ED/VP Clinical Development (Oncology)

Reports To: CEO
Location: Worcester Office (not remote)

Scope Summary:
The Executive Director/VP of Clinical Development (Oncologist) will provide strategic direction and technical leadership to the clinical development group from Phase I-IV for drug products, including: clinical-regulatory development plan; clinical trial design, implementation and execution; clinical data analysis and management; and clinical competitive intelligence. The role is responsible for overseeing trials in clinical development and pharmacovigilance according to agreed-upon deadlines, for establishing and maintaining close working relationships with clinical counterparts at Mustang's licensors, and for providing the clinical-regulatory landscape for each of the clinical programs. The Executive Director/VP of Clinical Development will act as a cross functional advisor and will work closely with the internal and/or external Clinical Development/Pharmacovigilance/Biostatistics group(s), R&D, Regulatory, and the Commercial Development teams to execute Phase I-IV clinical trial strategy and design.

Duties and Responsibilities Include But Are Not Limited To:

- Prepare clinical portions of Investigational New Drug submissions and Biologics License Applications, including protocols and protocol amendments, investigator brochures, drug safety update reports, clinical study reports, medical reports, efficacy and safety summaries, scientific rationales and benefit/risk ratios.
- Develop and maintain key opinion leader relationships and serve as the clinical lead for advisory meetings.
- Establish and maintain relationships with alliance partners, external companies (such as CROs), investigators and opinion leaders to optimize performance on clinical trial activities.
- Prepare manuscripts for technical journals and make presentations at scientific meetings.
- Work collaboratively with Research and Development providing input into design of preclinical studies to support drug products entering or in the clinic and by helping initiate Investigational New Drug submissions.
- Provides input to evaluate products for in licensing/out licensing.
- Participate in business development processes as needed.
- Accountable for clinical portion of regulatory documents such as Investigator Brochure updates, and Drug Safety Update Reports.
- Manage and be responsible for pharmacovigilance for clinical projects including review and reporting of SAEs with support from pharmacovigilance providers as available.
- Provide leadership and guidance for the clinical development/operations team to ensure efficient execution to meet deliverables and timelines.
- Accountable for medical monitor activities for Phase I-IV studies through direct execution of activities or supervision of a medical monitor dependent on current staffing.

Knowledge and Abilities:

- **Intellectual Agility and Insight** – Superior cognitive horsepower and ability; ability to simplify complex situations; ability to make sound judgments; ability to research and analyze various types of data. Must have the ability to relate to the scientific/medical community.
- **Strategic Thinker** – "Thought Leader." Big picture thinker who anticipates future trends and consequences and creates competitive strategies and plans. Continually thinks of new and innovative ways to tackle business challenges; demonstrated ability and desire to 'think outside the box.'
- **Patient-Focused** – A deep understanding of clinical operations, our patients and experience building relationships with key thought leaders.
- **Leadership & Teamwork** – Able to establish personal credibility quickly. Track record of working with people across a multitude of diverse situations. Proven ability to be a leader and to interact easily at all levels within the organization; tactful; mature; flexible. High level of collaboration, influencing skills and emotional intelligence.
- **Superior Communication Skills** – Written, verbal and presentation.
- **Strong Execution and Results Orientation** – Demonstrates a sense of urgency to overcome obstacles and achieve measurable results. Take-charge individual who is both resourceful and driven. Ability to effectively execute to meet deliverables and timelines. Cool under pressure and able to accommodate changing priorities.
- **Positive and Self-confident** – Executive presence with the courage and willingness to advocate positions based on science, not popularity.
- **Open-minded and Flexible** – Open to other points of view; willing to consider new ideas and be an early adopter of cutting-edge technologies and/or new approaches.
- **Risk Taker** – Willing to take educated business risks to advance the organization's objectives.
- **Integrity** – Maintains the highest ethical standards in all business dealings; character; sense of humor.

Education & Experience:

- MD required
- Board certification in internal medicine required; subspecialty certification in Oncology (and/or Hematology
- Minimum of 10 years' relevant industry experience in clinical development; Oncology experience required
- Experience providing leadership and guidance to a clinical development team
- Start-up/small company experience required, with willingness to be hands-on
- Travel < 25%