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| Job Title: | Manager/Sr. Manager, Operations |
| Department: | Biomanufacturing |

# General Summary

Reporting directly to the Vice President of Manufacturing Sciences, this person will provide leadership for the Scorpion Biological Services Biomanufacturing Operations group. This entails independently managing all day-to-day cleanroom operations including supervising Operations staff, scheduling manufacturing events, as well as management of the ongoing Environmental Control Program. In addition, this person will be responsible for the technology transfer of projects/processes into Operations from Process Development, as well as the manufacture of all cGMP-compliant, clinical-grade biologic products.

Strict attention to detail, high quality customer service skills and the ability to instill these qualities onto others on the team.

# Key Responsibilities

* Following FDA or appropriate global regulations and guidelines, this individual will lead all cGMP manufacturing activities including the training, scheduling and supervision of Operations staff.
* Provide leadership for technology transfer from Scorpion’s Process Development (PD) group and/or external client teams. Responsible for collaborating with PD group to modify existing “R&D” manufacturing processes and develop them for clinical-scale, cGMP-compliant manufacturing. This includes transfer of processes into the cleanroom environment, process troubleshooting and generation of all relevant cGMP documentation (Batch Records, Compounding Records, Operating Procedures…).
* Collaborate with Facilities staff in developing and managing the calibration, preventative maintenance and validation strategy as part of the Equipment Control Program. This includes the development and implementation of operation and maintenance protocols for equipment and the execution and documentation of equipment validations.
* Collaborate with facilities staff develop, manage and maintain the cleanroom environment ensuring compliance with global regulatory agencies at the highest-level including specifications for temperature, relative humidity, differential pressures, and air classifications.
* Supervise staff in the execution of ongoing Environmental Control Program. This includes developing and implementing facility cleaning procedures and environmental monitoring (EM) procedures. Responsibilities include the compilation and analyses of EM data (total air particulates, air viable counts, viable counts from settling plates and viable counts from contact plates) and generation of written reports.
* 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 vendors, calibration and service contracts and validation firms.
* Represent the Scorpion Biological Services biomanufacturing capabilities to outside customers and be able to respond to their questions independently and accurately.

# Education & Experience

* Requires a BS or MS Degree from an accredited college or university with major course work in a Scientific or Engineering discipline.
* Requires 15+ years (BS) or 10+ years (MS) of cleanroom operation and maintenance experience.
* Requires a strong background with 10+ in cGMP principles and Quality Management Systems.
* Experience working in a GMP manufacturing environment is essential.

# Knowledge & Skills

* Knowledge of both upstream and downstream biomanufacturing processes is essential.
* Knowledge of manufacturing processes in both mammalian and microbial systems is highly desirable.
* Analytical ability, both interpersonal and issue-related; good judgment and ethics; professional presence and demeanor.
* 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 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.

**Qualified applicants should submit their qualifications (cover letter, resume, etc.) to Chris Barnett at** **cbarnett@scorpionbio.com**