Position: Sr. Director, Quality Systems
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 Quality Systems, who will build and lead the Quality Systems function, providing strategic oversight of Paragon's GxP Quality Systems to ensure compliance, effectiveness, and scalability in support of pre-clinical, clinical, and commercial operations. This role leads document control, training, facilitates internal audits and vendor qualification activities, and oversees GxP computer systems. As a member of the QA Leadership Team, this individual drives operational excellence, continuous improvement, and a strong culture of quality and compliance. This position requires a hands-on self-starter who thrives in a fast-paced environment and can communicate effectively with executive leaders, external partners, and customers. This role will report to the SVP of Quality.

Key Responsibilites:

- Lead the GxP Quality Systems function, establishing strategic priorities, objectives, and organizational capabilities aligned with company goals
- Serve as a member of the QA Leadership Team by providing quality system leadership, promoting a culture of quality and compliance, and ensuring organizational inspection readiness, and by contributing to the overall Quality strategy and organizational effectiveness
- Provide GxP quality system oversight of internal operations and facilitation of vendor qualification activities
- Establish, implement, maintain, and continuously improve the GxP quality management system (QMS), ensuring alignment with applicable global regulatory requirements and industry standards
- Lead the implementation and ongoing management of document control processes and systems to ensure effective management of controlled GxP documents and records

- Develop and oversee GxP training strategy and programs, ensuring role-based training, compliance, and training effectiveness
- Establish and lead risk-based internal GxP audit programs and facilitate external GxP vendor qualifications
- Oversee audit findings, CAPA management, effectiveness assessments, and timely resolution of quality issues
- Provide strategic quality oversight of GxP computer systems, including implementation, validation, governance, lifecycle management, and data integrity
- Design, develop, configure, implement, maintain, enhance, and business administrator for Paragon's eQMS and quality operation systems used to support quality system business processes
- Drive QMS metrics, management reporting, and periodic assessments to evaluate system effectiveness and identify trends and opportunities for improvement.
- Partner with cross-functional leaders to establish consistent, efficient, and scalable quality system processes across the organization
- Advise senior leadership and functional management on complex quality compliance issues, assessing risk and actions
- Build, lead, and develop a high-performing Quality Systems function, establishing the organizational structure, capabilities, and resources to support evolving business needs

Key Things About You:

- Bachelor's or advanced degree in a scientific or related discipline with a minimum of 12 years experience in GxP quality in a biotechnology or pharmaceutical setting; biologics experience preferred
- Minimum of 5 years of progressive leadership and people management experience
- In depth knowledge of GxPs, including FDA/EMA regulations, ICH guidelines, and applicable international regulatory requirements
- Proven experience establishing, implementing, and scaling GxP Quality Management Systems (QMS), including experience with eQMS implementations, management, and enhancements
- Proven experience and expertise in successfully implementing and overseeing GxP Quality Systems, including document control, training, internal audits, vendor qualification, and GxP computer systems
- 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 skillss
- Able to navigate ambiguity and has a high sense of urgency
- Demonstrates a continuous improvement mindset with a strong commitment to upholding a high bar
- Able to travel domestically and internationally, up to 20%, 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 $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.