GMP Manufacturing Technical Lead
Manufacturing Science and Technology (MSAT)

Job Summary:

This is a hands-on applied position responsible for cGMP manufacturing and independent and collaborative support of multiple aspects of process and product development. The GMP Manufacturing Lead will lead development and improvement actions for manufacturing processes of multiple cell and gene therapies. Execution of GMP Manufacturing processes will be based on QA approved Batch Production Records (BPRs), Protocols and SOPs. Manufacturing processes include cell culture techniques in aseptic GMP environment.

Essential Duties and Responsibilities:

- Perform cGMP manufacturing processes as Operator and/or Verifier in a clean room environment and in the Process Development laboratory in compliance with QA control documents (BPRs, Protocols and SOPs).
- Draft, review and support drafting BPRs, Protocols, SOPs and reports with the assistance of other MSAT, Process Development (PD) and Assay Development (AD) scientists.
- Generate detailed records and documentation per BPRs and Protocol requirements.
- Collaboratively improve and/or troubleshoot manufacturing processes and propose needed protocols for data collections and/or experimentation.
- Instruct and train co-workers on processes and lab/manufacturing techniques.
- Closely coordinate and collaborate with other departments (QA, QC, PD, AD and Operations) to ensure adequate status of supplies and equipment for successful execution of Manufacturing runs.
- In collaboration with Quality, support execution of Deviations, Root Cause Analysis and CAPAs.

Basic Experience and Skills:

- B.S. or M.S. in biology, pharmaceutical science, biotechnology, or biomanufacturing.
- 4+ years, respectively of direct experience in development and improvement of pharmaceutical manufacturing processes for aseptic cGMP environment.
- Experience with process qualification/validation and GMP Change Control desired
- Applied experience with improving aseptic processes.
- Focused on the details in execution of laboratory and cGMP documentation.
- Excellent written and verbal communication with commitment to inclusion, collaboration and knowledge sharing.
- Knowledge of and experience with Cell and Gene Therapies is preferred.
- Work and thrive in a small/medium company/startup environment.

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.

Additional Preferred Qualifications:

Experience in cell culture with preference on primary immune cells.

Travel:

Expected at <10%.