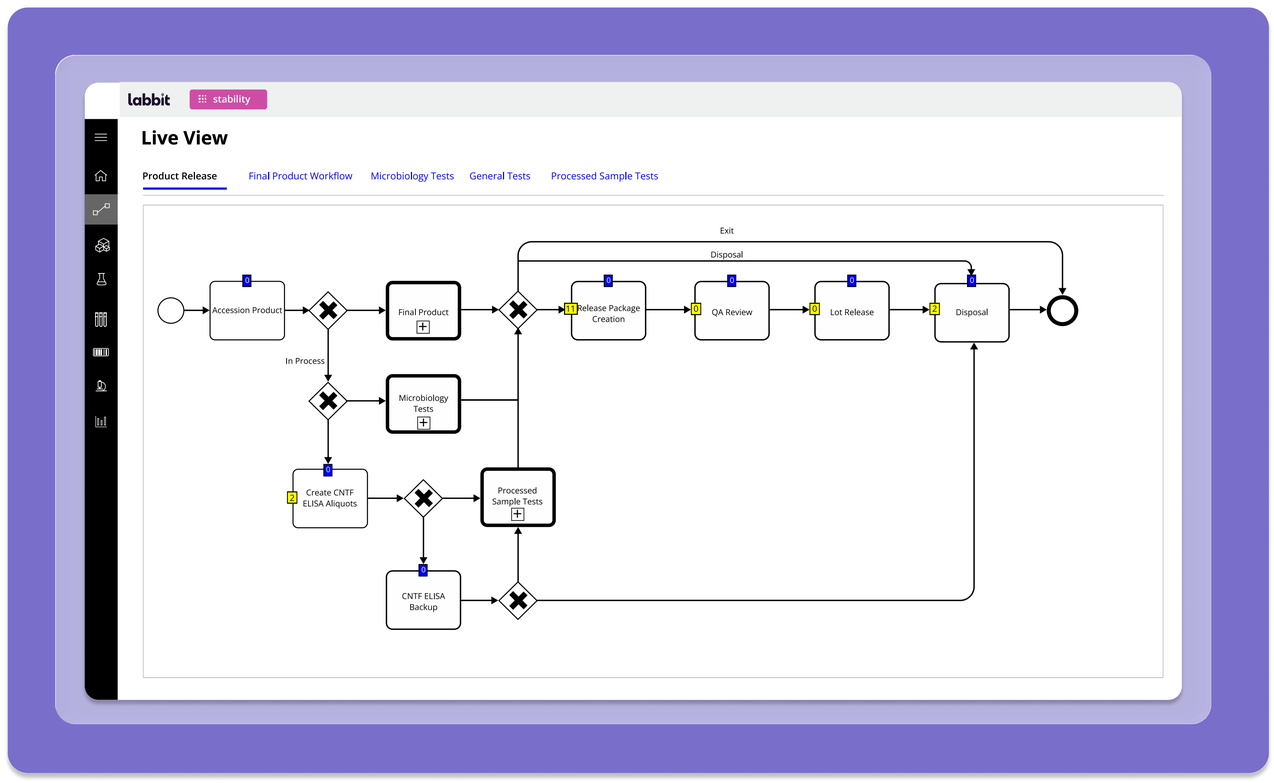
labbit

CELL & GENE THERAPY MANUFACTURING LIMS

Built to Enforce GMP in Regulated Cell & Gene Therapy Manufacturing

Labbit is the graph-native, workflow-first platform that unifies execution, compliance, and investigation for cell and gene therapy by capturing every relationship as work happens to enable faster decisions, stronger compliance, and continuous improvement.



Move Faster Without Sacrificing Control

Labbit lets teams respond quickly to changing requirements by adapting the LIMS within a controlled, validated framework, while maintaining traceability, enforcing GMP, and preserving control as they scale.

Flexibility Without the Validation Tax

By separating configuration from platform versions, teams can adapt workflows, fields, and process parameters within the validated envelope and revalidate only what changed.

Traceable By Design, Not Reconstruction

Every action, signature, and change is captured as a complete, immutable electronic record, including the context, conditions, and sequence that explain who did what, when, and why.

Compliance Enforced at the Decision Point

Labbit enforces compliance at the point of execution by blocking non-compliant actions, gating workflows on required approvals, and enforcing e-signatures within controlled steps.

From Event to Full Context, Instantly

Labbit connects events to their full context, enabling investigators to trace chain-of-custody, accelerate root cause analysis, strengthen CAPAs, and make faster decisions.

Process Intelligence, Built Into the Foundation

Labbit captures relationships natively, enabling teams to analyze patterns, uncover sources of variation, and answer new questions without data restructuring or engineering overhead.

One Platform, From Clinical to Commercial

Labbit scales from IND-stage workflows through commercial launch, with the configuration flexibility to adapt to growing volumes and manufacturing complexity.

Core Capabilities for Cell & Gene Therapy

No-Code Workflow Configuration

Build, modify, and version GMP workflows using BPMN—no custom code or developer involvement.

Chain-of-Identity and -Custody Traceability

Link patients, materials, samples, and process steps as connected, auditable data—from origin to release.

Electronic Batch Records

Execute guided, SOP-enforced batch records with point-of-action e-signatures and full operator attribution.

Separate Dev, Test, & Production Environments

Easily promote configuration changes through development, validation, and production with the right approvals at each stage.

Instrument & Software Integrations

Connect instruments and systems to automate data capture and ensure consistency.

AI and Analytics-Ready Data Capture

Capture process, sample, and quality data as connected graph data, ready for analysis without restructuring.

Support for Every Cell & Gene Therapy Modality

AUTOLOGOUS CELL THERAPY MANUFACTURING (CAR-T, TIL, TCR)

Complete Provenance for Patient-Specific Manufacturing

Labbit's graph-native model captures chain-of-identity from apheresis to product release, linking patient, material, sample, operator, and quality event across every step. E-signatures, real-time deviation flagging, and workflow enforcement capture each action in context, creating an inspection-ready record for every patient lot without reconstruction or unnecessary validation overhead.

VIRAL VECTOR & GENE THERAPY MANUFACTURING (AAV, LENTIVIRAL, CRISPR)

Controlled Evolution of Complex Gene Therapy Processes

Labbit links plasmid, vector, and patient dose as connected, traceable data, while structured workflows manage complex branching, handoffs, and conditional routing. As programs scale, teams can update assays and process parameters within a governed, validated framework, with versioned, impact-scoped changes that limit revalidation to what changed.

ALLOGENEIC CELL THERAPY MANUFACTURING & IPSC-DERIVED PRODUCTS

Consistency and Lineage at Commercial Scale

Labbit connects every stage from donor material through cell banking, expansion, and differentiation, providing the lineage visibility needed to demonstrate lot-to-lot consistency at scale. Workflows, assays, and process parameters can evolve within the validated state as production matures.

CGT CDMOs

A Single Platform for Multi-Client GMP Operations

Labbit isolates client data while maintaining consistent execution across programs, with configurable workflows that support diverse sponsor requirements without bespoke builds. Each IND or BLA retains a separate, complete traceability and audit trail, enabling CDMOs to manage client variability without compromising control or compliance.

Ready to Start Your Lab’s Digital Transformation?

Contact us for a personalized demo of the next generation of laboratory informatics.

www.labbit.com