

EdgeCell™

Specialized system
for cellular therapy labs and
tissue banks

SOFTWARE SOLUTIONS



Manage stem cell and tissue product information—from collection to utilization

Haemonetics understands that the collection, processing and storage of therapeutic cells and tissues require careful and precise processes, accurate documentation and seamless traceability to ensure the highest product quality, and to satisfy regulatory and accreditation requirements. However, we recognize that it is becoming increasingly more difficult for organizations to efficiently manage the required traceability of processes using manual methods and spreadsheets.

EdgeCell™ is our comprehensive software solution for the management of your Cellular Therapy, Cord Blood Bank and Tissue Bank programs. This specialized software solution enables you to more efficiently manage your stem cell and tissue product information — from collection to utilization — including electronically tracking and managing your donor, patient and product information in a centralized database. EdgeCell also helps you monitor and streamline your processes; enforce quality controls and maintain traceability; and meet quality and regulatory requirements as well as accreditation standards.

Manage your data from a comprehensive dashboard

The screenshot displays the EdgeCell software interface for managing patient and donor information. The main window shows a profile for Philip SMITH, with fields for birth name, spouse name, first name, middle name, date of birth, gender, and marital status. It also includes contact information (home, mobile, business phone) and email. A table of procurement protocols is visible, showing details such as closure date, physician in charge, and place of protocol. Below this, a table of planned procurements lists dates, types (Allo HPC-A), volumes, and completion status.

Type	Closure Date	Physician in charge of protocol	Place of protocol (1)	Place of protocol (2)	Place of protocol (3)	Physician 2	PI
Homologous	31/08/2012	Kidare Richard	270 76th Ave		29910 BLUFFTON	Casey Ben	(916)
Homologous	15/06/2012	Jackson Kevin	270 76th Ave		11042 NEW HYDE PAF	VANDEBWEYEN Ala	

Planned date	Type	Volume	Done
01/08/2012	Allo HPC-A	200	Yes
10/08/2012	Allo HPC-A	200	Yes
17/08/2012	Allo HPC-A	200	Yes

Manage patient and donor information, store and link documents (such as informed consent and protocols), schedule collections or procurements, maintain insurance and manage test result data all from a single, comprehensive dashboard.

Streamline operations, enforce quality controls and maintain traceability

Manage donors and patients

With EdgeCell™, you can properly identify your patients and donors, including linking mother to baby and donor to recipient; schedule collections or procurements, store documents and manage test results — all from a single, comprehensive dashboard. You can also:

- Link stored protocols, informed consent and other documents to donor or patient records
- Create rules to automate deferral postings based on medical history and test results; medical override option is available
- Improve consistency and help reduce errors with customizable, electronic medical questionnaires

Monitor and streamline processes

The EdgeCell solution is designed to automate and streamline your lab's collection, manufacturing/ transformation, storage and distribution processes for stem cells, cord blood and tissue products as well as centralize data generated from multiple sources, in a single product record. Key features include the ability to:

- Document testing, manufacturing/ transformation processes and product storage
- Assign, track and manage linked items, supplies and equipment used
- Leverage built-in configurable workflows for stem cells, cord blood and tissues
- Create processing “trays/kits” and assign to manufacturing processes to track as one item
- Improve inventory management with easily identified lot information and expiration dates
- Automate product storage, retrieval, movement history and tracking with the Biorepository
- Generate and print ISBT-128 and site-specific labels

Enforce quality controls and maintain traceability

We understand that proper handling and precise processing is required in order to help ensure product quality. By helping to enforce adherence to procedural protocols, standard operating procedures (SOPs), business rules and accreditation requirements, the EdgeCell solution can help your lab achieve process standardization, drive quality control and maintain traceability. With EdgeCell you can:

- Monitor and track manufacturing and transformation processes
- Help ensure quality by alerting users to non-conformances in process steps or test results
- Configure automatic calculations to improve accuracy and reduce mistakes
- Electronically track and manage products from receipt to utilization
- Reduce errors by interfacing with laboratory analyzers and equipment
- Handle label verification, release rules and distribution
- Facilitate holds and manage recalls



Record patient outcomes

With the EdgeCell solution, your donor, patient and product data is stored in a central database, enabling access to information and reports in real-time. This allows you to:

- Record adverse reactions and post-infusion details
- Confirm product distribution and patient infusion/implantation
- Access product information and patient engraftment outcomes
- Leverage built-in standard and custom reports

Improve the efficiency, compliance and traceability of your cell and tissue management programs

Whether products are intended for immediate use, or for long-term storage for patients who will require a future engraftment or transplant, the EdgeCell™ solution can meet your stem cell and tissue information management and operational needs —from collection to utilization, enabling your organization to:

- Achieve process standardization in your laboratory by helping to enforce adherence to SOPs, business rules and requirements
- Respond to emerging regulations and guidelines with configurable system settings, manufacturing processes, release rules and quality checks
- Simplify record keeping and streamline document management by centralizing data from multiple systems and sources in a single system, including linked supplies, kits and equipment
- Streamline processes and increase efficiency by improving inventory management, and managing multiple protocols, processing steps and lots
- Print ISBT-128 compliant and site-specific labels to identify and track product, samples, kits, supplies and more
- Facilitate product recall and lookback management with configurable rules and holds/blocking attributes
- Maintain traceability from receipt to final disposition
- Document and record patient engraftment outcomes

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About Haemonetics

Haemonetics is *THE* Blood Management Company. Our comprehensive portfolio of integrated devices, information management, and consulting services offers blood management solutions for each facet of the blood supply chain, helping improve clinical outcomes and reduce costs for blood and plasma collectors, hospitals, and patients around the world. We believe that through proper blood management, our products and services help prevent a transfusion to the patient who doesn't need one and provide the *right* blood product, at the *right* time, in the *right* dose to the patient who does.