Job Title: Quality Assurance Senior Manager / Associate Director / Director [multiple positions (2), level dependent upon experience]
Neurotech Department Quality

Job Description:
Neurotech Pharmaceuticals Inc. is an innovative biopharmaceutical company located in the heart of New England's biotechnology center at Cumberland, Rhode Island, using proprietary orphan drug biological drug device combination technology to deliver cell gene therapeutic factors for the treatment of chronic eye disease of the retina with an Encapsulated Cell Technology (ECT) platform. This position is a key opportunity to support the delivery of this treatment for patients: for example, as we prepare for the BLA filing for macular telangiectasia type 2 (MacTel).

The Quality Assurance Senior Manager / Associate Director / Director supports and provides leadership to the Quality Assurance organization in areas of cGMP Operations, Quality Systems, Validation, Inspection Readiness, Supplier Management, Compliance, Auditing, Documentation, and Training. The position provides leadership and support in the development, design, and implementation of cross funtional GMP processes, associated procedures, systems, and policies. Contributes aligned input for implementation and support strategies of quality system processes ensuring data integrity, documentation consistency, investigation thoroughness, and harmonization of QA processes and systems across Neurotech. Crossfunctionally supports the team with organizational transformation from clinical to commercialization and associated Biological License Application (BLA) filing activities.

The Quality Assurance Senior Manager / Associate Director / Director is expected to engage, lead, serve and / or support the following activities (not limited to):

- Lead Quality Assurance team member direct reports, inclusive of Associates, Specialists, and Managers
- Coaches / mentors staff as a means to ensure performance towards goals and provide professional development
- Serve as a member of the Quality Leadership and / or Quality Management Teams and advise management on Quality practices, issues of concern and resolution strategies and tactics with partners
- Cross functional partner with management and associates in Manufacturing, Quality, Operations and Development
- Providing advice and expertise to employees and colleagues to ensure the development, management, and implementation of Quality policies
- Advocating an employee quality culture of meeting Neurotech values of working hard and sharing the enjoyment of contributing successfully at delivering for Neurotech patients; support attracting, retaining, and developing our people for the health of others
- Lead Quality Operations and Quality Management System processes (Lot Disposition, Deviation, Change Control, CAPA, OOS, Complaints, etc.).
- Deliver training activities sharing expertise in GMP operations and compliance
- Developing strategies to ensure best practices and processes are incorporated into procedures and specified required training

- Adminster Quality oversight of Neurotech GxP document lifecycle states in the DMS
- Support and manage Management Reviews, Annual Product Reports, and Material Review Board Investigations
- Provide subject matter expertise with regard to internal and external auditing in compliance with the cGMPs CFRs (21 CFR part 210, 211, 600, 610, 820) and applicable areas of EudraLex volume 4, ICH, ISO (9001 and 13485), Barr Decision, and Biologic Device Combination Drug Product Design Control
- Lead metric and trend reporting with communicating periodic assessment of the health of Neurotech quality systems to drive anticipating and preventing issues and a continuos improvement quality culture
- Lead and contribute to company GMP based regulatory and Quality audits serving as Neurotech representative in manufacturing based inspections with the FDA and other government regulatory agencies
- Provide expertise in Quality Systems Design Control and Risk Management; support internal and external audit program and regulatory agency inspections (PAI and general)
- Implement and lead clinical and commercial product complaint triage process to ensure compliance with procedures, processes, and product quality improvements
- Contribute to, provide guidance and track progress to continuous improvement programs, initiatives and projects based upon root cause resolution
- Mature risk assessment program to assess and identify gaps, develop corrective measures and to mitigate issues
- Identify relevant compliance requirements that relate to validation, manufacturing and product testing and provide up-to-date information about regulatory requirements, as well as, new developments in industry practices
- Assure that all design control, clinical and commercial manufacturing, and distribution practices, procedures and processes are in full compliance with applicable regulations in the US and in international markets

Education and Experience

- Bachelor's Degree or higher in Science or Engineering or equivalent combination of education and experience (BS degree w/ minimum of 15 years; MS degree w/ minimum of 10 years, PhD w/ minimum of 7 years)
- Minimum of 10 years of Quality Assurance work experience within the cGMP biopharmaceuticals or pharmaceuticals industry
- Previous managerial and leadership experience in Quality Assurance commensurate with position responsibilities and requirements
- Biologic or Drug Device Combination Product QA Operations or QA Systems or External QA / Compliance experience is a plus
- Phase III Clinical Development to Commercial QA experience is a plus

Knowledge, Skills, and Abilities

- Experience in administration and / or management of GMP documentation, training and quality event / process systems; Trackwise QMS a plus

- Must have ability to use knowledge and interpersonal skills to partner, provide direction and develop people and teams cross-functionally at all organizational levels
- Well organized, detail-oriented, and advocate for right the first time principles, ethical decision making, quality partner on the production floor; must be able to effectively prioritize and accomplish work with guaranteed time principles
- Strong project management skills, intelligence and ability to be influential and “wear multiple hats” in a small organization to accomplish quality objectives
- Experience in pharmaceutical operations, supply chain management, Quality on the manufacturing floor, and global environment a plus
- Knowledge in external supplier auditing and qualification as well as GMP internal auditing
- Extensive knowledge of GMPs, strong understanding of FDA / ICH regulations, Barr Decision and Quality Systems; Strong background in Quality Assurance / Systems
- Excellent communication and writing skills; strong business acumen, 6σ knowledge, Kepner-Tregoe PSDM a plus
- Ability to work both interdependently and independently
- Proven ability to manage Quality projects / teams of complex scope and deliver results on schedule through the overall complexity
- Proven ability to lead, partner, and document product investigations to the true root cause effectively, employing techniques such as Kepner Tregoe PSDM
- Strong organizational skills and the ability to participate effectively on cross-functional teams and advance solutions