

Company:	Brogan Pharmaceuticals	Location:	US-IN-Crown Point
Status:	Full Time, Employee	Job Category:	Biotechnology and Pharmaceutical
Relevant Work Experience:	3 to 5+ years	Career Level:	Process Scientists BioPharmaceuticals
Education Level:	Bachelor's Degree	Aseptic Manufacturing	Parenteral Products

Job Description

Job Responsibilities / Activities:

Your responsibilities will offer you to develop a variety of expertise in various functional departments contributing to the manufacturing of finished drug products. You will be directly involved in ensuring that all products meet specifications for safety, potency, and efficacy. You will contribute to multitasking technical teams, building upon and improving existing processes, designs, and optimizing processes at the firm's FDA registered manufacturing facility. Day to day operations are conducted under standard operating procedure and conform to cGMP requirements.

- Establish and comply with proper documentation and training in compliance with 21 CFR Part 210 & 211
- Ability to work well with regulatory bodies (FDA, NRC, etc.)
- Assist in conducting IQ/OQ/PQ process of equipment.
- Assist in the creation and maintenance of up-to-date area SOPs and batch records.
- Assist in training of personnel in procedures and equipment operation.
- Assist in all phases of cGMP production, including maintaining a cGMP environment and troubleshooting during commissioning, start-up, validation, and cGMP production.
- Drafting and revision of Standard Operation Procedures (SOPs)
- Responsible for timely completion of safe operations, attention to detail, and good documentation skills.
- Responsible for completing daily cGMP operations according to SOPs and batch record instruction in a cGMP environment.
- Responsibility for working in controlled environments.
- Responsibility for radiation safety.
- Responsible for analytical chemistry testing and microbiological quality control.
- Responsible for preventative maintenance and record keeping for equipment.
- Responsible for assisting microbiological experimentation and formulation development.

Education Experience/Requirements: To be successful in this role you will require:

- Bachelor's Degree or higher, Certificate of training.
- Preferably experience in a biopharmaceutical or pharmaceutical cGMP manufacturing environment, or equivalent
- Experience in pharmaceutical quality assurance
- Strong knowledge of Federal Food, Drug and Cosmetic Act (FD&C Act)
- Working knowledge of production operations, scheduling, designing, planning, process evaluation, process calculations, etc.
- An ability to work independently, and as a member of a team in dynamic, multi-disciplinary, fast-paced GMP production environment that requires flexibility and initiative.

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