapidly evolving science:** CGT often requires lab scientists to continuously iterate on protocols and adjust assay parameters as therapies move from discovery to the clinic. Labs need a dynamic platform that supports continuous scientific innovation without requiring heavy customization.
2. **Patient-specific batches require end-to-end traceability:** CGT workflows must maintain both chain of identity (COI), which keeps materials and products linked to the correct donor or patient, and chain of custody (COC), which documents their handling through every transfer and handoff. A mix-up in a standard biotech lab may ruin a batch, but a mix-up in a patient-specific cell therapy workflow could be fatal to a patient.
3. **Configurability is a core requirement:** Given the rapidly changing nature of CGT and the complexity of patient sample data, a CGT LIMS must adapt to highly complex and unique workflows while maintaining strict GMP protocols. This balance is difficult for many LIMS to accommodate, especially out of the box.

We previously assessed six leading vendors to help buyers compare the top CGT LIMS solutions.

This guide goes deeper into the detailed requirements that quality control, operations, and IT professionals should evaluate when choosing a LIMS for cell and gene therapy. It examines seven core areas, from Chain of Identity and environmental monitoring to data architecture and inspection readiness.

For each area, we break down what the capability should look like in practice and the questions buyers should ask when evaluating potential platforms.

1 How should a Cell and Gene Therapy LIMS maintain Chain of Identity and Chain of Custody?

Few capabilities are more critical in cell and gene therapy than end-to-end traceability. Chain of identity links materials and products to the correct donor or patient, while chain of custody records each transfer, handoff, and processing step.

In autologous therapies, every manufacturing batch represents a single patient. In allogeneic therapies, donor-derived material may support multiple doses and patients. In either model, a traceability gap can compromise product quality and patient safety.

A modern CGT LIMS should enable users to trace a finished product back to its originating donor or sample in a single view, with complete provenance and custody records across manufacturing and testing.

What to evaluate

- **How are relationships between donors, patients, samples, materials, batches, doses, and finished products represented?**
- **Can users navigate the complete chain of identity and custody?**
- **How are transfers and handoffs recorded and verified?**
- **As new entity types and workflows are introduced, how is provenance maintained?**

2 What Environmental Monitoring Capabilities Should a Cell and Gene Therapy LIMS Include?

Maintaining laboratory cleanliness and monitoring conditions in real time are essential in CGT manufacturing. A CGT LIMS must be able to scale environmental monitoring as manufacturing volume increases, and track factors such as air particles, surface contamination, and personnel.

Importantly, a LIMS for CGT should include environmental monitoring by default, not as an add-on.

What to evaluate

Can scheduling scale dynamically with the number of active manufacturing runs?

Does the system provide real-time notifications when alert or action limits are reached, or does it capture data for review after the fact?

How are EM excursions linked to the associated batch record?

Is environmental monitoring a native workflow or a separate module?

3 How Does a Cell and Gene Therapy LIMS Balance Workflow Configurability with Control?

CGT quality teams need a system that is configurable during implementation but controlled in production. Balancing these requirements is difficult: the platform must give quality teams the flexibility to configure workflows while preventing operators from deviating from approved processes once those workflows are in use.

The system must also support the necessary compliance controls from the start and align with GMP requirements.

What to evaluate

Can the system block noncompliant actions during execution, such as the use of expired reagents, out-of-calibration equipment, or batch release with open deviations?

How does the system support 21 CFR Part 11 requirements for eSignatures? Is authentication required at the moment of signing, or does signing only require checking a box?

How does the system handle multi-operator workflows, scribed entries, and second-person verification?

Is workflow compliance truly enforced, or is it only configurable?

4 How Should a Cell and Gene Therapy LIMS Handle Change Control?

A common challenge for CGT is change control, an area that many LIMS struggle to accommodate. Because CGT evolves rapidly, every protocol change cannot trigger full system revalidation; doing so would be far too time-consuming.

Look for a LIMS with a clear architectural separation between the validated platform and the configuration layer. This separation allows teams to make updates quickly without requiring developer resources or vendor services, which can delay work by weeks and add unnecessary costs.

CGT science evolves continuously, and the LIMS must accommodate new process parameters, new analytical methods, and new metadata requirements that naturally emerge as programs advance through clinical phases.

What to evaluate

Can you alter workflows and fields within an isolated configuration layer without changing the underlying validated codebase?

Does the vendor force automated software updates that break your validated state, or can you test upgrades in a sandbox on your own timeline?

Can your team modify workflows in production without engaging the vendor?

5 What Electronic Batch Record Capabilities Does a Cell and Gene Therapy LIMS Require?

CGT workflows require core functionality often found in electronic batch record (EBR) solutions. This includes the ability to model and enforce manufacturing workflows, capture batch execution data in real time, and maintain chain of custody throughout production. While some teams may still choose to use both a LIMS and an EBR, certain CGT LIMS can replace a separate EBR entirely.

What to evaluate

Does the LIMS automatically capture raw material usage, equipment operations, process parameters, and QC results directly from instruments and the laboratory floor?

Does the system enforce a controlled sequence or can operators accidentally bypass required steps?

Does the platform integrate natively with ERP systems like SAP to handle real-time inventory tracking and automated material reconciliation?

Can the system compile the complete batch record automatically, or does it require manual data assembly?

6 What Data Architecture Is Best for a Cell and Gene Therapy LIMS?

The data architecture of a LIMS determines how easily you can query your data, establish provenance, and prepare your data to support future process intelligence and AI.

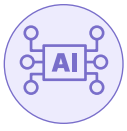
In traditional relational (SQL) systems, data is stored in rigid tables, often requiring complex data engineering and custom coding to trace a sample's history. In contrast, graph-native systems capture relationships between data automatically at the moment of execution. Because these relationships are stored natively rather than reconstructed across separate tables, tracing data lineage is much simpler.

This difference also affects a platform's readiness for process intelligence and AI. Relational models often require significant data engineering to surface patterns across operations, while graph-native models keep data permanently connected and ready for AI tools out of the box.

What to evaluate

Are relationships between entities stored in a relational schema or as first-class elements of the data model?

What is required to query process patterns across batches, operators, and instruments? Is this a native feature or a data engineering project?



Does the LIMS data model position your organization to take advantage of AI-driven process intelligence as the technology matures?

7 How Does a Cell and Gene Therapy LIMS Support Inspection Readiness?

For CGT teams approaching commercial scale, immediate access to well-structured data is essential for inspection readiness. Quality teams must be able to retrieve complete compliance records in a format that is immediately usable during audits, with data that upholds ALCOA+ principles throughout its lifecycle.

Reports must be human-readable and audit-ready by default, eliminating the need for manual exports and assembly. When an FDA inspector asks a question, the system must enable your team to trace the answer and its supporting records in real time.

What to evaluate

Can the system produce audit-ready reports without requiring teams to reconstruct relationships through custom queries or manual data assembly?

How does the system surface the complete history of a sample, batch, or operator action during an inspection?

Are reports human-readable, or do they require manipulation after export?

How does the system support ALCOA+ principles across data capture, review, changes, retention, and retrieval?

The right CGT LIMS balances patient-level traceability and GMP control with the flexibility to evolve alongside the science. Evaluating these seven areas can help teams select a platform that supports today's workflows and scales as their programs advance.

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