Job Title: Quality Control Bioanalytics Analyst / Specialist
[multiple positions (2-3), 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 Control Bioanalytics Analyst / Specialist provides a vital role in the bioanalytical lot release testing of commercial scale clinical supply and product stability testing, while also preparing Neurotech's Quality Control processes for commercial launch. These laboratory operational cGMP processes include raw material testing, in-process testing, final product specification testing, stability indicating testing, process validation, method transfer, method validations, and results trends. Expertise in the use of LIMS and Trackwise is very important. The Quality Control Analyst / Specialist will be an independent, reliable and interdependent thinker to monitor, collect, observe, report, review and troubleshoot laboratory results; supporting investigations to the root cause level. We value strong QC technical expertise, detailed technique, GMP compliance, including data integrity, to provide dependable reproducible results, documentation consistency and critical assessments of product quality. Our cell based biologic device combination drug product laboratory controls provides broad opportunities for those with a strong diverse bioanalytical assay experience performing bioassays, cell viability assays, potency determinations, ELISA assays, DNA assays, Western Blot, and proprietary product specific QC assay technologies. We value quality mindsets, analytical minds, who are engaged, positive and enjoy working productively with others to accomplish significant team achievements for our patients.

In addition to the core bioanalytical test methodologies, asssociated QC processes, and primary data reviews there are opportunities to provide primary and backup data reviews for critical environmental monitoring processes. Also, to regularly draft and revise documents such as SOPs, protocols, and summary technical reports, such as laboratory investigations, deviations, CAPAs, and Change Controls. In addition, as a contributor and a subject matter expert (SME) the Quality Control Analyst / Specialist will identify, recommend, and implement method improvements, QC workflow efficiencies and lead team continuous improvement initiatives. Experience operating in a GMP and Environmental Health & Safety (EHS) compliant environment is required. Experience with aseptic processing technique is also desirable and beneficial. The QC Analyst / Specialist supports the Neurotech team with Biological License Application (BLA) filing activities, Inspection Readiness, and Commercialization.

The Quality Control Bioanalytics Analyst / Specialist is expected to engage, lead, serve and / or support the following activities (not limited to):

- Work effectively with other colleagues, including analysts, associates, and managers; you will have routine access to leadership at all levels
- Work with your coach / mentor / manager / team as a means to ensure performance towards goals and provide professional development
- Serve as a member of the Quality organization and team, follow SOPs, promptly escalating issues of concern, partnering around solutions, and contributing to continuous improvement
- Proactive cross functional partner with management and associates in Quality, Manufacturing, Operations and Development
- Providing advice and expertise to colleagues in SME areas to ensure mutual development and understanding
- Actively participating in an employee quality culture of meeting Neurotech values of working hard as a team and sharing the enjoyment of contributing successfully at delivering for Neurotech patients
- Perform routine bioassays and cell cultures, preparation of assay controls and standards, preparation of plates and reagents
- Perform *in vitro* release testing (pulsing) and ELISA assay on finished product
- Perform DNA testing on in-process and finished product samples
- Perform cell viability testing on finished product
- Sampling and testing of raw materials (identity testing by Raman and other methods)
- Maintain and troubleshoot laboratory instruments and equipment, troubleshoot to root cause analytical assays, conduct laboratory investigation testing compliantly per procedures and Barr Decision
- Perform method transfers (from Development to QC), ensure robust method improvements, conduct method validations, interpret results and generate reports
- Create and revise SOPs, design study protocols for instrument and method qualifications / validations
- Review documents, laboratory results and calculations, train laboratory personnel
- Follow standard operating procedures, good documentation skills, maintain laboratory notebooks, ensure data integrity, use laboratory information management system (LIMS), provide attention to detail
- Maintenance of equipment and troubleshooting, as necessary
- Qualify critical test reagents and standards, maintain reagent and laboratory supplies

Education and Experience

- Bachelor's Degree or higher in a related Science (molecular or cellular biology, biochemistry, chemistry, biology) or equivalent combination of education and experience
    - Analyst: BS degree w/ minimum of 9 years; MS degree w/ minimum of 7 years; may consider PhD w/ minimum of 5 years if the right organizational match
    - Specialist: BS degree w/ minimum of 11 years; MS degree w/ minimum of 9 years; may consider PhD w/ minimum of 7 years if the right organizational match
- Minimum of 7 years (Analyst) / Minimum of 9 years (Specialist) of Quality Control laboratory work experience within the cGMP biopharmaceuticals or pharmaceuticals industry

- Previous laboratory testing in Quality Control with low invalid rates commensurate with position responsibilities and requirements
- Biologic or Drug Device Combination Product QC Operations Laboratory Release Testing or Stability Indicating Method Testing experience is a plus
- Phase III Clinical Development to Commercial QC experience is a plus

Knowledge, Skills, and Abilities

- Experienced in performing bioassays, cell / tissue cultures, aseptic processing technique, ELISA assays, viability assays, DNA assays
- Experience in GMP documentation, ethical decisions, data integrity; Laboratory Information Management Systems (LIMS) system, Trackwise QMS use a plus
- Well organized, detail-oriented, and able to embrace right the first time principles; must be able to effectively prioritize and accomplish work
- Good project management skills, intelligence and ability to be influential and “wear multiple hats” in a small organization to accomplish quality objectives
- Experience in multiple compliant pharmaceutical laboratory operations, a plus
- Experienced at delivering reliable results and provide effective lab investigation corrective actions and CAPAs is a plus
- Knowledge of GMPs, understanding of FDA / ICH / USP / EP regulations and compendia; good background in Quality Control Lab Systems; experience and comfort with regulatory inspectors during lab inspections a plus
- Excellent communication and writing skills; strong business acumen, 6σ knowledge, Kepner-Tregoe PSDM a plus
- Ability to work both independently and interdependently
- Proven ability to manage Quality Control project responsibilities of complex scope and deliver results on schedule through the complexity
- Strong organizational skills and the ability to participate effectively on cross-functional teams and advance solutions
- Proficient in basic laboratory and / or clean room aseptic techniques, good documentation skills, and knowledge of laboratory safety
- Candidate needs to be highly motivated and flexible, with the ability to work as part of a small team with other analysts
- Strong oral and written communication skills with experience in writing SOPs and technical reports
- Reliable, with a willingness to learn and contribute proactively
- Effective communication and interpersonal skills within all levels of the organization