



In order to strengthen our team in Basel, we are looking for a new colleague at the earliest possible date as a

Senior Regulatory Affairs Manager (m/w)

Tasks

- Ensuring that regulatory requirements for the approval of medical devices are met during the product development process
 - Support and consulting for research & development and brand management in the interpretation of regulatory requirements throughout the entire lifecycle of the products and ensuring that the technical documentation of the products complies with the respective requirements for medical devices
 - Communication of new regulatory approval requirements to research & development as well as brand management and support in the implementation thereof
 - Participation in interdisciplinary product development teams
 - Assessment of products with regard to their risk potential
 - Responsibility for the regulatory content of product-related information and its release
 - Conducting conformity assessment procedures for the products and initiating the preparation of the declaration of conformity
 - Support of international product registration
 - Support in the preparation and execution of audits
 - Support in continuing improvement of quality procedures and regulatory processes
- 8+ years experience in regulatory affairs and in international approvals in the field of medical devices or pharmaceuticals. Experience in quality management and / or product development is an advantage
 - TÜV certified Regulatory Manager or equivalent education
 - Knowledge of MDD 93/42/EEC as well as MDR 2017/745 (product classification, definition of applicable standards, conformity assessment procedures)
 - Experience in working in interdisciplinary teams
 - Excellent MS-Office knowledge, experience in handling document control and ERP systems (e.g. SAP)
 - German and English proficiency written and spoken, additional languages are an advantage

Your prospects

Challenging job in an exciting environment

International employer with team-oriented working atmosphere

Attractive employment conditions

Do your professional and personal qualifications match our requirements? We look forward to receiving your application.

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Your Profile

- Scientific, medical or engineering background, or corresponding industry experience



**biohorizons
camlog**

Are you looking for a new challenge in a successful company? At CAMLOG, we produce innovative products for implant dentistry. With the CAMLOG® implant system, we are one of the market leaders in our industry. We owe this position not only to customers who value us as a reliable partner, but also to our highly motivated employees. They ensure the continuous technical and qualitative development of our products and processes.