

Since 2020, elexxion AG has been developing, producing and selling high-quality laser technology „made in Germany“ for the dental sector. We are certified according to Din EN 13458:2016. For a continued successful growth we strengthen our team. We are looking to recruit at once:

## *Quality & Regulatory Compliance Manager (m/w/d)*

### **Responsibilities:**

- establishing and maintaining the quality management system;
- performing internal audit and management review;
- communication with notify body and authorities, and escort external audit;
- following up CAPA;
- leading the transition to new standard and regulation, such as MDR;
- creating and maintaining technical documentations;
- leading CE registration and supporting product registration for other countries and regions;
- involving in new product design and development and guide the R&D process from quality & regulatory compliance perspective;
- performing computer system validation; and
- other tasks assigned by the CEO.

### **Qualifications:**

- bachelor degree in engineering, laser, electrical, mechanical, medical device or other related fields;
- more than 3 years quality and regulatory experience in production and R&D environment in medical device industry;
- be familiar with the requirement of ISO 13485, have internal audit certificate, an external auditor certificate will be preferred;
- have experience in establish and maintain quality management system;
- be familiar with the requirement of EU medical device regulatory requirement;
- have experience in create and maintain technical documentation, and CE registration;
- good at coordination, communication and problem resolving;
- fluent spoken and written English and German.

elexxion AG offers you an interesting field of activity and a full-time employment.

If you recognize yourself in this profile, we look forward to receiving your detailed application, including salary expectation and earliest possible starting date, preferably by email to Mr. Schlapeta ([schlapeta@elexxion.com](mailto:schlapeta@elexxion.com)).