Volumina Medical

Verification and Validation Engineer

Medical device, Pharma

- Based in Lausanne (Biopôle, Epalinges)
- Salary: commensurate with experience

Volumina Medical is a multi-award-winning start-up active in the field of medical devices supported by a solid network of investors. The company develops breakthrough innovations for plastic and reconstructive surgery. The first product is an implantable polymeric biomaterial (class 3 medical device, comparable to pharma products) and targets the regeneration of soft tissue of the human body which are damaged after tumor excision, genetic malformation or trauma (for example to compensate for volume loss in the breast for breast cancer patients).

The technical team is recruiting a verification and validation engineer, wanting to express her/his talents within the company. The candidate will play a major role in the development of the company and must be ready to take on responsibilities.

Your key mission is to ensure all systems and equipment are running according to the necessary specifications and operate within regulations. You will also ensure that the manufacturing and testing processes are validated or verified according to the verification and validation planning and according to medical device regulations and risk analysis.
You will be taking an active role in defining requirements, creating and executing verification and validation plans, coordinating V&V activity and delivering the evidence to substantiate the safety and efficacy of devices.

It includes notably the following activities and responsibilities

- Create verification and validation plans that satisfy rigorous requirements of medical device development.
- Ensure product requirements are testable and traceable through well-defined test protocols and aligned with regulatory requirements.
- Write and execute verification and validation procedures (biological tests, chemical characterization testing, physical testing, e.g: compression of biomaterials, rheology, analysis using microscopy, …)
- Ensure test results and reports are accurate, appropriately documented, and support all product requirements.
- Plan and execute the validation of equipment, plan and implement their maintenance and/or calibration (ex: microscopes, mechanical testing bench, fridges, …)
- Develop testing protocols and document test results
- Ensure all V&V contributors stay on track for timely delivery of test results
- Contribute to and support risk management activity.
- Create supporting documentation for regulatory submissions and participate in resolving questions.

Required Skills and Experience

- Validated experience (min. 3 years) in implantable medical device verification and validation
- Expertise in statistical methods for sample size determination and test analyses
- Knowledge of medical device test standards (e.g. ISO 10993)
- Material sciences engineer, Master in Material sciences, Bio-engineer, Process engineer (HES), PhD in material sciences or in chemistry, pharmacist in industry.
- Knowledge in polymers, chemical processes and materials characterization (FTIR, purity, microscopy, Mass spectroscopy, NMR, …).
- Capacity to speak and to write technical documents in English.

Your mindset and personality

- You are organized, disciplined and care about details.
- You are proactive and able to work autonomously.
- You are objective oriented and challenges stimulate you.
- You enjoy working in a multidisciplinary team and having interactions with others.
- You care about patients and improving their life is motivating you.
- You enjoy testing work and writing technical and regulatory documents.

We offer you

- A dynamic and stimulating work environment, at the cutting edge of innovation and biomedical technology.
- The opportunity to express your talents.
- The integration into an interactive team, where you can propose ideas.
- To contribute to improve medical care.

To apply, please send your complete application (CV + cover letter) to Amélie Béduer, CEO and Co-Founder at Volumina Medica amelie.beduer@volumina-medical.ch