Head of Quality – Job Description

About Aurion Biotech

Based in Seattle, Boston and Tokyo, Aurion Biotech is a clinical-stage biotech company. Our purpose is to restore vision to millions of patients with life-changing regenerative therapies. Our first candidate is for the treatment of corneal edema, and one of the first clinically validated cell therapies for corneal care. Healthy corneal endothelial cells from a donor cornea are cultured in a novel, multi-step, proprietary and patented process. Cells from a single donor can be used to treat more than 100 recipient eyes. In early research and clinical trials in Japan, patients have experienced significant and durable improvements in key measures of corneal health: visual acuity, corneal thickness and corneal endothelial cell density. The Aurion Biotech team is preparing for clinical trials in the U.S. To learn more about Aurion Biotech, a division of CorneaGen Inc., please visit www.aurionbiotech.com

To submit your resume and cover letter, please email us at jobs@aurionbiotech.com

Primary Purpose:

Aurion Biotech is seeking an outstanding and highly experienced candidate to further build and lead all GxP Quality functions across the company. The Head of Quality will have oversight of and accountability for Quality Assurance, Quality Control, R&D Quality, Document Control, Supplier Quality and Quality Systems. The Head of Quality will grow and lead a team of professionals ensuring GxP compliance with applicable country regulations and guidelines and the company's policies and procedures. The Head of Quality will be a member of the Leadership Team.

Essential Duties and Responsibilities

These may include but are not limited to:

- Drive and cultivate a culture of quality throughout the company to help ensure compliance with all applicable regulations, guidelines, and corporate standards, policies, and procedures
- Establish strategic goals for Quality, partnering especially with Process and Analytical Development, Manufacturing, Regulatory, and Clinical Operations.
- Develop phase-appropriate Quality operating models in accordance with ICH risk-based compliance guidance; set a strong foundation for future commercial operations.
- Partner with other functions to shape and execute the path from pre-IND work through commercialization.

- Continue to build and expand the company's Quality System to ensure that it is optimally designed and implemented.
- Identify critical compliance and/or business issues related to cGxP CDMOs, CROs, Contract Test Laboratories and manufacturers of critical starting materials. Create and execute remediation strategies and tactical plans as needed using a risk-based approach.
- Collaborate with External Partner Quality organizations at CROs, CMOs, Contract Laboratories, and critical starting materials manufacturers to ensure uninterrupted supply ensuring full support to current and future production plans.
- Drive major/critical deviation investigations to ensure minimal risk to product quality, efficacy, and safety.
- Manage the development and reporting of Quality metrics and periodic reporting describing compliance trends and any areas of risk with associated mitigation plans.
- Work collaboratively with Regulatory Affairs colleagues to manage, direct and monitor the preparation, assembly and filing of Regulatory submissions to support clinical trial applications and new product marketing applications, including interactions between the company and health authority representatives to facilitate US and international IND, NDA, BLA and other submissions.
- Lead and facilitate Quality related continuous improvement initiatives and activities.
- Ensure that the company, its contractors and vendors are prepared for FDA and Health Authority inspections.
- Coordinate and host all FDA and Health Authority inspections.
- Ensure all Quality agreements are effectively negotiated to meet the near- and long-term needs of Aurion as agreed with legal, finance and functional heads.
- Develop departmental budget and product cost structure and identify cost improvement opportunities. Have full budget responsibility and accountability. Review and approve departmental expense and capital budget

Qualifications

To perform this job successfully, an individual must be able to perform each essential duty satisfactorily. The requirements listed below are representative of the education, experience, knowledge, skill, and/or ability required. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

Education and Experience

- Bachelor's degree or Master's degree in a scientific discipline with at least 12 years of work experience in the Pharmaceutical/Biotechnology industry with at least 8-12 years' experience in Quality Assurance, or equivalent levels of education and / or experience.
- Cell and Gene Therapy and aseptic manufacturing experience is strongly desired.
- Experience in tech transfer of processes and GMP facility operations from design through commissioning and operation strongly desired.
- Experience building Quality Systems in young, science-driven organizations.
- Experience shepherding the Quality organization's contributions to successful commercialization of a product.
- Experience leading high performing Quality teams.
- Experience hosting FDA and Health Authority inspections.
- Experience working with US and international CMOs and clinical sites.

Required Skills/Knowledge/Abilities

- Strong knowledge of regulatory requirements for manufacturing sterile products, advanced therapies, and combination products.
- Expert knowledge of FDA and ICH GxP regulations and guidelines, across all disciplines including GMP, GLP, GCP, and GDP.
- Knowledge and practical experience implementing and leading all the elements of a compliant Quality System.
- Track record of strong personal performance combined with demonstrated ability to build and lead high performing teams in a fast growth environment.
- Must be a safety and compliance role model.
- Demonstrated problem-solving and critical thinking skills.
- Excellent people leader with strong coaching and mentoring skills.
- The role is based in Seattle. Travel may be required up to 20% of the time.
- Demonstrates passion for the Mission and Values of Aurion Biotech.