Code: 2552

Title: Quality Control Manager
Location: Northridge, Ca
Department: GMP Cleanroom

Description: The purpose of this role is to help the Senior Clinical Scientific Laboratory Director maintain the Quality Control program at HemaCare. This role will determine the priority and workflow for all QC activities and oversee testing by contract laboratories relevant to the GMP products and cleanroom maintenance. The QC Manager will be responsible for all microbiological environmental monitoring of the cleanroom suite along with in-process control testing of material and samples generated within the cleanroom. Their secondary function will be to test material and samples generated by cleanroom staff when manufacturing research use only (RUO) product/material.

Responsibilities:

- Overall management and maintenance of the Quality Control Program at HemaCare in adherence to FDA, EU, ICH, and ISO standards and regulations.
- Responsible for the performance management and hiring of employees in the Quality Control department.
- Create and direct environmental test functions and applications and trend the data.
- Aid in the initial inspection of materials that arrive for the GMP program for the Cleanroom and QC department.
    - Raw material testing of incoming materials may be required.
- Review of process validations plans and reports as needed.
- Review all in-process and final product testing (if not performed by him/her-self and if applicable).
- Provide technical and statistical expertise.
- Formulate, document and maintain quality control standards and on-going quality control objectives.
- Create, document and implement inspection criteria and procedures.
- Manage interaction with contract labs and review the cleanroom specific testing data generated by them for all GMP product.
- Investigation of out of specification results, deviations and Corrective and Preventive Actions (CAPAs)Development of assays as applicable
- Design, develop and implement quality control training programs
- Create, Review, Revise, and/or Approve Standard Operating Procedures (SOPs) and other relevant documents.
- Manage and prioritize multiple projects for multi-discipline lab (EM, in-process and release testing, stability, assay development) if applicable.
- Review the QC components of the batch records.
- Any and all duties as deemed necessary and as assigned.

Supervisory Responsibilities: This position has direct supervisory responsibility

- Supervise Quality Control Specialists and Associates
- Responsible for staff development in areas such as GMP training, technical skills, safety, and performance management which includes hiring, completing annual performance reviews, and providing professional development opportunities.
- Supervise any staff involved in the testing of the cleanroom suite of GMP in-process or final product testing.

Requirements:

- Discretion in handling confidential and sensitive matters
- Organized, responsible, and dependable
- Detailed work ethic, accountable, and disciplined in actions
- Willingness to take ownership and complete tasks on time
- Ability to work within a cGMP cleanroom production cleanroom environment
- 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 investigate out of trends and specifications

Education, Experience and Licensure

- Must possess 5 or more years of working within a cleanroom environment
- A minimum of 5 years microbiological and environmental monitoring of an ISO and/or cGMP facility is required
- A four-year degree in a biological science or equivalent discipline or a comparable combination of experience and education is required
- A minimum of 2 years managerial or supervisory experience within a cGMP environment is required
- Working understanding of US FDA and global regulatory compliance preferred

Pay Range: BOE

Posted Date: 7/1/2019

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We celebrate diversity and are committed to creating an inclusive environment for all employees.