Principal Scientist/Associate Director, Upstream Process Development and Manufacturing

Cellics Therapeutics is a pioneering and nimble biotech company using its innovative Cellular Nanoparticle (CNP) platform technology to develop nano-therapeutics and drive breakthrough drug delivery. Aside from the chance to work with a great team toward a common goal, Cellics offers a highly motivational and rewarding work environment with top benefits and a competitive salary. Our team is small and mighty. Each employee is empowered to shape our culture and our future success!

Position Summary:

Cellics Therapeutics is seeking a Principal Scientist/Associate Director, Upstream Process Development and Manufacturing to lead the execution of CMC strategies in cell culture process development and manufacturing in support of our drug development and regulatory filings. The candidate will provide hands-on support as well as strategic, technical, and scientific leadership to the team and support tech transfer to manufacturing.

Essential Duties and Responsibilities:

- Provide technical leadership, management and oversight for the development of stable mammalian cell lines and establishment of cell banks for GMP manufacturing.
- Oversee the development, optimization, and characterization of robust upstream manufacturing processes based upon quality by design (QbD) principles.
- Oversee the scale-up, and manufacturing of biologics drug substance to support nonclinical and clinical studies.
- Support risk assessment, investigations, change management, and CAPAs.
- Conduct technical review of manufacturing batch records.
- Prepare CMC documentation for regulatory and/or patent filings.
- Establish and maintain an understanding of current trends and emerging cell line and upstream process development technologies.
- Set clearly defined goals/objectives to ensure delivery of high-quality results.
- Provide clear communication to CMC team, functional teams, and management regarding progress against technical objectives/milestones.
- Ensure well-organized, clear, and complete documentations of all activities across areas of responsibility.

Qualifications:

- Ph.D. or M.S. in (bio)chemical engineering, biochemistry, or a closely related field.
- 5+ years of experience for Ph.D. or 10+ years of experience for M.S. in cell culture process development and characterization.

- Proven hands-on experience with Rock-station and Stirred Tank bioreactor is required.
- Hands-on experience of Ambr250 programming and operation preferred.
- Experience building relationships and working with CDMOs.
- Familiar with cGMP regulations and ICH guidelines.
- Experienced in tech transfer of a process from development to manufacturing or between manufacturing sites.
- Demonstrated ability to apply engineering principles and statistical analysis, including design of experiments, to solve processing issues and evaluate opportunities for process improvements.
- Experience in preparing CMC documentation for regulatory submissions.
- Self-directed and proactive individual with ability to thrive in a fast-paced, entrepreneurial, dynamic environment with highly performing colleagues.
- Comfortable executing on multiple projects independently, adaptable and a team-player.

Pay range $160,000-$190,000/year