JOB PROFILE

Job Title: VP, Biologics CMC

Department	Type	Location
Center of Biologics Research	Full-time	Chengdu, China

Job Summary:

We are seeking a highly talented, motivated, and experienced CMC expert to join our Biologics R&D team and lead the CMC team in the overall process development of innovative biologic projects.

Key Responsibilities:

- Responsible for the overall process development of innovative biologic projects from PCC and IND to BLA/NDA filing (covering cell culture, purification, process development, pilot scale-up, technology transfer, etc.); lead the CMC team to complete the IND application (meet the timeline and quality requirements of R&D goals and the regulatory requirements of the targeted market); support BLA/NDA applications and on-site inspections.
- Organize cross-functional Biologics CMC teams to evaluate technical challenges, then propose the process development strategy and study plan.
- Coordinate the work of the Biologics CMC team and other functional groups; participate in the setup of early-stage R&D pharmaceutical druggability criteria; responsible for high-quality technology transfer to downstream manufacturing.
- Final review of pharmaceutical technical data packages.
- Coordinate with external CRO and CDMO companies; supervise the progress of outsourced projects.
- Familiar with NMPA, FDA, EMA, and other domestic and foreign regulations. Able to act upon updates of technical review in a timely manner and optimize the internal R&D strategies accordingly.
- Problem-solving technical issues encountered during Biologics CMC research.
- Continually assess and update our existing technology platforms from the standpoints of cost reduction, efficiency improvement, and quality improvement, which may be in accordance with international industry development trends.
- Efficient team management, including recruitment, training, performance review, and promotion of qualified candidates.

Position Requirements:

- Ph.D. in biochemistry, bioengineering, molecular biology, immunology, pharmacy, or other related fields with 8+ years of experience in the process development of antibody drugs or recombinant proteins; international background or relevant work experience in global pharmaceutical companies is preferred.
- Previous leadership experience in protein drug process development and supporting BLA/NDA applications.
- Familiar with innovative protein drug process development and GMP regulations; be familiar with quality research and establishing quality standards.
- Familiar with the different stages of antibody-drug process development, including initial process establishment, optimization, scale-up, in-depth development, process modification, validation, etc., with competency in using QbD concept to design and guide process and quality research processes.
- Familiar with the bioreactor cell culture process, protein purification, and formulation process.
- Familiar with the registration and declaration of biologic drugs, relevant laws and regulations in GMP manufacturing, and relevant research guidelines.
- Self-motivated with a strong sense of responsibility. Exceptional communication, organization, leadership

and team management skills are required.

- Applicant must be proficient in both written and oral English and Chinese.