POSITION: Quality Assurance Specialist I

DATE: November 2021

REPORTS TO: VP, Quality Assurance

DEPARTMENT: Quality

STATUS: Full-time, Exempt

LOCATION: Seattle (Hybrid office/remote)

ACCOUNTABILITY OBJECTIVE:
This position assists and supports the organization with initial compliance and ongoing preparation of conformance to established quality assurance processes and standards for GXP. In addition, s/he supports the creation, management, and maintenance of GXP documentation in compliance with regulations within the Impel NeuroPharma electronic quality management system (eQMS) as an administrator, and may facilitate internal training on quality assurance requirements, processes, and procedures.

ESSENTIAL DUTIES AND RESPONSIBILITIES include the following. Other duties may be assigned.

MasterControl tasks:

- Perform eQMS system activities to ensure data integrity and efficient use in compliance with regulations
- Work closely with system users to address questions, issues, and requests in a timely manner
- Work with MasterControl IT to resolve issues and answer questions
- Provide feedback to the system administrator to facilitate system and process improvements
- Monitor system upgrades to keep up with the latest system features
- Assist in the configuration of all system modules, including system and general settings management
- Point person for eQMS change requests
- Review and approve document tasks and change packets, reassigning or correcting as necessary

Document Control tasks:

- Troubleshoot user collaboration and change packet errors
- Assist in on-going systems education
- Final format documents to comply with Impel requirements
- Coordinate document release dates with training coordinator(s)
- Correct document metadata on InfoCards

- Monitor and report on document control, change mangement, CAPA, audits, and other QMS programs for management review

General Quality Tasks:

- Provide support for the supplier audit process
- Maintain the supplier files and where applicable, audit schedule
- Originates DocuSign envelopes
- Assist in the implementation of quality system processes and procedures
- Assist in location and retrieval of documents for suppliers and consultants
- Issue and track laboratory notebooks

EDUCATION, EXPERIENCE AND/OR SKILLS REQUIRED

- BA/BS in relevant discipline of education or equivalent years of experience.
- 2 years experience in Quality department and GxP environment; preference given to candidates with Medical Device, Pharmaceutical or Biotech industry experience
- Experience working with electronic Quality Management System (eQMS) software required; MasterControl experience preferred
- Ability to determine documentation requirements, prioritize, and create timelines for a variety of interdepartmental needs
- Working knowledge of Word, Excel, and PowerPoint
- Knowledge of current industry regulations
- Ability to understand complex instructions and carry out procedures complying with instructions
- Where permitted by applicable law, must have received or be willing to receive the COVID-19 vaccine by date of hire

CULTURAL COMPETENCIES

- **Collaborative**: Works together in an intersection of common goals by sharing knowledge, learning and building consensus with others.
- **Flexibility**: Develops new or diverse strategies to achieve organizational goals. Able to lead in a changing and challenging work environment. Manages competing demands and unexpected events.
- **Ownership:** Demonstrates full ownership and takes accountability for actions.
- **Initiative**: Measures self against a standard of excellence. Demonstrates persistence and overcomes obstacles, takes calculated risks to accomplish goals. Ability to work a demanding, primarily self-directed work schedule.
- **Professionalism**: Works well in a fast-paced environment; treats others with respect and consideration; accepts responsibility for own actions. Understands business implications of decisions, aligns work with strategic goals. Meets deadlines and commitments.

- **Communication Skills**: Clearly and persuasively communicates verbally and in writing. Listens and seeks clarification; manages difficult situations; maintains confidentiality.
- **Problem Solving**: Conducts appropriate analysis and makes clear, consistent, and timely decisions.
- **Detail minded**: Demonstrates accuracy and thoroughness; monitors own work to ensures quality and organization. Strong attention to detail while multitasking.

PHYSICAL DEMANDS

The physical demands described here are representative of those that must be met by an employee to successfully perform the essential functions of this job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions. Must have demonstrated ability to multitask in high pressure, changing conditions. Sitting, standing, stooping, and lifting of packages up to 30 pounds may be required.

WORKING CONDITIONS

When based in the office, expect a noise level typically moderate for offices and labs.

PRIMARY LOCATION & TRAVEL

Seattle, Washington. Limited travel may be required.