

Position: Executive Vice President, Head of Regulatory Affairs and Toxicology

Location: Remote (U.S.)

Reports to: Head of Research and Development

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

Paragon is seeking an Executive Vice President, Head of Regulatory Affairs and Toxicology to lead global regulatory strategy and nonclinical safety for our portfolio of complex biologics and monoclonal antibodies. This executive will oversee both the Regulatory Affairs and Toxicology groups, guiding programs from candidate selection through IND-enabling studies, IND/CTA submission and early clinical development, and will serve as Paragon's primary voice with health authorities. This role reports to the Head of Research and Development.

Key Responsibilities:

- Lead and develop the Regulatory Affairs and Toxicology groups, setting priorities, building team capabilities and scaling both functions as the portfolio grows
- Define the global regulatory strategy for each program, from candidate selection through IND/CTA and early clinical development, including expedited pathway opportunities (e.g., Fast Track, Orphan Drug)
- Set the nonclinical safety strategy for biologics, including species selection and relevance, tissue cross-reactivity, GLP toxicology study design, safety pharmacology and first-in-human dose justification
- Oversee the design, conduct and reporting of nonclinical studies with CROs, ensuring GLP compliance, scientific quality and on-time delivery
- Lead the preparation and submission of high-quality regulatory filings, including INDs/CTAs, pre-IND and scientific advice briefing packages, annual reports and IND amendments
- Serve as Paragon's primary contact with FDA, EMA and other health authorities, leading meeting strategy, preparation and negotiations
- Partner with CMC, clinical, quality and program leadership to integrate regulatory and toxicology requirements into development plans, timelines and budgets

- Present regulatory and nonclinical safety strategy and risks to the Board, investors and prospective partners, and lead regulatory and toxicology diligence for partnering, licensing and new company formation

Key Things About You:

- Advanced degree (PhD, PharmD, DVM, MD or equivalent) in toxicology, pharmacology or a related life science, with 20+ years of biopharma experience, including 10+ years in senior regulatory and/or nonclinical safety leadership roles; DABT certification and/or RAC preferred
- Deep expertise in regulatory strategy and nonclinical safety for biologics and monoclonal antibodies, including ICH S6(R1), M3(R2) and related FDA and EMA guidance
- Proven track record of leading multiple successful IND/CTA submissions and early-phase regulatory interactions for biologics
- Direct experience designing and overseeing GLP toxicology programs, and managing CRO relationships for nonclinical studies
- Extensive experience leading face-to-face health authority meetings (e.g., pre-IND, INTERACT, Scientific Advice) and negotiating regulatory outcomes
- Strategic, hands-on leader who builds high-performing teams and thrives in a lean, fast-moving environment who demonstrates a continuous improvement mindset
- Exceptional verbal and written communication skills
- Ability to attend in-person all company meetings (location will vary), as well as travel up to 20% of the time, as required by work

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 \$400,000 to \$425,000. Actual pay offered may vary depending on job related knowledge, experience, education, and geographic location.

Interested in this opportunity? Please submit your resume directly to careers@paragonlabs.com. When applying, please include the title of the role you are interested in in the subject line. Should your background and experience match our needs, we will be in touch!

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.

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