



JOB TITLE: Manager, Quality Systems/Document Control - Seattle

ABOUT THE POSITION

This is a newly-created role at Aurion Biotech. It is a unique and exciting opportunity to join a growing team of passionate professionals at the forefront of cell therapy innovation in ophthalmology. As Manager of Quality Systems, you will play a critical role in accomplishing our mission.

The Manager Quality Systems is responsible for supporting the development of early-phase clinical quality system activities. This highly motivated member of the Quality Unit will help establish and maintain the quality management system (QMS) and drive document and change control processes within the electronic document management system (EDMS), while serving as the system owner. Additional responsibilities include supporting internal and external audits, deviation/CAPA management, all while promoting a culture of compliance throughout the organization through continuous improvement initiatives.

KEY RESPONSIBILITIES

- Work with Quality Head to define and implement the Quality Management System (QMS)
- Write, review and revise Standard Operating Procedures (SOPs)
- Review and control documents in accordance with document control procedures.
- Oversee document templates and change control processes
- Managing QMS events such as deviations, CAPAs, and change controls related to systems
- Owns system administrative activities for the QMS
- Addresses any user-related issues and provides end user support in the QMS
- Assists in user provisioning of the quality management system
- Partner with functional leaders to define system training plans and ensure timely completion of all training assignments
- Support internal and external audits
- Other duties as assigned.

QUALIFICATIONS AND EDUCATION

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.

- BA/BS in Science
- 6 to 9 years' experience in Quality Systems in GMP environment

REQUIRED SKILLS, KNOWLEDGE, AND ABILITIES

- Familiarity with FDA, ICH, and EU Regulations and Guidelines
- Experience with ensuring alignment with relevant GxP guidance and regulations
- Involvement in continuous improvement initiatives
- Familiarity with Contract Manufacturing Organizations (CMO) desirable
- Proficient use of MS Office products, as well as ownership of GMP electronic applications (e.g., Veeva)
- Ability to meet deadlines, adapt to rapid changes, and work in a fast-paced team environment
- Ability to work effectively both independently and with other team members.
- Interpersonal skills including the ability to influence without authority and negotiate and resolve challenges with poise, tact, and diplomacy

ABOUT AURION BIOTECH

Based in Seattle and Boston, Aurion Biotech is a clinical-stage biotech company. Our mission is to restore vision to millions of patients with our life-changing regenerative therapies. Our first candidate is for the treatment of corneal endothelial disease, and one of the first clinically validated cell therapies in corneal care. In Japan, we've completed early research, dose ranging and confirmatory clinical studies; and we have submitted an NDA to the PMDA for market approval. In the US, we are preparing an IND submission to the FDA. Based on results to date, we believe that our cell therapy has the potential to fundamentally transform the treatment of patients suffering from corneal endothelial dystrophies. We are growing rapidly and seek to hire highly motivated candidates from diverse backgrounds, cultures, and experiences, who share our values:

Stewardship: We make the world a better place for our patients, our communities, our clinicians, and our colleagues. We act responsibly as individuals, as employees, and as a company.

Transformation: We embrace our challenges, our successes, and our failures. We are curious, we take risks, and we collaborate.



Grit: We break down walls and strive to achieve the impossible. We are persistent and resilient, and we deliver on our commitments.

Aurion Biotech has a lot to accomplish in the next few years and this role is key to our success.

The company is backed by leading ophthalmology investors, including Deerfield, Alcon, Flying L Partners, Visionary Ventures, KKR's Falcon Vision Fund, and Petrichor. To learn more, visit www.aurionbiotech.com.