PARAGON LABS

Position: Sr. Director/Director, Cell Culture Development
Location: Remote

About Paragon

Paragon Laboratories is an emerging biotechnology company dedicated to discovering and developing best-in-class complex biologics for diseases with significant unmet need. With a dedicated in-house team of scientific experts in drug development, Paragon pursues differentiated therapeutic concepts and advances them rapidly toward proof-of-concept validation. As programs mature, Paragon supports their continued development through new company formation and strategic partnerships.

The Role

We are seeking a Senior Director/Director of Cell Culture Development to lead external process development and manufacturing support for protein-based biologics. This individual will oversee CDMOs, provide stewardship of cell line and cell culture development, and coordinate purification and drug product interfaces. The role will advance assets through clinical development with responsibility for scale-up, technology transfer, and manufacturing troubleshooting.

Key Responsibilites

- Lead CDMOs in developing and scaling protein production processes from laboratory studies through technology transfer and GMP manufacturing
- Provide technical leadership for cell line and cell culture development and coordinate purification activities and drug substance–drug product interfaces as required by program needs
- Analyze development and manufacturing data to understand process performance, and identify future improvements
- Support manufacturing campaigns, including troubleshooting, root-cause analysis, corrective actions, deviation resolution, and campaign assessments
- Review and approve master and executed batch records within functional responsibility and support investigations with Quality Assurance
- Apply QbD principles to establish phase-appropriate product and process understanding and control strategies
- Partner with Research, Development, Quality, and Manufacturing to advance programs from discovery through first-in-human studies and subsequent clinical development
- Author and review CMC content for INDs, IMPDs, amendments, and BLAs, and contribute to Investigator's Brochures as appropriate

221 Crescent Street
Building 23, STE 105
Waltham, MA 02453

PARAGONLABS.COM

- Prepare internal procedures, technical reports, and presentations, and contribute to the goals and strategic direction of an integrated TechOps organization

Key Things About You

- PhD in biology, biochemistry, biochemical engineering, or a related discipline, or an equivalent combination of education and experience
- At least 10 years of biologics development and manufacturing experience, including relevant postdoctoral experience
- Strong expertise in cell culture process development, scale-up, and manufacturing, with significant knowledge of current Good Manufacturing Practice (cGMP) requirements
- Demonstrated success advancing assets from preclinical development through IND and into late-stage development; commercialization experience preferred
- Substantial experience leading technology transfer to CDMOs and supporting manufacturing campaigns
- Experience collaborating with Analytical Development, Formulations and Drug Product Development, Manufacturing, and Supply Chain; drug product development expertise preferred
- Strong leadership skills, a growth mindset, and a commitment to learning and creating a psychologically safe environment
- Excellent communication, prioritization, and problem-solving skills in a fast-moving organization
- Demonstrates a continuous improvement mindset with a strong commitment to upholding a high bar
- Exceptional verbal and written communication skills
- Ability to participate in calls across international time zones and travel domestically and internationally up to 25%

What We Offer You

- A chance to thrive in a fast-moving, entrepreneurial environment where you can help shape our culture from the ground up, stretch beyond the boundaries of your role, accelerate meaningful medicines, and learn at every turn
- Competitive compensation, including base salary, performance bonus, equity grant opportunities
- Comprehensive medical, dental, and vision coverage, as well as access to tax-advantaged savings accounts, life and disability insurance, and a 401(k) match
- Flexible time off, +12 company holidays, plus Winter and Summer shutdowns

- Commitment to ongoing professional development opportunities including all-company trainings
- Remote working environment with bi-annual and semi-regular in-person meetings to address complex problems, build relationships and have some fun

The expected salary range offer for this role is $225,000 to $265,000. Actual pay offered may vary depending on job related knowledge, experience, education, and geographic location.

Paragon Labs is an equal opportunity employer. We consider all qualified employment applicants without regard to race, religion, color, gender, age, national origin, sexual orientation, gender identity, gender expression, partnership status, status as a protected veteran, status as an individual with a disability, or any other status protected by federal, state, or local law. Individuals who hold legal work authorization applicable to employment at Paragon Labs in the United States will be considered without regard to citizenship/alienage.

221 Crescent Street
Building 23, STE 105
Waltham, MA 02453

PARAGONLABS.COM