Quality Engineer

Implantable medical devices class III

- 100%
- Based in Lausanne (Biopôle Epalinges)

Volumina Medical is a start-up, spin-off of the Swiss Federal Institute of Technology (EPFL), active in the field of medical devices. The company develops breakthrough innovations for plastic and reconstructive surgery. The first product is an implantable biomaterial and targets the regeneration of soft parts of the human body which are damaged due to ageing, tumor excision, genetic malformation, or trauma.

To strengthen our Quality and Regulatory Affairs Team, we are looking for a highly motivated **Quality Engineer** to support the Quality function from Research and Development activities, ensuring that medical device development is conducted in compliance with applicable regulatory and quality requirements, to the maintenance of a robust Quality Management System (QMS) for class III medical devices. The candidate will demonstrate strong interpersonal communication skills to lead Volumina Medical Teams in the effective use of the QMS. This role will report to the Global Head of Quality and Regulatory Affairs.

As **Quality Engineer,** your **key responsibilities** will be**:**

1) **Executing QMS daily operations** such as but not limited to:
    - Contribute to the development, implementation and monitoring of the QMS, in compliance with ISO 13485, 21 CFR Part 820, and MDR 2017/745,
    - Drive Quality Assurance (QA) activities across Teams and ensure adherence to procedures,
    - Review and Approve quality documentation (Quality Control (QC)/incoming inspection/training records),
    - Lead the Change Control and Non-Conformity Processes and coordinate follow-up with the Team,
    - Collect, analyse and report Quality Key Performance Indicators (KPIs) and ensure continuous improvement of the QMS, and
    - Provide support with risk management activities.

2) **Driving the suppliers' management process**:
    - Support the Team with identification, qualification and evaluation of suppliers,
    - Ensure annual assessment of suppliers are completed according to Quality Plan,
    - Review Quality Agreements when required,
    - Support the Teams by managing orders with suppliers, and
    - Act as the main Quality contact for all Company's suppliers.

3) **Contributing to the audit process**:
    - Prepare and follow internal and suppliers' audits planning,
    - Participate in preparation and conduct of internal and/or suppliers audits, and
    - Contribute to the preparation and execution of the Notified Body Audits as Quality SME.

4) **Contributing to product development by providing Design Control support**:
    - Contribute to the creation and maintenance of the Design History File (DHF), and ensure its traceability and consistency through the product development phases,
    - Contribute to Design Verification (DV) activities (e.g., drafting DV protocols/reports, handling of non-conformities/deviations),
    - Manage testing activities with qualified sub-contractors (samples preparation and shipping), and
    - Ensure stability studies follow-up (collect and analysis of the data, drafting stability study protocol and report).

5) **Training and cross-functional QA support**:
    - Train Teams to QMS requirements and contribute to establishing a sustainable quality culture, ensuring that quality is systematically embedded in processes, projects and in the mission of each team.

- Report deviation and/or non-conformities to the Quality Management Representative (QMR).
- Provide clear, solution-oriented QA support to Volumina Medical Teams.
- Provide support to the Teams in writing and reviewing QMS and technical documents.

Additional activities include ad-hoc support to Quality Control related activities, Clinical and regulatory activities.

Your formation and experience:

- Engineering degree or Bachelor/Master in Sciences and/or Quality Assurance/Regulatory Affairs.
- Minimum 3-5 years of experience in Quality Assurance in Pharma/Biotech/Medical Device industry.
- Strong knowledge of relevant medical device regulations (e.g., 21 CFR, MDR 2017/745) and standards (e.g., ISO 13485, ISO 14971).
- Proven experience in contributing to QMS development and maintenance.
- Good knowledge and understanding of medical device development process (Design Control).
- Ability to review, critically analyse, and provide relevant feedback on technical and quality documentation.
- Oral and written proficiency in English is required.

Your mindset and personality :

- You are rigorous with a strong attention to detail, and you are highly organised.
- You are proactive and able to work autonomously.
- You have problem-solving ability.
- You are objective-oriented, and challenges stimulate you.
- You enjoy working in a multidisciplinary team and having interactions with others.

We offer :

- A dynamic and stimulating work environment, at the cutting edge of innovation and biomedical technology.
- The opportunity to express your talents and grow with the team.
- The integration into an interactive team, where you can propose ideas.
- To contribute to improving the life of millions of patients.

Join us to become an essential part of our exciting journey in developing groundbreaking innovation !

Please send your full application (CV, Motivation Letter, work certificates, references and any relevant additional document) to:

- Elisa Roy-Cros (elisa.roycros@volumina-medical.ch)
- Amélie Béduer (amelie.beduer@volumina-medical.ch)

Please indicate “Application – Quality Engineer” in the subject of your email message.