

Position: Director/Senior Director, Toxicology

Location: Remote

Reports to: Carl Dambowski, Head of Research

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/Senior Director of Toxicology to help lead the design and oversight of nonclinical toxicology and safety pharmacology studies conducted at Contract Research Organizations (CROs). As a key member of the regulatory affairs and toxicology team you will support drug development programs from the preclinical candidate selection stage through Phase 2 initiation in consultation with cross-functional team members and niche expert consultants as needed. The position reports to the Head of Research.

Key Responsibilities:

- Conduct preliminary risk assessment of drug candidates, including characterization of known and theoretical target-related liabilities based on literature and regulatory summaries
- Design nonclinical safety assessment strategies and establish project timelines and budgets to support programs from pre-IND stage through market applications
- Establish and maintain contracts and external relationships with CROs and consultants
- Ability to work independently as a subject matter expert in toxicology and safety pharmacology with limited supervision
- Leverage past experience and be resourceful with your network to evaluate novel modalities and constructs for biologic candidates.
- Collaborate with research, CMC, clinical, and regulatory colleagues to optimize toxicology planning and execution with respect to species selection, drug supply / reagent requirements, method development / validation, and study timing / duration / dose selection
- Design, execute, and monitor nonclinical safety studies at CROs (single/repeat dose toxicity of appropriate duration, DART, and specialty studies as needed) in accordance with applicable standards (e.g., FDA, ICH, WHO, and GLP)
- Author nonclinical sections of clinical and regulatory documents

- Report progress of projects and interpretation of results in a timely and concise manner to project teams and senior management
- Keep up to date with pertinent literature, regulatory guidances and regulations

Key Things About You:

- PhD in Pharmacology, Toxicology, or related discipline
- Minimum of 8 years industry experience as a toxicologist (level will be commiserate with years of experience)
- Comprehensive understanding of drug development, including safety assessment models and FDA/ICH guidances
- Hands-on and leadership experience in nonclinical development and a track record of contributions to clinical and regulatory filings. Experience with biologics is required
- Excellent oral communication skills to clearly explain complex issues and progress reports to a variety of audiences across functions and across levels at both internal and external meetings
- Demonstrates a continuous improvement mindset with a strong commitment to upholding a high bar
- Exceptional verbal and written communication skills
- Ability to attend bi-annual in-person all company meetings (location will vary) as well as travel (US) up to 25% as the role and business needs requires

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, a Lifestyle Savings Account, 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 \$310,000. The pay range reflects the base pay range Paragon reasonably expects to pay for this role at the time of posting. Individual compensation depends on factors such as education, experience, job-related knowledge, and demonstrated skills.



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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