Code: 2521

Title: Laboratory Technician I
Status: Non-Exempt / Full Time
Department: General Laboratory

Description: The Laboratory Technician I will be responsible for performing laboratory testing, recording of results as well the manufacturing and labeling of blood products.

General Laboratory Essential Responsibilities

- Manufacture and process blood products by following Standard Operating Procedures (SOPs) and Good Manufacturing Practices (cGMP's)
- Assist in revision and creation of SOPs
- Operate hematology analyzer and perform pH testing
- Perform Quality Control and preventative maintenance on laboratory equipment as assigned. Maintain records in compliance with manufacturing and regulatory guidelines
- Prepare, pack, and send out samples from blood collections for testing
- Prepare and pack blood products for distribution to customers
- Label blood products, including assigning labels and recording information
- Identify and troubleshoot problems encountered in assigned tasks and properly document corrective actions. Confer with supervisor for resolution of problems
- Ability to identify and aid in the investigation of deviations
- Able to read, interpret, and understand company and industry manuals and compliance standards such as Standard Operation Procedure manuals, Current Good Manufacturing Practices, FDA, UE, and AABB regulations
- Perform environmental monitoring as well as read and record the results
- Knows and follows safety rules relative to area(s) or responsibility. Follows Standard Operating Procedures (SOPs) and Current Good Manufacturing Practices (cGMPs) and external regulations regarding the products and procedures

Cleanroom Essential Responsibilities

- Personnel will properly gown into a Class A and Class B environment
- Aseptic production of primary human cells within the cleanroom suite using accompanying documentation according to GMP guideline
- Maintenance, cleaning, calibrating, and qualification of cleanroom equipment as required
- Maintenance and cleaning of cGMP/clean room areas
- Select personnel will be responsible for the maintenance of released materials for inventory control.
- Inventory maintenance of gowning and cleaning supplies within the cleanroom suite
- Select personnel will be responsible for the maintenance of the manufacturing kit maintenance – Preparation of the kits for use within the clean room to be reviewed by Quality Assurance personnel.

Quality Control Testing Responsibilities

- Removal of expired materials from the laboratory
- Environmental monitoring of the cleanroom suite
    - Viable Air
    - Non-Viable Air
    - Viable Surface Monitoring
- Initiate deviations and perform investigations of Environmental Monitoring excursions
- Enter all environmental monitoring data and results into a database
- Maintain and author specification documentation for materials within the General Lab, QC, and cleanroom areas.
- Identify alternative vendors for new and existing supplies
- Submit/ prepare shipments of samples to external groups for testing which includes, but is not limited to:
    - Serology
    - Environmental Monitoring identification
    - Sterility
    - Mycoplasma
- In addition to the tasks above, may be assigned other duties as needed

Supervisory Responsibilities This position has no direct supervisory responsibility

Requirements:

- Discretion in handling confidential and sensitive matters
- Meets department quality standards.
- Good time management skills; ability to complete assignments within established timelines.
- Proficient use of Microsoft Office products including Word, Excel, Outlook, and PowerPoint.
- Ability to quickly learn new software programs as needed.

Education, Experience and Licensure

- High school diploma or comparable education required.
- College credits or college degree preferred
- Minimum of 0-6 months of clinical, cleanroom, or pharmaceutical lab experience required
- Familiarity with GMP environment preferred

Pay Range: BOE

Posted Date: December 19, 2018

We are an EOE employer - M/F/D/V