



GMP Manufacturing Associate I / II Manufacturing Science and Technology (MSAT)

Job Summary:

This position is responsible for cGMP manufacturing and supporting, independently and in collaboration with others, multiple aspects of process and product development. The GMP Manufacturing Associate will also lead or co-lead maintenance and monitoring actions at the cGMP Manufacturing Facility and train other personnel in all manufacturing processes. Execution of GMP Manufacturing will be based on QA approved Batch Production Records (BPRs), Protocols and SOPs. Manufacturing processes include overall cell culture techniques in aseptic GMP environment. Occasional manufacturing actions until 6 PM (on 1 weekday) and for 3 hours on 2 weekend days per month.

Essential Duties and Responsibilities:

- Perform cGMP manufacturing processes as Operator and/or Verifier in a clean room environment, in compliance with QA control documents (BPRs, Protocols and SOPs)
- Draft and contribute to drafting BPRs, Protocols and SOPs with the assistance of other MSAT, Process Development and Assay Development scientists
- Instruct coworkers on lab/manufacturing techniques
- Generate detailed records and documentation per BPRs and Protocol requirements
- Interface independently and collaboratively with Facilities and Supplies Management to ensure availability of adequate Manufacturing supplies and proper equipment function
- Generate and submit samples to Analytical and Quality Control for internal and external testing and reports

Basic Experience and Skills:

- B.S. in biology, biotechnology, or biomanufacturing or 2 years direct experience in aseptic cell culture techniques, preferentially in cGMP environment
- Attention to detail in execution of written protocols
- Excellent communication skills
- Ability to work and thrive in a small company/startup environment and support multiple demands

Additional Preferred Qualifications:

- Experience in cell culture with preference on primary immune cells

Physical Demands:

The physical demands are representative of those that must be met by an employee to successfully perform the essential functions of this job. While performing the duties of this job, the employee is regularly required to experience prolonged sitting, some bending, stooping, and stretching. Hand-eye coordination and manual dexterity sufficient to operate laboratory and office equipment is required. A normal range of hearing and vision correctable to 20/20 is required. Occasional lifting up to 25 pounds following safety regulations.

Travel:

Expected to be <10%