

Effectum Medical is a young company that is breaking new ground in the areas of quality management and regulatory affairs in the medical device industry. Our vision is to facilitate and accelerate medical device product innovation by offering an affordable, outsourced quality management system (QMS) and legal manufacturing. Our customers are start-ups, as well as global medical device manufacturers.

To further grow our company, we are looking for a

Head Quality Management (80-100%)

to join our team.

In this position you

- manage the area QM in line with the targets defined by the executive management team
- are responsible for the maintenance of our QMS
- are the person responsible for regulatory compliance (PRRC) of Effectum Medical with authority to give directives in order to ensure fulfillment of quality requirements of Effectum Medical
- are key contact to Notified Body and Competent Authorities and responsible to manage all interactions
- lead Complaint Management and Vigilance activities, CAPA and Post-market Surveillance
- are a Member of the Change Control Board review and approval and you have the overall responsibility for the change process
- review and update regulations, norms and standards and integrate these into our QMS
- monitor and report the effectiveness of QMS and communicate required improvements with an action plan to executive board
- increase the awareness of regulatory requirements and QMS throughout the organization
- take the final decision about approval of contractors / suppliers, and QAAs
- initiate and lead internal and external audits
- release and reject products (incoming inspection)

You have

- at least 5 years of professional experience in the medical device industry and min 3 years in quality management
- knowledge of ISO 13485, MDR, IVDD/R, QSR 21 CFR Part 820, and the certification processes for medical devices in Europe and the USA
- a customer focused approach to coordinate and supervise stakeholders
- excellent communication and interpersonal skills, ability to gain consensus on key quality decisions
- excellent knowledge of English, written and spoken, and good conversational skills in German



E F F E C T U M M E D I C A L
YOUR START-UP TO MARKET

We offer

- the possibility of working in a motivated team with a common goal – accelerating innovation in the medical devices industry
- flexibility – as of February 2021 our offices are located in the center of Olten, partially working from home is possible
- the ability to actively shape and further develop the company with us to reach our common goal
- personal development opportunities in a growing company

Do you share our vision to facilitate and accelerate medical device product innovation by offering an affordable, outsourced quality management system (QMS) and legal manufacturing? If the answer is “YES!” we are looking forward to getting to know you. Please send your application to [monika.truempler\(at\)effectummedical.com](mailto:monika.truempler@effectummedical.com)