Position: Vice President, Clinical Pharmacology
Location: Remote (U.S.)
Reports to: SVP, Translational Sciences

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 a Vice President, Clinical Pharmacology to build and lead the translational and clinical pharmacology and pharmacometrics function across our portfolio of complex biologics and monoclonal antibodies. This leader will establish model-informed drug development and dose-selection strategy from development candidate (DC) nomination through clinical proof of concept and beyond, including first-in-human dose selection, dose-escalation and dose and regimen optimization. This role reports to the SVP, Translational Sciences.

Key Responsibilities:

- Lead the translational pharmacology strategy for each program from development candidate nomination onward, integrating in vitro, in vivo, nonclinical and clinical data to predict and characterize human pharmacokinetics (PK) and pharmacodynamics (PD)
- Own first-in-human dose selection and justification for biologics, including MABEL, NOAEL and receptor-occupancy-based approaches, in partnership with Toxicology and Regulatory Affairs
- Develop and apply fit-for-purpose quantitative approaches, including translational PK/PD, target-mediated drug disposition, population PK, PBPK, exposure-response, mechanistic modeling and quantitative systems pharmacology, where appropriate, to inform dose, regimen and study design decisions
- Design the clinical pharmacology components of early-phase trials, including dose-escalation schemes, PK/PD, biomarker and immunogenicity sampling strategies, and prospectively defined criteria for dose and schedule selection; lead ongoing review of emerging clinical data to guide escalation and regimen decisions
- Define dose and regimen recommendations for later-phase development using integrated exposure, efficacy, safety, biomarker and patient-level data, including dose optimization, special populations and route or formulation changes

- Oversee population PK, PK/PD and exposure-response analyses, including analysis plans, data specifications, interpretation, reporting and integration into program decisions
- Develop strategies to evaluate intrinsic and extrinsic factors affecting exposure and response, including organ impairment, body size, age, concomitant medications and other clinically relevant covariates; address drug-interaction and pediatric development questions where applicable
- Shape immunogenicity strategy and assessment of anti-drug antibody (ADA) impact on PK, PD, safety and efficacy, with bioanalytical and CMC partners
- Oversee bioanalytical, PK and modeling vendors and CROs, ensuring scientific quality, timely delivery and regulatory-grade data analyses and reports
- Author and review clinical pharmacology sections of regulatory submissions (e.g., IND/CTA, Investigator's Brochure, briefing documents, BLA/MAA) and represent the function in health authority interactions, responses and labeling discussions
- Build and lead the clinical pharmacology and pharmacometrics function, establishing processes and standards that scale with the portfolio

Key Things About You:

- PhD, PharmD or MD (or equivalent) in pharmacology, pharmaceutical sciences, pharmacometrics or a related field, with 15+ years of biopharma experience in clinical pharmacology, including 7+ years in leadership roles
- Deep expertise in the PK/PD of biologics and monoclonal antibodies, including target-mediated drug disposition, immunogenicity and translational scaling from nonclinical species to humans
- Proven track record of setting first-in-human doses and leading dose-selection and dose-optimization strategy for multiple biologics programs through IND/CTA and early-phase trials and later-stage development
- Expert in pharmacometric and modeling approaches (e.g., population PK, PK/PD, exposure-response, PBPK) and proficient in standard tools (e.g., NONMEM, Monolix, Phoenix WinNonlin, R)
- Strong working knowledge of FDA and EMA guidance on clinical pharmacology, first-in-human dose selection and dose optimization, with experience leading health authority interactions and supporting regulatory submissions
- Experience across multiple therapeutic areas and in partnering closely with Toxicology, Bioanalytical Sciences, Biomarker Sciences, CMC, Clinical Development, Clinical Operations, Biostatistics, Data Management, Safety and Regulatory Affairs
- Rigorous, collaborative scientific leader who builds high-performing teams and thrives in a lean, fast-moving environment

- Demonstrates a continuous improvement mindset with a strong commitment to upholding a high bar
- Exceptional verbal and written communication skills with the ability to translate complex quantitative analyses into clear recommendations for program teams, governance bodies, executive leadership and health authorities
- Ability to attend bi-annual in-person all company meetings (location will vary), as well as travel as business needs require (e.g., health authority, CRO and scientific meetings)

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 $335,000 to $350,000. Actual pay offered may vary depending on job related knowledge, experience, education, and geographic location.

Paragon Laboratories 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.