Quality Assurance Specialist

Req ID #: 2604
Location: Northridge, CA

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 This position will provide support to ensure the organization maintains compliance with Quality Systems, current Good Manufacturing Practices (cGMPs), current Good Tissue Practice (cGTPs), and in adherence with all applicable Federal, State, local, international, and industry regulations and standards. This individual will actively perform a variety of activities needed to establish and maintain compliance; including but not limited to donor deferral management, nonconformance management, quality assurance and internal and external audits.

Responsibilities:

- Performs job functions in compliance with internal Standard Operating Procedures, Current Good Manufacturing and Tissues Practices, all Federal and State regulations and accrediting agency standards.
- Maintains training competency on applicable Quality Assurance, Quality Systems, and Regulatory policies and procedures.
- Maintains all forms, logs and other applicable records and spreadsheets.
- Participates in defining and revising policies and procedures related to the position.
- Assists in the preparation of records prior to and during external assessments.
- Maintains confidentiality of proprietary materials and information.
- Assists other QA staff with regulatory and quality functions as deemed necessary
- Assess and triage QSR Reports and notify management and departments for any issues impacting SQuIPP of products.
- Assign QSR numbers for applicable reports including but not limited to deviations, MRBs, Exceptions, Post Donation Information and adverse reactions.
- Assess for deviation error codes and determine investigation categories.
- Maintain the QSR log and track reports from discovery to closure.
- Assist with investigations and corrective and preventive actions (CAPA).
- Assist with conducting internal audits and assist during external audits.
- Assign tracking numbers for internal audits and maintain all applicable documentation and records as it relates to the audit.
- Maintain all applicable documentation and records as it relates to the external audit process.
- Assist in compiling and disseminating of quality systems statistical data as directed and as assigned by management in preparation for Quality Assurance Management Meetings.

- Maintains and updates donor deferral documentation on donation records, donor charts and all other applicable records.
- Input donor deferral data into appropriate Blood Establishment Computer System including but not limited to onsite deferral, reactive test results and deferrals resulted from post donation information.
- Assist with special projects as assigned.

Supervisory Responsibilities This Position has no direct supervisory responsibility.

Requirements:

- Meets department quality standards.
- Good time management skills; ability to complete assignments within established timelines.
- Ability to work with minimal supervision, set priorities, and perform multiple tasks simultaneously.
- Knows and follows safety rules relative to area(s) or responsibility.
- Flexibility is required to meet sudden and unpredictable needs of the department and/or the company
- Ability to apply professional standards to work situations.
- Discretion in handling confidential and sensitive matters
- Proficient use of Microsoft Office applications including Word, Excel, Outlook and PowerPoint.
- Ability to quickly learn new software programs as needed.

Education, Experience and Licensure

- B.S., B.A. or Associate Degree preferred, but not required if work history is equivalent
- Minimum three (3) years of related experience or equivalent combination of education and experience in a regulated 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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