Vice President, Clinical Affairs

LymphoDrain Clinical Program – United States & Europe

Position	Vice President, Clinical Affairs
Reports to	Chief Operating Officer (COO)
Department	Clinical Affairs
Location	Lymphatica Medtech SA headquarters (Switzerland), with extensive travel to clinical sites and offices in the United States and Europe
Employment type	Full-time, possibility of remote position
Travel	Extensive (estimated 30–50%), including regular travel between Europe and the United States

Company Overview

Lymphatica Medtech SA is a Swiss medical technology company developing LymphoDrain, an active implantable device designed to restore physiological lymphatic drainage in patients suffering from lymphedema. Following successful first-in-human feasibility studies, the company is entering its next phase of clinical development and organizational growth, and is preparing to launch pivotal clinical trials in the United States and Europe in support of regulatory approval and market access.

Position Summary

The VP, Clinical Affairs will provide leadership, guidance, and direction to an international clinical team, with primary accountability for ensuring a successful pivotal clinical trial for LymphoDrain in the United States and Europe, alongside any pilot and feasibility studies required to support the company's clinical and regulatory strategy. This is a senior, hands-on leadership role for an experienced clinical affairs executive who can both set strategy and execute in the field.

The VP will plan and execute all clinical trial activities, define the division of work between Contract Research Organizations (CROs) and internal resources, and build and lead the clinical organization required to deliver the program – including hiring Clinical Research Associates (CRAs) and other clinical personnel. Working closely with the COO and the Head of QARA, the VP will help align the clinical program with FDA expectations (including IDE and PMA strategy) and with CMS reimbursement considerations, while also coordinating Key Opinion Leaders (KOLs), a potential Medical Advisory Board, and engagement with relevant medical societies.

Reporting to the COO and serving as a core member of the management team, the VP, Clinical Affairs will actively participate in developing and maintaining the company's global strategy, setting the vision and direction for the clinical organization, maintaining the clinical roadmap, and ensuring successful execution of the clinical pipeline – with the LymphoDrain pivotal trial as the top priority.

Key Responsibilities

Clinical Strategy & Pivotal Trial Leadership

- Own end-to-end responsibility for the successful design, execution, and reporting of LymphoDrain's pivotal clinical trial(s) in the US and Europe, as the primary measure of success for this role.

- Plan and oversee pilot / feasibility studies as needed to de-risk and inform the pivotal program.
- Define and continuously refine the global clinical development plan and roadmap, in line with corporate strategy, the regulatory pathway (FDA IDE/PMA, EU MDR), and reimbursement objectives.
- Design trial protocols, endpoints, and statistical analysis plans, optimizing time to market through innovative and efficient trial design and solid oversight of trial execution.
- Oversee site selection and activation, patient recruitment strategy, data management, monitoring, safety reporting, and study close-out, ensuring compliance with applicable regulations, standards, the company QMS, and project timelines.

CRO & External Partner Management

- Define the overall CRO strategy: decide which clinical trial activities are outsourced to CROs and specialized vendors versus managed internally, based on cost, quality, timelines, and strategic fit.
- Lead the identification, selection, contracting, and day-to-day management and oversight of CROs and other external partners (e.g., core labs, biostatistics, medical writing).
- Negotiate scope, budgets, and timelines with CROs and hold external partners accountable to performance and quality standards through robust governance.

Clinical Team Building & Leadership

- Design and form the international clinical organization required to support pivotal trial execution, defining team structure, roles, and the hiring plan.
- Recruit, hire, and onboard clinical personnel – including Clinical Research Associates (CRAs), clinical project managers, and other clinical operations staff – across the US and Europe.
- Provide leadership, mentorship, and performance management to the clinical team, fostering a high-performing, compliant, and collaborative culture.

Regulatory, Quality & Reimbursement Collaboration

- Partner closely with the COO and the Head of QARA (Quality Assurance & Regulatory Affairs) to proactively identify and resolve issues with the FDA and other regulatory authorities.
- Actively engage with the FDA to support alignment on the Investigational Device Exemption (IDE) process and on Premarket Approval (PMA) strategy and submissions.
- Contribute to the clinical evidence generation strategy needed to support CMS (Centers for Medicare & Medicaid Services) coverage and reimbursement discussions.
- Assist Regulatory Affairs with completion of required clinical sections of regulatory reports for the FDA and regulatory agencies outside the US.
- Oversee the set-up and maintenance of clinical evaluation documentation, including literature reviews and clinical evaluation reports, in accordance with applicable regulations and company procedures.

