



Code: 2554

Title: Laboratory Technician II

Location: Northridge, Ca

Department: GMP, Cleanroom

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

Responsibilities:

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
- Present a professional image to HemaCare customers, internal and external
- Will be the lead trainer as well as coordinate training with the Laboratory Director for all lab technician functions
- Aid in the equipment maintenance and validation program for General Lab
- Aid in the process development of GMP procedures that will be performed within the cleanroom with the assistance of the Senior Clinical Scientific Laboratory Director

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.
- Aid in the coordination of Media Fills and gowning qualifications

Quality Control Testing Responsibilities

- Review and perform the removal of expired materials from the laboratory
- Environmental monitoring of the cleanroom suite
 - Viable Air
 - Non-Viable Air
 - Viable Surface Monitoring
- Coordinate and perform environmental monitoring in the Cell Processing and General Lab as well as read and record the results
- Some coordination for reading the data from EM plates in conjunction with the Laboratory Director
- Initiate deviations and perform investigations of Environmental Monitoring excursions
- Trend and analyze EM data as it pertains to facility integrity
- Maintain and author specification documentation for materials within the General Lab, QC, and cleanroom areas.
- Identify alternative vendors for new and existing supplies
- Review of in-process, in-operation, and media fill data
- Testing of intermediate product produced within the Cleanroom and General Lab
- 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:

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

Education, Experience and Licensure

- Minimum high school diploma. College credits or college degree preferred.
- Minimum of 3-5 years of clinical and/or pharmaceutical lab experience.
- Minimum of 1-2 years of working within a GMP environment.



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.