Position: Senior Director, Head of GMP Quality Assurance
Location: Remote
Reports to: Senior Vice President, Quality

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 Sr. Director, Head of GMP Quality Assurance (QA), who will build and lead the GMP QA function, ensuring effective GMP oversight and establishment of scalable GMP standards to support Paragon's clinical development. This individual provides strategic and operational leadership, drives regulatory compliance, and partners effectively with cross-functional teams and external vendors to foster a proactive culture of quality. This position requires a hands-on self-starter who thrives in a fast-paced environment and can communicate effectively with executive leaders. This position will report to the SVP of Quality.

Key Responsibilites

- Lead the GMP QA function, establishing strategic priorities, objectives, and organizational capabilities aligned with company goals.
- Serve as a member of the QA Leadership Team, contributing to overall Quality strategy and organizational effectiveness.
- Provide GMP quality oversight of internal operations and external vendors (CMOs, contract laboratories, and other GMP partners).
- Establish, implement, and maintain a scalable phase-appropriate GMP QA quality management system (QMS).
- Oversee core GMP quality processes, including deviations, investigations, CAPAs, change controls, batch record review, product disposition, complaints, and temperature excursions.
- Participate in the selection and qualification of GMP vendors, including the negotiation and execution of GMP quality agreements.
- Verify internal and external vendor compliance with applicable GMP regulations and maintain a state of inspection readiness and continuous improvement.

- Establish risk-based quality oversight and governance of GMP vendors.
- Drive quality metrics, trending, and continuous improvement to enhance GMP quality system effectiveness.
- Partner cross-functionally to integrate quality into operational and business decisions while enabling development milestones.
- Provide GMP quality review and feedback on GMP documentation, regulatory application submission, and agency responses and information requests.
- Advise senior leadership and functional management on complex quality compliance issues, assessing risk and determining actions.
- Build, lead, and develop a high-performing GMP QA organization capable of scaling to support late-phase and commercial operations.

Key Things About You

- Bachelor's or advanced degree in a scientific or related discipline with a minimum of 12 years combined experience in GMP Quality and Manufacturing in a biotechnology or pharmaceutical setting; biologics experience required.
- Minimum of 5 years of progressive leadership and people management experience.
- In depth knowledge of cGMPs, including FDA/EMA regulations, ICH guidelines, and applicable international regulatory requirements.
- Proven experience establishing, implementing, and scaling GMP Quality Management Systems (QMS), including experience with eQMS implementations, management, and enhancements.
- Proven experience in successfully overseeing GMP manufacturing, testing, and external manufacturing vendors, including CMOs and contract laboratories.
- Demonstrated expertise in quality systems, specializing in GMP implementation of phase-appropriate processes to support deviations, investigations, CAPAs, change controls, batch record review, product disposition, complaints, and temperature excursions.
- Experience leading and supporting regulatory inspections, internal and external audits, and regulatory compliance initiatives.
- Ability to apply sound, risk-based quality judgement and balance compliance with business and operational priorities.
- Strong analytical, investigative, and problem-solving skills, with the ability to design creative solutions to complex challenges.
- Demonstrated ability to build, develop, mentor, and lead high-performing teams in a dynamic environment.

- Excellent interpersonal and communication skills required, including strong executive communication, influencing, and cross-functional leadership skills.
- Able to travel domestically and internationally, up to 20%.

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 $260,000 to $280,000. 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.