Code: 2526

Title: Quality and Regulatory Manager
Status: Exempt
Location: Northridge (Los Angeles area)
Department: Quality & Regulatory

Description: 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:

- Utilize applicable aseptic techniques to plan, perform, and chart the following procedures in accordance with HemaCare policies and procedures
- Automated plateletpheresis and leukapheresis including set-up, run, quality control, troubleshooting and routine maintenance.
- White blood cell collections and other special procedures as required
- Whole blood procedures
- Make appropriate mechanical adjustments to apheresis machines based on product integrity and physical status of donor
- Expertise in venous access, identification, and treatment of donor reactions
- Expertise in blood donor medical history
- Expertise in assessment of laboratory reports
- Appropriate handling of information regarding positive test results
- Ability to work cohesively as a team member and at times in a non-verbal manner while under pressure and time constraints
- Consistently manage self in ways that express professionalism
- Demonstrate warmth and compassion in a meaningful manner
- Ability to understand and use correctly the Blood Establishment Computer Software (BECS)

Quality Management Activities:

- Process improvement activities including developing statistical reports for tracking and trending quality system reports for reporting to executive management.
- Evaluate & 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.
- 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 development of Corrective Actions and Preventative Actions if 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.
- Maintain Validation Master Plans to ensure compliance with regulatory requirements and current industry practices.
- 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.
- Proficient use of Microsoft Office products including Word, Excel, Outlook, and PowerPoint.
- Ability to quickly learn new software programs as needed.
- Must be able to resolve issues of a general and routine nature and exercise appropriate judgment to escalate issues to senior management.
- Must be able to effectively prioritize routine and non-routine work assignments to ensure goals and timelines are met.
- Must be able to read, interpret, understand and apply company and industry policies, procedures and best practices, ensuring compliance with Standard Operating Procedures, Current cGMP, and cGTP, FDA and AABB regulations.

Education, Experience and Licensure

- Bachelor's degree in life science discipline preferred. In lieu of degree, 7-10 years of comparable experience is required. Advanced degree is a plus.
- Seven - ten years of experience in blood banking, blood donor center operations, pharmaceuticals or medical devices preferred.
- Strong working knowledge of FDA, EMA, AABB, and OSHA is required
- Experience in cellular therapy products or familiarity with the life sciences industry (Pharmaceutical) desired.
- Previous experience in change of control process.
- Experience in GMP production sites.
- 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.
- Experience in using software systems for donor management and manufacturing operations.
- Demonstrated excellence in all communication and interpersonal skills; able to develop and maintain cooperative working relationships with other staff members, management, and customers.

Pay Range: BOE
Posted Date: 12/20/2018

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