Vice President of Clinical Operations

Job Title: Vice President of Clinical Operations
Location: Toronto, Ontario (Hybrid role, in office 3 days per week)
Travel Requirements: Occasional travel, when necessary.
Reports To: Chief Executive Officer (CEO)

About RetiSpec

RetiSpec is a Toronto-based medical AI company that aims to enable widespread early and accurate detection of neurodegenerative disease markers through a simple eye exam. RetiSpec's AI solutions leverage existing retinal imaging cameras available in most eye clinics to provide real-time results at the point of care — this means that the experience is familiar and comfortable. RetiSpec's AI solutions are currently available for Research Use Only.

Position Overview

The Vice President of Clinical Operations will be responsible for overseeing and managing all clinical activities at RetiSpec, including the planning, execution, and managing clinical studies to support regulatory submissions, product development, and commercial activities. This role will ensure that all clinical and research initiatives comply with regulatory requirements, quality and ethical standards, and company objectives.

The ideal candidate is detail-oriented, self-sufficient, and thrives in a fast paced startup/scale-up environment. We value individuals who are outgoing, collaborative and bring a results-driven approach to leadership.

With new disease-modifying drugs coming to market, alongside advancements in diagnostic devices, the Alzheimer's landscape is at an important inflection point; making this an exciting and impactful time to be working in this space. This role will have the opportunity to leverage cutting-edge technology driving positive change to patient health outcomes.

Key Responsibilities

Strategic Leadership:

- Develop and implement clinical and research strategies aligned with RetiSpec's business objectives and regulatory submissions, including for FDA, Health Canada, and other global regulatory agencies.
- Provide strategic oversight of all clinical affairs and operations, including planning, budgeting, and execution of clinical trials.
- Collaborate with the science team to guide grants and non-dillutive funding initiatives, ensuring alignment with strategic priorities.
- Identify high-level risks and lead resolutions for clinical operations issues.
- Cultivate working relationships with potential and existing partners that promote strategic

development.
- Implement innovative solutions and process improvements across the function. .

Clinical Trial Management:

- Oversee the design and execution of clinical trials, ensuring compliance with regulatory requirements (e.g., GCP), company SOPs, and ethical standards.
- Lead site selection, patient recruitment strategies, and clinical monitoring activities.
- Develop and implement risk management plans, proactively addressing issues to ensure seamless progress of clinical studies.
- Manage clinical budgets, timelines, and resources to drive operational efficiency.
- Identify and implement cost-effective strategies while maintaining the highest quality standards.

Team Leadership and Development:

- Build, lead, and mentor a high-performing clinical team, fostering a culture of accountability, collaboration, and continuous improvement.
- Provide training and development opportunities to enhance team expertise in clinical research and management.

Regulatory Compliance and Documentation:

- Ensure clinical operations adhere to FDA, EMA, and Health Canada, and other global regulatory guidelines.
- Oversee and assist with the preparation and submission of clinical documentation to support regulatory submissions.

Cross-Functional Collaboration:

- Collaborate with R&D, regulatory, and quality teams to align clinical operations with product development goals.
- Partner with external vendors, CROs, and trial sites to ensure seamless execution of clinical programs.

Qualifications

- Advanced degree in health or life sciences , medical, or related fields (MSc, PhD, MD preferred).
- Minimum 8-10 years of clinical operations experience, including 5 years in a leadership role within the medical device industry, with clinical diagnostic experience preferred.
- Extensive knowledge of clinical trial design, management, and regulatory requirements (GCP, FDA, EMA, etc.).
- Proven track record of successfully leading clinical trials from planning to regulatory submission.
- Strong leadership skills with the ability to motivate and develop a team.
- Excellent organizational, communication, and project management skills.
- Experience with Alzheimer's disease or neurodegenerative diseases and in a fast paced startup environment is an asset.

Key Competencies

- Detail-Oriented: Ability to manage complex operations with precision.
- Strategic Vision: Align clinical operations with company goals and navigate regulatory environments.
- Leadership: Inspire and lead cross-functional teams..
- Analytical Skills: Strong problem-solving abilities with a data-driven approach to clinical trial management.
- Communication: Excellent written and verbal communication skills for diverse.

Why Join RetiSpec?

- Be part of a dynamic, innovative company at the forefront of Alzheimer's diagnostics.
- Play a key role in bringing cutting-edge technology to market and making a real impact on patient care.
- Work in a collaborative and growth focused environment with opportunities for career advancement.

RetiSpec is committed to fostering an inclusive, barrier-free, and accessible environment. Part of this commitment includes arranging accommodations to ensure an equitable opportunity to participate in the recruitment and selection process. If you require any accommodations during the application or interview process, please let us know and we will work with you to meet your needs.