Quality Assurance and Regulatory Affairs Manager

Req ID #: 2606
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
Manage Quality Assurance and Regulatory Affairs for HemaCare Corporation operations following 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.

Responsibilities:

- Responsible for monitoring compliance with all applicable regulations: local, State, Federal, International, FDA, AABB, OSHA and other applicable agencies.
- Monitor compliance through performing internal audits, managing deviations, review and approval of standard operational procedures (SOPs), master batch records, validation plans, other controlled documents and the review and assessment of Quality Systems reports.
- Provide consultation for operations concerning IRB approvals, regulations, appropriate standard operating procedures, and validation protocols.
- Prepare for, facilitate and participate in quarterly Quality Management Meeting and routine Change Control Meetings.
- Perform internal audits, manage results and report results to executive management.
- Participate as a team member or serve as project lead and manage quality improvement projects.
- Support cross-functional project teams in the development and implementation of validation plans and protocols.
- May serve as Quality support in cross-functional GMP project teams
- Develop, review, and revise general QA department (QMS) SOPs.
- Perform final QA batch record reviews for the release of GMP products.
- Perform QA disposition of incoming materials.
- Review manufacturing, environmental monitoring, and quality control data for in process and finished products.

- May perform Quality functions in the cleanroom following applicable gowning procedures.
- Assist or lead special projects as assigned.
- Performs all other duties, at the discretion of management, as assigned.
- Quality Management Activities:
- Process improvement activities including developing statistical reports for tracking and trending quality system reports for reporting to executive management.
- Evaluate and review operational policies and procedures to ensure that SOPs are clear, accurate, concise, and complete before approval.
- Evaluate and approve employee training and competency programs to ensure compliance with all regulatory requirements.
- Responsible for developing, maintaining and training on QA, Quality Systems, and Regulatory policies and procedures.
- Provide initial and ongoing annual training for GMP, GTP, GCP, GLP, and GDP for all staff.
- Provide training on the use of electronic Quality Management System software.
- Communicate with and advise customers regarding quality assurance requirements and activities.
- Work with other QA management staff to ensure an adequate internal assessment program is maintained.
- Review Change Control and Document Change Control request to ensure all aspects of the proposed changes and project plan are adequate before issuing approval.
- Quality system reports oversight including deviations, complaint, exceptions, MRBs, etc. Monitors compliance and generates statistics for tracking and trending purposes. Assist in the investigation and development of Corrective Actions and Preventative Actions, as necessary.
- Work closely with HemaCare Medical Directors to ensure that operational/clinical activities, policies and procedures meet standards to ensure donor, staff and patient safety.
- Regulatory Management Activities
- Interface with regulatory agencies, accreditation bodies and customers on issues related to Quality and Regulatory systems and IRB issues.
- Monitor all applicable government and accreditation agency regulations and requirements to ensure compliance. Notify operations of regulatory changes.
- Review and approve operational SOPs for regulatory compliance.
- Support regulatory inspections and Customer Supplier Qualification Audits, coordinate responses, maintain all applicable documentation and records.
- Process and maintain all required licenses, permits, registrations and accreditations.
- Supplier/Vendor Management Activities

- Coordinate and Manage Supplier/Vendor Qualifications for HemaCare's suppliers/vendors. Maintain all applicable documentation and records.
- Coordinate with operations to ensure all critical supplies and services are assessed for criticality and are obtained from approved suppliers.
- Ensure approved suppliers are re-qualified at appropriate intervals.
- Monitor FDA warning letters to ensure currently approved suppliers are not under regulatory restrictions which might impact HemaCare's critical supplies.
- Perform onsite audits of suppliers as a component of supplier qualifications/requalification as deemed necessary.
- Validation Management Activities
- Responsible for ensuring the organization's validation program and practices are compliant with all of the most current applicable regulatory requirements and are current with the industry standard. Also, be responsible for prioritizing tracking, and reporting of major validation initiatives.
- Lead cross-functional project teams in the development and implementation of validation plans and protocols.
- Review and approve validation plans related to equipment, software, process, facility, and cleanroom related protocols.
- Review and approve completed validation documentation.
- Present HemaCare's validation processes and documentation during external audits (e.g., FDA, AABB, customer and other regulatory agency inspections).
- Donor Deferral and Document Control Management Activities
- May have oversight of donor deferral activities including product quarantine/retrieval/recall, consignee notifications and Federal, State and County notifications and review of records: Post Donation Information, abnormal test results, potential duplicate donors.
- May have oversight of document control activities including working with document control staff to maintain strict document control of SOPs, forms, validation plans and other associated documents.
- Training Management Activities
- May have oversight of training management activities including coordinating, scheduling, documenting, and maintaining training activities within a cGMP environment. Training consists of but is not limited to new hire training, annual refresher training, departmental and interdepartmental specific training, competency assessments and remedial training for all HemaCare employees.
- Supervisory Responsibilities May supervise other QA & RA staff as assigned.
- Trains, hires, disciplines and terminates employees, conduct performance evaluations and recommends opportunities for advancement. Ability to evaluate and manage skills and

development needs of individuals and teams, manage the IPMP for direct reports and mentor associates to facilitate professional and departmental growth.

Requirements:

- Meets and maintains 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) of responsibility.
- Flexibility is required to meet sudden and unpredictable needs of the department and the company.
- Ability to apply professional standards to work situations.
- Discretion in handling confidential and sensitive matters.

Education, Experience and Licensure

- Bachelor's degree in biological science discipline preferred. In lieu of degree, seven to ten years of comparable progressive experience is required. Advanced degree is a plus.
- Seven to ten years of progressive quality or manufacturing experience in cell therapy, pharmaceutical, biotech, or biologics operations preferred.
- Strong working knowledge and ability to apply GMPs and GTPs in conformance to FDA, EU and AABB standards.
- Must have a good understanding of regulatory compliance frameworks applicable to blood banking, cellular therapy and human subject research protection requirements.
- Thorough understanding of key supporting quality systems including document management, training, change control, deviation, non-conformance, and CAPA. Requires expertise in performing root-cause analysis.
- Demonstrates excellence in all communication and interpersonal skills; able to develop and maintain cooperative working relationships with other staff members, management, and customers.
- Proficient use of Microsoft Office products including Word, Excel, Outlook, and PowerPoint.
- Ability to quickly learn new software programs as needed.

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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