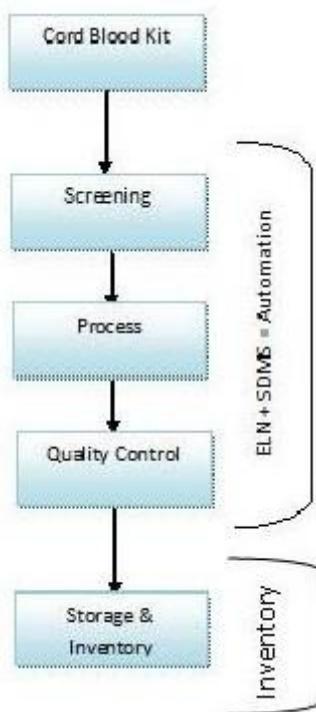




WHAT'S UP WITH CORD BLOOD REPOSITORIES

Cord blood repositories today process several units which is becoming more and more difficult for such banks to use manual procedures to record information that called for by regulatory bodies like UFDA, AABB or FACT.

There is no point in blaming the repositories, this sector is taken aback looking at the implementation, maintenance and total cost of ownership of automation solutions for this need and at the same time comply with the regulatory norms.



Logilab SDMS & ELN when combined proved to be winning combination

Q: What if you had an electronic system for easily generating Kits and Receiving units?

A: Logilab ELN helps cord blood banks in creating collection kits with barcode labelling.

Q: What if you can locate a specific Unit IDs screening, processing, QC information in a single go?

A: Logilab SDMS and ELN is a central repository of all your unit data. The system allows you to access your unit data in no time

“We implemented Logilab SDMS & ELN based automation for our cord blood repository. We are experiencing a remarkable change in our way of handling data in terms of throughput, compliance & reach for data on our units”

Daniel Gibson (R&D Supervisor, Anthony Nolan, Nottingham)

GET THE PICTURE

Anthony Nolan used an excel based database for recording information on the cord blood units that they receive, process, quality test and cryostore.

This was a complete manual processes and was completely dependent on personnel working in the lab to record information into paper and excel. Even though they were accredited by net-FACT and their manual process was very well setup and practiced they felt the need for automation.

Their current system was indeed maintaining all the necessary information both in paper, electronic files in a central server. However the traceability, quick reachability to specific information. Compliance with respect to 21 CFR Part 11 etc were not good enough.

AUTOMATED CORD BLOOD BANK

FieldKey	Field Label	Result	User Name	Sh	
1	I00016	DocStatus	FINAL	Administrator	FACSCan
2	I00017	AR No	SEPAX 5	Administrator	FACSCan
3	I00018	Beads	2,000	Administrator	FACSCan
1	I00019	Total CD45	27,938	Administrator	FACSCan
5	I00020	Total Stems	172	Administrator	FACSCan
3	I00021	Total Mononuclear Cells	14,331	Administrator	FACSCan
7	I00022	Live CD45	27,732	Administrator	FACSCan
3	I00023	Live Stems	171	Administrator	FACSCan
3	I00024	Live Mononuclear Cells	14,322	Administrator	FACSCan
0	PNAME	Product Name	Cord	Administrator	FACSCan
1	SAMPID	AR Number	SEPAX 5	Administrator	FACSCan

Full Traceability

Full Traceability

LogiLab SDMS & ELN has been designed for regulated labs and have full traceability for data including version and release controls

Instrument output at appropriate cells and approve results. The ELN also helps in complete view of a specific Unit-ID data based user designed template. Screening, QC data, including processing data are available in a single location. The reviewer and approver were able to check all the necessary data before the unit can be approved for processing and cryostorage or to be quarantined or could be used for research purpose.

Inventory & Cryo-Storage

A fully configurable inventory and storage management system was deployed that can handle storage, issue, disposal of cord units. The system also has traceability of temperature outages that happened during the unit storage or movement.

Key Benefits

- ✓ Automated raw-data, meta-data and human readable data capture. Automated results extraction & population
- ✓ ELN based data entry, calculations, unit-ID centric overview of complete process
- ✓ ELN based Approval and decision for further action on the unit
- ✓ ANL stopped printing paper or storing reports in network folders and stopped excel based manual results entry.
 - ✓ Complete date & time stamped traceability right from kit shipment to cryo-storage.



SDMS
Logilab



ELN
Logilab

Agaram Technologies (HQ)

Priyan plaza 76
Nelson Road Aminjikarai
Chennai 600 029, India
T: +91 44 42082005
E: info@agaramtech.com

info@agaramtech.com

Agaram Technologies (KOREA)

941 Hogye-Geumjeong SK V1 Center
42, LS-ro, Dongan-gu, Anyang-si,
Gyeonggi-do 14118, KOREA
T: +82 31 429 8958
E: info@agaramtech.com

Agaram Technologies(USA)

20130, Lakeview Center Plaza
Suite 400, Ashburn, VA 20147
U.S.A
T: +1 703 297 8591
E: info@agaramtech.com

www.agaramtech.com

The system was configured to generate unique KIT barcodes to be shipped to hospitals for collection. Units when received at the cord blood bank were scanned and the necessary barcode labels for screening is generated. Units are screened on hematology analyzers and flow cytometers for basic criteria for moving the unit for further processing within the cord bank. Screening results published by the hematology and flow cytometers are captured by the SDMS as human readable pdf files while storing the original raw-data for further reference.

Automated Parsing

The automated parsing capability of the SDMS_ELN helps in quickly extracting data of interest from the screening instrument output. Right from data capture to extraction and display of data happens in complete automated fashion i.e. with little or no human intervention.

Unit Processing, QC, R&D, Storage or Disposal

System was also configured to capture every piece of information right from the shipping temperature logs, screening tests, Unit processing by Sepax® and Coolmix® instruments, quality control results from hematology, flow cytometer, bacteriology, virology, and HLA typing instruments. Data from all the instruments are captured through schedulers, processed by the parsing engine to extract data of interest. The ELN is used as a front end tool to input manual data, check calculated data, review data extracted from