

Laboratory Specialist

Req ID #: 2625

Location: Lowell, MA

For over 40 years, HemaCare, a Charles River company, has worked to making a positive impact on the world by providing the highest quality cellular material and services to biotech and pharmaceutical companies and research organizations that are performing innovative research and developing novel cell-based therapies.

We recognize that our success depends on the vision and passion of our employees; that is why we are devoted to making HemaCare a rewarding and valuable place to work. We believe in making a difference, and at HemaCare, you will make a difference every day.

JOB SUMMARY

The Laboratory Specialist works under the general supervision of the Apheresis Site Manager: Performs donor/subject and blood product complete cell counts (CBCs); Performs donor/subject and blood product specific cell counts; Determines viability of cellular products; Prepares components from whole blood; Creates or revises standard operating procedures; Performs equipment validations: Performs assay optimization/validations. Prepares shipments of cell products to clients with appropriate shipping container systems and tracking devices as needed to include all required paperwork; responsible for ordering site medical supplies for the site and controlling inventory for lab and apheresis unit at site.

Responsibilities:

- Performs donor/subject and blood product complete cell counts (CBCs): Uses cell counter to perform complete blood counts; maintains appropriate related records.
- Responsible for daily QC of laboratory instruments and scheduling of preventative maintenance of equipment as needed.
- Performs donor/subject and blood product specific cell counts using MACSQuant[®] flow cytometer, including, but not limited to, CD34+ and CD45+ cell counts.
- Determines viability of cellular products using MACSQuant device.
- Prepares components from whole blood units, e.g. true off-the-clot serum.
- Creates or revises standard operating procedures as needed.
- Performs equipment validations as needed.
- Performs laboratory assay optimization/validations as needed.
- Packages cell products according to customer's specifications and company standard operating procedures.
- Prepares paperwork for cell shipments including packing slips, product yield reports, and leukapheresis collection records for inclusion with the shipment and COAs as applicable.
- On site contact point for all couriers: Fed Ex, UPS, World Courier, Quick, local couriers. Must ensure packages have left site each day per required pick up time. (working with assistance from Logistics Coordinator in Memphis)
- Orders and receives in inventory for the site in conjunction with assistance from Logistics Coordinator at Memphis site. Verifies contents of incoming shipments meet specifications and PO requirements, and documents receipt. Responsible for resolving discrepancies with help of Logistics Coordinator in Memphis and with vendor supplying the item in question.



- Assists apheresis team with packaging of viral marker samples that go out daily and being point of contact for daily courier pickup of the viral marker samples.
- Assists the Apheresis Site Manager with review of daily records and QC for site in conjunction with the Compliance and Regulatory team based in Memphis.
- Will serve on site call tree for answering of phone calls from monitoring alarm company. Refrigerator and freezer equipment in laboratory and room temperature and humidity remote monitoring at site.
- Assist Compliance and Regulatory department to pull site specific records for internal audit needs or for external audits.
- Performs other duties as assigned.

Supervisory Responsibilities This position has no direct supervisory responsibility

Requirements:

- Knowledge of cGMPs, cGLPs and applicable cGTPs.
- Ability to instruct others with technical and non-technical background.
- Ability to recognize, analyze and resolve technical problems.
- Excellent oral and written communication skills.
- Ability to comprehend written technical and non-technical procedures.
- Ability to organize work. Must be able to handle multiple projects and provide feedback.
- Ability to keep accurate, detailed records.
- Ability to work in a highly regulated environment.
- Ability to work in an automated, computerized environment.
- Ability to maintain a professional and courteous attitude at all times
- Ability to work independently and manage own workflow.
- Ability to work flexible hours.

Education, Experience and Licensure

- Bachelor of Science in Medical Technology (MT) preferred or medical laboratory technician (MLT) degree with requisite state license for practice in state of Massachusetts.
- Three or more years' experience in a laboratory environment

About HemaCare

HemaCare, a Charles River company, is a global leader and trusted brand in the customization of human-derived biological products and services for biomedical research, drug discovery, and cell and gene therapy development. HemaCare's vertically integrated solutions support preclinical research, clinical studies from phases 1 to 3, and commercialization with high-quality RUO and GMP-compliant starting material and apheresis collections.

In January 2020, HemaCare was acquired by Charles River Laboratories, an early-stage contract research organization (CRO). Combined with Charles River's integrated, early-stage portfolio of discovery, safety assessment, and manufacturing support services, the acquisition creates a unique, comprehensive solution for researchers and cell therapy developers and manufacturers worldwide to help accelerate their critical programs from basic research and proof-of-concept to regulatory approval and commercialization. Utilizing this broad portfolio of products and services enables our clients to create a more flexible drug development model, which reduces their costs and enhances



their productivity and effectiveness to increase speed to market. We work closely with our clients throughout the clinical process to maximize success and drive positive clinical outcomes.

Together, with over 17,000 employees within 80 facilities in 23 countries around the globe, we are strategically positioned to coordinate worldwide resources and apply multidisciplinary perspectives in resolving our client's unique challenges. Our client base includes global pharmaceutical and biotechnology companies, government agencies, and hospitals and academic institutions around the world.

At HemaCare, we are passionate about our role in improving the quality of people's lives. We have proudly supported the development of 100% of the current commercially available FDA-approved immunocellular therapies. Our mission is to provide a best-in-class portfolio of high quality, customizable human cellular material and services to support drug discovery, scientific research, and cell therapy. This resonates from our employees and impacts our customers because we know that every day is an opportunity to advance discoveries and make a difference in someone's life.

For more information, please visit www.hemacare.com.

Equal Employment Opportunity

HemaCare, a Charles River Laboratories Company, is an Equal Opportunity Employer M/F/Disabled/Vet

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