Biotechnician III – Monoclonal Antibody Manufacturing

This role is responsible for overseeing and supporting the overall GMP cell culture manufacturing process, in the production of monoclonal antibodies. Maintain laboratory in proper working order through organization and procurement of supplies, routine maintenance of laboratory equipment, organization and maintenance of reagents and general laboratory hygiene. Responsible to verify and ensure proper processes and procedures are followed in accordance with SOP’s.

Duties:

* Supervise manufacturing personnel in cell culture, processing and receiving.
* Technical Lead in cell culture and processing areas.
* Take lead role in troubleshooting processes, variances and equipment problems.
* Work closely with Project Management to monitor production schedules against timelines.
* Assist management with GMP and Safety Training of staff.
* Responsible for maintaining product/raw materials inventory, segregation of products and other supplies.
* Maintain accurate and current documentation.
* Keep track of all equipment for calibration and maintenance.
* Document production history using SOP’s, Master Batch Records in a GMP environment.
* Communicate all aspects of projects with department head both orally and written (i.e. weekly reports)
* Provide leadership to team including scheduling, training, coaching and conducting performance reviews.
* Perform additional job duties necessary with manufacturing areas as assigned.

Skills & Technical Expertise:

* Have an excellent understanding and knowledge of cell culture and aseptic techniques
* Experience in coordination of manufacturing activities with other departments to maintain project schedules.
* Excellent written and verbal communication skills.
* Ability to lift or move 30 lbs throughout plant environment.
* Ability to work as a team player and independently.

Education:

* BS in Life Sciences discipline and 5+ year’s cell culture experience.
* Experience within biologic, pharmaceutical or medical device industry performing direct hands on work in cell culture and with processes to produce biologics (i.e. monoclonal antibodies).
* Strong knowledge of QSR, cGMP and ISO regulations and guidelines.