



JOB DESCRIPTION: Process Development, Director

ABOUT THE POSITION

Aurion Biotech is seeking a Director, Drug Process Development in Cambridge, MA. As a central development resource at the company, the Process Development director will work closely with non-clinical, clinical, analytical, manufacturing, and quality teams. The successful candidate will provide technical and strategic leadership for the development of cell production processes, formulation, cryopreservation, aseptic filling process, storage, and stability. This is an outstanding opportunity for a talented and self-motivated scientist to contribute to bringing cutting-edge cellular therapies to patients while gaining valuable career experience.

KEY RESPONSIBILITIES

- Lead the design and execute detailed experiments using QbD principles, Design of Experiments (DoE), and process characterization/modeling techniques to develop and understand Drug Product processes and to define robust, integrated control strategies.
- Performs gap analysis and risk assessments to identify problems and deficiencies, as well as provide recommendations for studies and solutions to manufacturing process and alignment with regulatory and commercial manufacturing requirements
- Develop and implement Process Performance Qualification (PPQ) strategy and post-approval process improvements with effective balance among quality, financial, and inventory risks
- Build processes and strong relationships with external manufacturing organizations
- Support regulatory strategy and activities, including authoring and review of CMC documentation for regulatory filings
- Support the development of standard operating procedures, FMEA, batch records, and analytical sampling plans
- Lead tech transfer activities to manufacturing sites

QUALIFICATIONS AND EDUCATION

- A PhD in the pertinent life sciences or engineering, with 10+ years relevant industry experience



- Prior experience in successfully managing manufacturing sciences or process development functions in complex biological processes and experience in cell therapy is a plus
- Ability and track record of successfully supporting biologics programs through early- or late-stage clinical development is required.
- Demonstrated experience leading a diverse technical organization as well as interfacing with external manufacturing providers, partners, and or academic collaborations.
- Technology transfer and extensive biologics technical experience is required.
- Experience with process characterization and scale-up required
- Experience using DOE and statistical analysis using state-of-the-art software packages (JMP...)
- Outstanding communication, analytical and organizational skills
- Highly collaborative team player who fosters open communication and facilitates mutual understanding and cooperation between all stakeholders

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 Management, KKR's Falcon Vision Fund, and Visionary Ventures.

To learn more, visit www.aurionbiotech.com.