KOL Engagement & Medical Advisory Board

- Identify, engage, and coordinate Key Opinion Leaders (KOLs) in vascular surgery, lymphatic surgery, breast reconstruction, and related specialties to support trial design, site selection, and clinical adoption.
- Assess the need for, and where appropriate establish and manage, a Medical Advisory Board to provide clinical and scientific guidance on trial design, data interpretation, and product development.
- Leverage KOL relationships, clinical publications, and market/study data to evaluate competitive and synergistic technologies and inform clinical and commercial strategy.

Medical Society & Stakeholder Engagement

- Support and help coordinate the company's engagement with relevant medical societies – e.g., the Society for Vascular Surgery (SVS), societies focused on breast reconstructive surgery, and lymphedema / lymphatic surgery societies – to build clinical credibility and awareness of LymphoDrain.
- Represent the company at relevant scientific congresses, society meetings, and medical conferences.

Cross-functional Leadership & Governance

- As a member of the management team, actively contribute to developing and maintaining the company's global strategy.
- Provide regular reporting on clinical program status, risks, and milestones to the COO, the management team, and the Board of Directors.
- Support fundraising and financing activities (e.g., investor due diligence, grant applications) with clinical program data and credibility.
- Own budgeting, resource planning, and operational excellence for the Clinical Affairs function.

Qualifications

Required Competencies

- Extensive experience leading clinical development of complex, high-technology, patient-focused active implantable medical devices and associated peripherals, from early feasibility through pivotal trials.
- Proven track record securing device approvals in both US (FDA IDE/PMA) and European (MDR/CE marking) regulatory environments.
- Demonstrated success designing and executing pivotal clinical trials, including protocol design, site management, and regulatory interactions.
- Strong experience selecting, negotiating with, and managing CROs and other clinical vendors.
- Experience building and scaling international clinical teams, including hiring and managing CRAs.
- Working knowledge of CMS coverage and reimbursement processes as they relate to clinical evidence generation.
- Knowledge of current and emerging healthcare industry trends and technologies.
- Ability to evaluate non-company, competitive, and synergistic product offerings and estimate their market potential based on KOL interactions and clinical, research, and market publications.
- Knowledge of lymphatic and vascular health; experience working with physicians and surgeons in vascular surgery and/or breast reconstruction surgery is a plus.
- A demonstrated continuous desire to understand, learn, and implement industry best practices and trends.
- Strong leadership, executive presence, and communication skills; high performer and results-driven.
- Ability to foster strong relationships with internal and external stakeholders.
- Open and ready to work in an international and multicultural environment, specifically with Swiss, Italian, and US-based teams.

Required Skills

- Ability to create and maintain solid relationships with academic and research institutions, clinical sites, and KOLs; experience forming and managing a Medical Advisory Board is a plus.
- Contract identification, negotiation, and management.
- Ability to navigate in and foster a strong sense of collaboration.
- Project leadership and project management, including budget ownership and risk management.
- Creative thinking and problem-solving.
- Strategic mindset, able to support clinical strategy, business planning, and fundraising.
- Ability to instill a sense of timing, planning, and urgency for both internal and external teams.
- Ability to work well independently and as a member of a team.
- Effective written and verbal communication skills, including for regulatory and Board-level reporting.
- Fluency in English essential; French and Italian are a plus.
- Ability to interact effortlessly with a wide range of stakeholders, from lymphologists and vascular or reconstructive surgeons to regulatory agencies and payers.

Minimum Education & Experience

- BA or BS degree in a health-related, life sciences, or engineering field.
- Master's degree (or MD/PhD) preferred.
- Minimum 15 years of healthcare industry experience.
- Minimum 10 years of medical device experience, including direct leadership of pivotal clinical trials.
- Direct experience in vascular, lymphatic, or reconstructive surgery device categories is strongly preferred.

This job description reflects the general nature and level of work performed and is not intended to be an exhaustive list of all duties, responsibilities, and qualifications. Lymphatica Medtech SA reserves the right to modify this description at any time.