Position: Director, CMC Program & Strategy
Location: Remote
Reports to: Senior Director, CMC Program & Strategy

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 Director, CMC Program & Strategy, to join the CMC team. This role will be responsible for handling all aspects of the external DS and DP CDMO relationship for multiple CMC Programs including, but not limited to meetings, timelines, tech transfer, DS/DP manufacturing, all related documentation via managing the exchange of information via internal and external SharePoint sites. This position requires a self-starter, who can organize projects effectively in a fast-paced setting. This position will report to the Senior Director, CMC Program Strategy.

Key Responsibilities

- Manage all operational and project management aspects of the external DS and DP CDMO relationship
- Work with CMC team members to identify resource constraints, risks, and conflicts that could impact the team's bandwidth
- Provide Project Management support for CMC programs, including building and maintaining the CMC timelines by interfacing with our external partners and facilitating cross-functional collaboration with the Research and Global Program Management teams
- Collaborate closely with the cross-functional Program Management team to ensure integration of CMC activities into overall program plans, monitor project deliverables and ensure tasks are on track
- Submit purchase orders, review and approve vendor revenue recognition, accruals, and invoices
- Assist with tracking resourcing for the outsourced activities for all of CMC as needed

Key Things About You

- BS or MS in a scientific, technical, or related discipline required; advanced degree in pharmaceutics, pharmaceutical sciences, biochemistry, analytical sciences, chemical engineering, or a related discipline preferred.

- 10+ years of experience in biotech or pharmaceutical industry with 3-5 years of Biologics development and manufacturing experience
- 5+ years of Technical Operations/CMC Project Management experience
- Experience working with clinical stage candidates across all phases of Clinical Development (e.g., Ph1 to Ph3), including regulatory submissions. Experience with Ph3 to Commercial, such as DS or DP Process Characterization and PPQ is a plus
- Good technical knowledge of DS/DP Process development, Analytical, Regulatory, Quality, GMP requirements, and device
- High level of expertise with Smartsheet, Microsoft Project, and Lucen Timeline
- PMP Certification is highly desired
- Demonstrates a continuous improvement mindset with a strong commitment to upholding a high bar
- Exceptional verbal and written communication skills
- Able to travel up to 15%, including mandatory all-company meetings (2-3 x a year)

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 $240,000. 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.