Aclarion

Position: Director of Clinical Affairs

Reports to: Chief Strategy Officer

Location: Remote

Travel: Up to 25%

The role: The **Director of Clinical Affairs** is responsible for defining the vision and clinical strategies that will support meeting Aclarion's product development and commercialization objectives. The Director of Clinical Affairs is responsible for the design and successful execution of clinical trials that demonstrate medical product safety and efficacy, as well as ensuring that trials are conducted in full compliance to all other applicable regulatory requirements.

The Director of Clinical Affairs typically manages a staff of Clinical Project Manager(s), and external vendors such as Clinical Research Organizations, Core Labs, Medical Monitors, Data Management, and Biostatistics. The Director of Clinical Affairs takes the leadership role for analysis and interpretation of clinical results for regulatory submissions and publications.

This role reports directly to the Chief Strategy Officer and will collaborate with RA/QA and Reimbursement to align on key priorities supporting the Aclarion portfolio through developing and promoting clinical evidence.

This is an incredible opportunity to join a fast growing, highly motivated team.

Key Responsibilities:

Establish the strategic vision for the clinical affairs department:

- Partner with team to obtain clinical trials approvals from regulatory bodies such as the FDA, Health Canada, Competent Authorities, China, Japan, etc.
- Assess clinical staffing needs and department organizational structure to align with current and future business objectives
- Lead the process of identifying, evaluating, and approving clinical research projects in collaboration with Aclarion stakeholders that will leverage clinical research evidence to gain regulatory approval and drive market share
- Provide knowledge and strategic planning support to the company's business units, sales and marketing, engineering and regulatory departments related to clinical research
- Support clinical research related regulatory and compliance activities
- Lead the clinical research team, including daily operations, resource management, budgeting, and workload prioritization
- Develop and mentor clinical research personnel to create a best-in-class clinical research team

- Develop SOPs and work instructions to assure internal files and clinical study files (patient; site; country) conform to Good Clinical Practice regulations and standards

Oversee the planning, execution, and management of all clinical research studies and activities including but not limited to:

- Study design development and clinical protocols implementation
- Study submissions to "global regulatory" agencies, e.g.: FDA, Health Canada, EU, Competent Authorities, etc.
- Compliance with applicable regulatory requirements; example FDA, Health Canada, ISO, ICH/GCP, and HIPAA, etc. requirements
- Study-site assistance with IRB process and documentation preparation
- Investigator requirements, recruitment, and contracts
- Study-site budgetary needs
- Timely Data collection, processing, and archiving/maintenance
- Statistical analysis and interpretation of clinical data
- Final reports

Additional Responsibilities:

- Responsible of the development of annual regulatory and compliance reporting
- As needed, support the identification, selection, and continuing management of external clinical support organizations (e.g., CROs, biostatistics support, etc.)
- Ensure organizational alignment in the design and execution of initiative effort
- Establishes clearly defined department and individual goals
- Provide leadership to include effective feedback on culture, results, and future, coaching and mentoring, performance management and career development
- Develop/maintain relationships with Key opinions leaders and other professionals on issues related to Aclarion research program
- Build collaborative relationships with matrix partners including Marketing, Sales, Clinical Affairs, and RA/QA

Knowledge & Skills:

- Minimum 10 years of clinical research experience required
- Minimum 5 years of supervisory or management experience in clinical research required
- Knowledge of applicable federal and international regulations and guidelines (FDA, ISO, ICH/GCP, HIPAA, EU MEDDEV) required

- Solid track record in successfully executing Phase I – III clinical and post-market trials.
- Background in MRI/MRS, spine and regenerative therapies is preferred
- Well-developed verbal and written communication skills
- Detail-oriented with strong organizational skills
- Creative problem-solving and critical thinking skills
- Flexibility and willingness to work with a variety of people
- Strong technical writing skills
- Familiarity with data acquisition platforms (EDC) and firm understanding of bio-statistical concepts
- Working knowledge of MS Office, spreadsheets, and graphical presentation programs; database platforms.

Minimum Requirements:

- Bachelor's Degree, Master's Degree preferred
- The ability to fluently read, write, understand, and communicate in English
- 10 Years of Relevant Experience in Healthcare, Pharma, Biotech or MedTech
- 5 Years of Demonstrated Leadership
- At least 7 years in experience with clinical trials management, manuscript development and investigator-initiated research, and research compliance preferred
- Understanding of Medical/Legal/Regulatory review processes and compliance environment for medical device/healthcare industry

Aclarion is an initial stage commercial start-up with proprietary cloud-based SaaS diagnostic technology company transforming patient lives through harnessing the power of MR Spectroscopy (MRS). Our technology is a game-changing innovation that is based on a decade of research and development and clinical experience. We are constantly looking in the future to treat challenging diseases.

We are a global team united by a common vision to transform healthcare by making focused MRS a standard of care for patients. Our culture is centered on innovation - challenging & empowering our people to be great at what they do. Our ecosystem is our forte, comprised of diversity - people with different ideas, skills, interests, and cultural backgrounds.