

STEMSOFT Software uniquely offers:

A proven bioinformatics solution for cellular therapy

Our team of experienced technical and healthcare professionals have an average of 10 years experience focused exclusively on bioinformatics applications for cellular therapy. STEMSOFT has developed a unique central database model that integrates both clinical and laboratory cellular therapy data to support comprehensive outcome analyses.

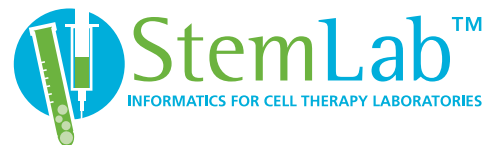
Industry knowledge

Having implemented our software solutions in over 40 cell processing laboratories around the world, we understand the challenges, opportunities, and practicalities of the cellular therapy industry. In addition, STEMSOFT Software has long-standing relationships with complementary clinical organizations working to establish central patient registries.



Cellular Therapy Manufacturing Software

Information From Bench to Bedside



For a demonstration of how StemLab™ can meet your needs, please contact
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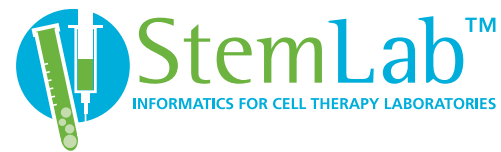
for detailed information about other STEMSOFT Software informatics solutions...





Your Complete Cellular Therapy Manufacturing Software Solution

StemLab™ software supports the collection, processing, storage and distribution or administration of high-quality cellular therapy products. StemLab™ is specifically developed for academic laboratories, cord blood banks and biotech companies who manufacture cell therapy, gene therapy, and immune therapy products. StemLab™ is built to ensure quality and regulatory compliance standards are met by establishing procedural protocols, monitoring manufacturing processes and documenting lot to lot traceability.



Features

For Quality Product Information

- Record all product sampling and assay results including support for device and HL7 interfaces
- Enhance workflow efficiency and quality of data entry with designated fields as 'required' or enforced double entry for validated data fields
- Document vital data points such as infectious disease screening, sterility, tissue typing, hemoglobinopathy testing, viability, colony-forming units and blood typing
- Standardize processes through protocol driven procedures that track collections, manipulations, segments and products
- Generate and read ISBT 128 barcode labels along with support for both 1D and 2D barcodes

For Laboratory Operational Information

- Enforce operational sequencing with the ability to include forced data entry pre-requisites, supervisor review status and record lock following final approval
- Document deviations, complaints and other events and link to a full CAPA system
- Access electronic standard operation procedures (SOP's), or link to a full document management system
- Track all consumable and equipment information and relate each use to individual product manufacturing processes for lot to lot traceability
- Customize freezer configurations and easily track product and related specimen inventories
- Perform ad hoc queries and generate customized reports for outcome analysis and ongoing quality assurance information review

Benefits

Process Standardization

- Improve protocol compliance and reduce documentation errors

Quality Assurance

- Compile data for trend and quality assurance analyses of processes, procedure and products

Regulatory Compliance

- Comply with HIPAA, GMP, IND, 21 CFR Part 11 and regulatory requirements for documentation of identity, purity and potency of products

