

Company:	Brogan Pharmaceuticals	Location:	US-IN-Crown Point
Status:	Full Time, Employee	Job Category:	Biotechnology and Pharmaceutical
Relevant Work Experience:	5+ Years	Career Level:	Dir. Operations/Engineering
Education Level:	Bachelor's Degree	Aseptic Processing	Parenteral Products

Job Description

This position is responsible for the supervision of the overall cGMP injectable manufacturing operations for the production of both contract manufacturing and clinical products. The position evaluates the need for process changes/improvements for products in commercial manufacturing. This position will reports to the President and will be the lead individual for engineering, maintenance, validation, and project management as they relate to facilities, equipment, and maintenance.

- Responsible for overall cGMP plant management and support services functions for injectable drug products.
- Assists with the development of budget projections, material and staffing forecasts.
- Develops production schedules to meet clinical supply goals for project teams and CMO activities.
- Ensures that the required engineering runs performed to study process improvements and changes to existing processes are performed to meet the needs of commercial manufacturing.
- Assist with the design and build out of a facility expansion if required.
- Assist with the technology transfer of manufacturing process to commercial manufacturing or to outside contract manufacturing sites when required.
- Develops, implements and maintains personnel policies, procedures and production control systems.
- Ensures cGMP compliance, ensuring that all production equipment is properly validated and production processes meet quality standards.
- Measure and appraise subordinates' performance against job duties and objectives. Provide accurate feedback.
- Recommend/approve merit increases, promotions, hires and terminations.

The foregoing job description is not all-inclusive of the duties to which the employee may be assigned. In order to maximize flexibility and efficiency and to promote and encourage cross-training, employees will be assigned to additional duties as are deemed necessary or desirable for future advancement within management.

Requirements

- BS or BA degree in a technical discipline preferred.
- A minimum of 10 years experience in the production of biopharmaceuticals, with a minimum of 5 years supervisory experience in a GMP production environment.
- Has a detailed process and equipment knowledge of cleanrooms and barrier isolator technology.
- Has a thorough understanding of GMP requirements for the production of injectable drug products.
- Experience with a successful facility licensure a plus.
- Excellent communication skills, both oral and written.
- Demonstrated supervisory skills.

Brogan Pharmaceuticals is dedicated to the achievement of equality of opportunity for all its employees and applicants for employment without regard to race, color, religion, sex, gender identity, sexual orientation, marital status, age, national origin, disability, veteran status or any other protected group status under federal, state or local law.

Please direct inquiries or deliver resume and CV to: hr@broganpharma.com