

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:	Director of Quality Systems BioPharmaceuticals
Education Level:	Bachelor's Degree	Aseptic Manufacturing	Parenteral Products

Job Description

Job Responsibilities / Activities:

The Director of Quality Systems combines the disciplines of Quality Assurance and Regulatory Compliance and is responsible for maintaining a satisfactory level of compliance regarding all regulatory, quality and customer-related requirements affiliated with Current Good Manufacturing Practices (CGMP).

The person maintains the quality assurance programs and facilities, ensuring regulatory compliance, providing regulatory guidance and conducting and/or coordinating internal and external vendor audits to ensure compliance with regulations pertaining to Good Laboratory Practices (GLPs), Good Manufacturing Practices (GMPs), Good Clinical Practices (GCPs).

This position is ultimately responsible for the release of finished product for distribution, Standard Operating Procedure approval, maintenance of all batch-related documentation, customer complaint replies and proposed corrective action, inspection and approval or rejection of all incoming product and packaging materials, in-process inspections and computer validation. All regulatory agency correspondence and quality or regulatory-related customer correspondence is conducted through this position.

- Applies Good Manufacturing Practices in all areas of responsibility.
- Demonstrates and promotes the company vision.
- Establish and comply with proper documentation and training in compliance with 21 CFR Part 210 & 211
- Leadership role for Quality Assurance Department including implementation of systems and procedures focused on process improvement and defect prevention. Pursue efficiency improvements and cost reduction efforts consistent with regulatory compliance.
- Maintain knowledge of industry standards relating to clinical supply management, packaging, distribution, change control, CAPA, etc.
- Serve as primary contact for all regulatory compliance issues related to FDA, DEA and all other state and federal agencies (IN Dept. of Health, OSHA, DEP, NRC, DOT)
- Approve customer compliance-related written correspondence (e.g. audit replies, customer complaint responses, investigation reports).
- Coordinate review, generation, revision and approval of all Standard Operating Procedures, and batch records, while ensure training compliance of the same.
- Interact regularly with Quality Assurance staff to identify trends in non-conformance issues, customer complaints and deviations.
- Recommend actions to address safety, regulatory and licensing considerations for future business activities.

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

- Quality Assurance professional with a minimum of 10 years QA / Regulatory Compliance experience in the pharmaceutical, chemical, medical device or biotech industry.
- Professional with a degree in life sciences. Advanced academic training (MS, PhD, MBA) is highly desirable.
- 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.
- A strong leader, solid team player and excellent communicator capable of working collaboratively with colleagues in all functions and have developed and provided effective leadership for a successful, productive and well-respected QA/RC organization.
- Parenteral drug product manufacturing is a plus.

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.