Lymphatica Medtech SA
Route de l Maladière 58 – 1022 Chavannes-près-Renens
Switzerland

Vice President of Engineering (VP Engineering)

Company: Lymphatica Medtech SA
Location: On-site (presence required)
Reports to: CEO
Role Type: Executive / Full-time

About Lymphatica Medtech SA

Lymphatica Medtech SA is a medical device company developing an innovative **Class III therapeutic device for the treatment of lymphedema**, a chronic and underserved condition affecting millions of patients worldwide.
The company is advancing from **late-stage development into IDE submission and clinical trials**, with a clear roadmap toward **PMA approval and market entry**, and is seeking a **senior engineering leader to integrate into the leadership team and support this critical execution phase**.

Role Overview

The Vice President of Engineering will lead all engineering activities across the full product lifecycle, with primary responsibility for **engineering execution from IDE readiness through clinical development, PMA approval, and commercialization**.
This role is critical at a pivotal stage of the company's evolution, requiring a leader who can translate technical excellence into disciplined execution, team alignment, and on-time product delivery.

This is a **hands-on executive role**, requiring strong technical depth, deep familiarity with **Class III regulatory expectations**, and a sustained **on-site presence**. Equally important, the VP Engineering will provide visible, decisive leadership—setting direction, making trade-offs, and ensuring accountability.

The VP Engineering will be a core member of the leadership team, reporting to the CEO, playing a central role in shaping company priorities, driving cross-functional execution, and building the engineering organization needed to support the overall company strategy and execution.

Success in this role will be measured not only by technical outcomes, but by the ability to lead teams through complexity, make tough decisions, and deliver the company's first products to market on time and to the highest quality standards.

Key Responsibilities

1. **Engineering & Product Leadership**

- Provide clear technical and organizational leadership to ensure focus, prioritization, and timely decision-making in a high-stakes, regulated environment.
- Own the **end-to-end engineering function** for a Class III medical device, from late-stage development through commercialization.
- Ensure robust **system architecture**, requirements management, and traceability across the full design control framework.
- Lead **design verification and validation (V&V)** activities in preparation for IDE submission and clinical use.
- Maintain strict compliance with **Design Controls** (21 CFR 820 / ISO 13485) throughout development and change management.
- Drive execution discipline across teams, balancing technical rigor with pragmatic delivery to meet clinical and commercial milestones.

2. **Regulatory & Clinical Execution**

- Drive engineering contributions to **IDE and PMA submissions**, including technical documentation, testing strategies, and regulatory responses.
- Act as a key technical counterpart in **FDA interactions**, inspections, and audits.
- Support clinical trials from an engineering perspective, including device reliability, usability, failure analysis, and corrective actions.
- Lead **risk management activities** in accordance with ISO 14971 (hazard analysis, FMEA, benefit–risk documentation).
- Ensure strong cross-functional alignment with Regulatory, Clinical, and Quality teams to anticipate risks, resolve issues quickly, and maintain momentum toward approvals.

3. **Manufacturing & Industrialization**

- Lead **design for manufacturability and assembly (DFM/DFA)** and manufacturing readiness.

- Oversee **transfer to manufacturing** in collaboration with the Head of Manufacturing and Supply Chain, working closely with contract manufacturers and key suppliers.
- Own engineering change management post–design freeze, including support for clinical and commercial builds.

4. **Team & Cross-Functional Leadership**

- Lead, inspire, and mentor a multidisciplinary engineering team (mechanical, electrical, software, systems), fostering a culture of accountability, collaboration, and high performance.
- Work closely with Quality, Regulatory Affairs, Clinical, and Operations to ensure aligned execution.
- Establish scalable engineering processes, tools, and KPIs appropriate for a regulated, growing organization.
- Build organizational capability by attracting, developing, and retaining top engineering talent as the company scales.
- Contribute as a senior member of the **leadership team**, supporting company-wide planning and decision-making.
- Serve as a visible leader across the organization, modeling strong communication, ownership, and execution at a critical inflection point for the company.

Required Qualifications

Experience

- **15+ years** of engineering experience in medical devices or similarly regulated industries.
- **Proven track record bringing at least one Class III medical device from concept or late-stage development through FDA approval and market entry.**
- Direct, hands-on experience with **IDE preparation, clinical-stage devices, and PMA submissions**.
- Experience leading engineering teams in a **design-controlled, regulated environment**.

Technical Expertise

- Strong background in **medical device systems engineering**.
- Strong background in mechanical and micro-mechanical system engineering.
- Deep understanding of:
    - FDA QSR (21 CFR 820)

    - ISO 13485
    - ISO 14971
    - Design Controls, V&V, and engineering change management
- Experience with **hardware-based therapeutic devices** (implantable preferred).
- Experience with implant grade silicone design and manufacturing preferred.
- Experience with medical pumping technologies preferred.

Leadership & Personal Attributes

- Senior executive profile with a **hands-on, execution-focused mindset**.
- Comfortable operating in a **lean, fast-moving scale-up environment**.
- Experienced team Leader, with proven ability to keep engineering teams **motivated**, **aligned on** short-term **priorities**, and **focused on long-term** technical and organizational **goals** during a demanding execution phase.
- Clear, structured communicator able to engage effectively with regulators, partners, and internal stakeholders.
- **On-site presence required**; this role is not remote.

Nice to Have

- Experience with **EU MDR** in addition to FDA.
- Background in startups or scale-ups transitioning from development into commercialization.
- Experience supporting **post-market activities** and product lifecycle management.

Why Join Lymphatica Medtech SA

- Join the leadership team at a **pivotal moment** as the company enters IDE submission and clinical trials, in a young and motivated environment.
- Lead engineering for a **high-impact Class III device** addressing a major unmet medical need.
- Shape the engineering organization, technical strategy, and execution path through **FDA approval and market launch**.

In case of interest, write to: marco.pisano@lymphatica.ch