



JOB DESCRIPTION: *Senior Director, Clinical Operations*

ABOUT THE POSITION

The Senior Director of Clinical Operations will be responsible for the management, oversight, and hands-on execution of clinical programs ensuring they are completed according to timelines, budgets, and regulatory and corporate quality standards. This candidate will serve as a key functional leader and subject matter expert. The candidate will work collaboratively with other functional leads in the achievement of departmental and corporate objectives and initiatives. With extensive industry knowledge and experience, the candidate will proactively seek to improve the efficiency, effectiveness, and quality of Aurion Biotech's clinical trial activities.

Reporting to Vice President of Clinical and Medical Affairs.

KEY RESPONSIBILITIES

- Responsible for the management and implementation of clinical operational functions, allocating and directing internal resources and effectively outsourcing, when necessary, to achieve project goals in a timely manner.
- Accountable for the strategic planning and execution of clinical trials, ensuring they are conducted within timelines, budget, and regulatory and corporate quality standards.
- Actively lead and/or participate in the development of critical study documents such as protocols, ICFs, study manuals, investigator brochures, clinical study reports, etc.
- Responsible for leading constructive interactions with clinical sites to ensure that all trials and programs have clearly defined plans, strategies, and milestones.
- Identify any outsourcing needs, and oversee the selection, management, and performance of CROs, vendors, and external consultants.
- Be accountable for the budgeting, forecasting, and overall management of clinical budgets.
- Develop and maintain strong, positive collaborations with internal and external functional leaders.
- Promote a strong quality culture within Clinical Operations ensuring clinical trials are conducted according to ICH/GCP requirements, corporate/departmental SOPs/policies, and industry best practices.



- Lead responses to any audits as required (site, internal file and process, and regulatory agencies)
- Develop and execute resourcing plans to ensure adequate and appropriate monitoring of all trials.
- Provide accurate, current updates to executive management related to the status of clinical trials (e.g., monthly, or as needed).

QUALIFICATION AND EDUCATION

- A bachelor's degree or higher in a relevant field, preferably related to biological or life science. Higher/professional degree a plus.
- 15+ years Clinical Operations experience.
- 10+ years in a management role.
- 5+ years experience in the field of ophthalmology.
- Strong experience in the set-up and management of domestic and international early and late phase clinical trials either directly or via CRO/vendor management.
- Experience managing multiple projects and priorities.
- Strong working knowledge of GCP/ICH guidelines.
- Experience developing and managing departmental and study budgets and timelines.
- Strong interpersonal skills with demonstrated ability to effectively work with internal and external cross-functional groups.
- Extensive knowledge of drug development functions relevant to clinical trial conduct (e.g., data management, biostatistics, pharmacovigilance, CMC/supply chain management, etc.).
- Demonstrated ability to collaborate effectively in cross-functional teams, to lead and develop a high-performing team and to mentor team members at all levels.
- Excellent written, communication and interpersonal skills, and demonstrated cultural agility.
- Embody and champion Aurion Biotech's values

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 edema secondary to 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 studies, and are preparing a submission to the PMDA for market approval. In the US, we are



preparing an IND submission to the FDA for clinical trials. 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 biotech and ophthalmology investors, including Deerfield Management, Flying L Partners, Petrichor Healthcare Capital, KKR's Falcon Vision Fund, and Visionary Ventures.

To learn more, visit www.aurionbiotech.com.