Onchilles Pharma Job Description

Job Title:	Head of Clinical Operations
Classification:	Exempt
Reports to:	CEO/President

Position Summary:

This role is responsible for providing regulatory and clinical operations support for our expanding oncology drug portfolio. The Head of Clinical Operations is a strong and experienced industry veteran to lead clinical project management, medical protocol writing, regulatory document preparation, clinical SOP implementation and quality assurance with an emphasis on clinical CRO management, data transfer and site identification/initiation/training. You will be a hands-on leader willing to roll-up your sleeves in order to ensure the highest quality of work output.

Key Responsibilities; include but may not be limited to the following:

- In partnership with the clinical development team, develop the company's clinical study strategy and drive study execution utilizing available resources.
- Lead all operational aspects of cross functional therapeutic programs.
- Vendor Selection and Management: Lead the full-service Contract Research Organizations (CROs), and other third-party vendor selection process, specification development, and management/oversight of all clinical trial-related partners and vendors.
- Patient Recruitment: Lead the operational strategy and execution for identifying, recruiting and patients for study inclusion.
- Quality: Lead the development and continuous improvement of clinical SOPs and GCPs and provide oversight of clinical monitoring quality & adherence to established processes and plans.
- Deliverables: Develop, manage, and maintain study deliverables (i.e. timelines, all study plans, etc.) through collaboration with internal and external stakeholders using data and strong inter-personal influencing skills to make robust data driven decisions.
- Partnering: Proactive management of internal partners/stakeholders including Clinical/Medical, Safety, Regulatory, and other affiliates and foster partnerships across existing multi-disciplinary teams.

- Risk Management: Proactively identify potential risks and develop & implement action plans to avoid or mitigate program risks and make appropriate trade-offs of balancing risks with study deliverables and costs.
- Oversight: In partnership with Clinical leadership, provide oversight to ensure safety concerns and/or adverse events are identified; develop and implement corrective actions accordingly, and participate in internal/external study related audits, as needed.
- External Communication: Present at scientific leadership team meetings, investigator and site initiation meetings other meetings, as required.
- Leadership: Liaise with study investigators and external partners to support clinical studies and drive enrollment. Be the point of contact when sites inquire about patient inclusion/exclusion criteria for ongoing trials. Perform external study feasibility with investigators for trials in start-up.
- In partnership with Chemistry, Manufacturing and Controls (CMC), forecast clinical trial (CT) material on a study and program level, overseeing the process for ordering clinical trial material, setting up and monitoring the systems whereby material is shipped to the investigator, maintaining procedures to account for the CT material, checking the expiration of CT material and requesting extensions if necessary.
- Documentation and Study Plans: In partnership with a CRO, oversee preparation of all applicable documents required for the conduct of the study (e.g., Project Plan, Risk Management Plan, Study and site Monitoring Plans, Trial Master File [TMF], Biospecimen lab manuals, etc.).
- Contribute to the preparation and review of clinical program documents (briefing books, clinical study protocol and consent forms, regulatory documents including submissions to IRBs and ECs, clinical study reports [CSR] and submissions) and other study related documents assuring quality and consistency.
- Help to create and maintain an inclusive, collaborative and dynamic team-focused work environment.

REQUIREMENTS:

- Bachelor's degree or higher in Life Sciences or Project Management
- Minimum 10 years of Clinical Operations management experience required

- Oncology drug development experience and Phase I/II clinical trial management are essential. Clinical trial experience for intratumorally administered therapeutics is highly desirable.
- Excellent understanding and demonstrated application of FDA guidelines, Good Clinical Practices (GCP), ICH and applicable Standard Operating Procedures.
- Demonstrated ability and track record to recruit, manage, mentor & train other operations team members in a positive and effective manner.
- Ability to effectively communicate and influence senior level stakeholders to gain buy-in on clinical strategy.
- Excellent organization skills; capable of documenting and managing complex processes in a punctual manner.
- Must have demonstrated ability to work in independent manner.

COMPETENCIES:

- Analytical - Collects and researches data; Uses intuition and experience to complement data.
- Problem Solving - Identifies and resolves problems in a timely manner; Gathers and analyzes information skillfully; Develops alternative solutions.
- Ethics - Works with integrity and ethically.
- Innovation - Displays original thinking and creativity; Meets challenges with resourcefulness; Generates suggestions for improving work; Develops innovative approaches and ideas; Presents ideas and information in a manner that gets others' attention.
- Planning/Organizing - Uses time efficiently.
- Quality - Demonstrates accuracy and thoroughness; Looks for ways to improve and promote quality; Monitors own work to ensure quality.

Individuals seeking employment at Onchilles Pharma are considered without regards to race, color, religion, national origin, age, sex, marital status, ancestry, physical or mental disability, veteran status, gender identity, or sexual orientation.

For additional information or to apply, please contact hr@onchillespharma.com