# Volumina Medical

# **Quality Engineer**

Quality Control testing of an innovative implant for soft tissue reconstruction

Permanent / Based in Lausanne, Switzerland / Full time, 100%

Volumina Medical is a start-up, spin-off from EPFL (Ecole Polytechnique Fédérale de Lausanne), active in the field of implantable medical devices for reconstructive and plastic surgery. Since 2018, we develop cutting-edge injectable polymer-based biomaterials designed to reconstruct damaged tissues, e.g. after tumor ablation or due to aging.

The start-up Company is preparing for a growth phase, involving clinical activities as well as for market launch of its highly innovative lead product. In order to accompany this growth, we are looking for a highly motivated candidate to be responsible for the quality aspects of the product. The candidate will be in charge of the quality control activities of our semi-finished and finished products (GMP manufacturing of class 3 medical devices), and of some quality assurance activities.

#### Your mission

- Lead and perform quality control testing of semi-finished and finished products (physico-chemical properties, involving analytical techniques such as pH, mechanical properties measurement, microscopy, HPLC, GPC, ...)
- Lead and perform incoming inspection of raw materials and consumables used in manufacturing
- Lead and perform environmental monitoring of the clean room
- Identify and develop relevant new analytical techniques for improving the control of the quality of the product
- Participate to the improvement and (re-)validation of quality control methods
- Be responsible for the management of quality control samples and manage the interactions with external service providers in a timely manner
- Record and communicate quality control results to the production team and to management
- Manage all documents related to his/her activities following the quality sytem of the Company
- Participate to development and/or validation projects as quality referee
- Manage non-conformities related to his/her activities
- Manage one or two quality assurance process(es)

## Your background and experience

- HES degree or equivalent, bachelor or master degree in Chemistry, Polymer Chemistry, Chemical Engineering, Analytics and Characterization, with 1-3 years of experience
- CFC profiles with 10 years of experience will also be considered
- Experience in quality control and analytical techniques, preferably in the medical device or pharma industry
- Experience in quality assurance is a plus: change control, CAPA or supplier management
- Oral and written proficiency in English is a plus
- Programming skills are a plus

### Your personality

- You enjoy laboratory work and care about the quality of your results and their documentation
- You are organized and rigorous in your work
- You are proactive, polyvalent 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

### We are offering

- A dynamic and stimulating work environment, at the forefront of biomedical technology and innovation and on a dynamic life-science campus
- The opportunity to express your skills and to grow together with the team
- The integration into a multidisciplinary team, where your opinions count
- To contribute in improving quality of life for millions of patients in the long term

To apply, please send your application (CV, motivation letter, reference letters and work certificates if available) to Laurence Rivier, Senior Validation Engineer, laurence.rivier@volumina-medical.ch

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