SCORPION BIOLOGICAL SERVICES
JOB DESCRIPTION

Position Title: Process Engineer /Process Scientist	
Department Name: Process and Analytical Development	
Supervisors Title: Sr. Director/Head- Process and Analytical Development	

Position Summary

This person will provide engineering and/or scientific expertise for the Scorpion Biological Services Biomanufacturing Process Development group. This entails independently managing day-to-day process development activities in conjunction with team members, project leaders and customers to enable cGMP production of pre-clinical and clinical-grade biologics, including therapeutic proteins, cell-based therapies and plasmid and viral vectors. This person will have strict attention to detail and exceptional customer service skills.

Essential Duties and Responsibilities

- Assist in the development and optimization of upstream and downstream production processes that follow FDA and/or appropriate global regulations and guidelines.
- Assist in technology transfer from external client teams. Responsible for collaborating with cGMP operations group to modify existing manufacturing processes and developing them for clinical-scale, cGMP-compliant manufacturing. This includes transfer of processes into the cleanroom environment, process troubleshooting and, in collaboration with the Biomanufacturing Operations team, generation of all relevant cGMP documentation (Batch Records, Compounding Records, Operating Procedures, etc.).
- Collaborate with Facilities staff in maintaining the calibration, preventative maintenance and validation strategy for all Process Development equipment. This includes the development and implementation of operation and maintenance protocols for equipment and the execution and documentation of equipment validations as necessary.
- Assist in preparing CMC documents related to Process Development projects.
- Support Quality Assurance group by assisting in employee training, document control, validation support, calibration and preventative maintenance support, change control deviation reporting, CAPA, risk analysis, etc.
- Manage relationships with outside contractors including equipment and consumable vendors, calibration and service contracts and validation firms.

Position Requirements

Education and Experience:

- Requires a BS, MS or Ph.D. Degree from an accredited college or university with major course work in a Scientific or Engineering discipline.
- Requires 0-2 years (Ph.D.), 2-5years (MS) or 5+ years (BS) of Biologics process development experience.
- Strong working knowledge of cGMP principles and Quality Management Systems.

- Experience working in a cGMP clinical and/or commercial-scale manufacturing environment is highly desirable.

Skills :

- Knowledge of both upstream and downstream biomanufacturing processes is preferred.
- Experience with day-to-day biologics laboratory techniques.
- Knowledge of manufacturing processes in both mammalian and microbial systems is desirable, such as:
    - Aseptic processing
    - Cell therapy: stem/progenitor cells, iPSC differentiation, vaccines, exosomes
    - Protein therapeutics: mAbs, bispecific proteins, therapeutic enzymes, vaccines
    - Microbial fermentation – scale-up
    - Mammalian cell culture: suspension & adherent – scale-up
    - Product recovery: filtration, centrifugation, microfiltration, etc.
    - Protein purification: UF/DF, ion exchange, Protein A/G, HTP, HIC
    - Product formulation / stabilization
- Experience in biologics analytical characterization is highly desirable.
- Analytical ability, both interpersonal and issue-related; good judgment and ethics; professional presence and demeanor.
- Ability to continuously learn new techniques and skills and apply them to personal career growth.
- Outstanding interpersonal skills: ability to build strong relationships with cross-functional team members and lead through influence.
- Must maintain a working knowledge of phase-appropriate cGMPs as they apply to various phases of product clinical development.
- Must obtain a working knowledge of current global regulatory requirements and guidelines and perform within all Scorpion Biological Services Standard Operating Procedures (SOPs) and policies.
- Ability to take responsibility and “get the job done” in a high-energy, high-intensity, results-oriented environment.
- Excellent verbal and written communication skills; strong presentation skills as this role requires the ability to communicate and connect with all levels of the organization.
- Must possess good to excellent writing and PC skills with a knowledge base in Microsoft Word, Excel, Power Point, and Project.
- Working knowledge of Engineering software applications (Visio, SuperPro Designer, Matlab, Minitab, etc.) highly desirable.

Work Environment

Work in a well-lighted air conditioned and heated laboratory/department. May be exposed to electrical, mechanical and chemical hazards and other conditions common to a laboratory environment. May be exposed to pathogens and other conditions common to a clinical laboratory environment. May have bodily exposure to refrigerator/freezer temperature, especially hands and face. Will work extended hours during peak periods. May be required to work any time of the day, evening or night during the week or weekend.

- Will sit, stand, walk, and bend during working hours.
- Requires ability to reach, lift and carry up to 20 lbs.
- Requires manual and finger dexterity and eye-hand coordination.
- Requires normal or corrected vision and hearing corrected to a normal range.