QualiMed®
Innovative Medizinprodukte GmbH

Regulatory Affairs Manager (RAM)

Attributes	Description
Position / Title	Regulatory Affairs Manager (RAM)
Department / Area	Regulatory Affairs (Zulassung von Medizinprodukten)
Reports to	Head of Regulatory Affairs
Language	German English (fluent English in speaking and writing)
Education	Medical Technology Engineer or equivalent with masters degree preferred with a focus on and special skills, respectively, in Regulatory Affairs and Quality Management
Experience	Experiences in Quality Management and / or Regulatory Affairs in the field of medical devices for at least 3 years are mandatory
Primary Tasks and Responsibilities	• Development and execution of regulatory affairs (RA) plans and strategies for new products and foreign countries registration (RA) processes. • Compilation and updating of corresponding Product Master Files (PMF) and other filings for registrations worldwide. • Support and execution on RA filings (e.g. DIMDI Notifications, Recalls, MDD Vigilance, PSUR reports, Annual Reports). • Collaboration on the development of product and process validation and verification plans as well as corresponding support of the development department and development processes including Design Control (12-Step Development Methodology). • Support of Quality Management (QM) in general (e.g. maintenance of the ISO 13485 /MDD based quality system) and especially in the area of overlapping tasks (e.g. LPI (labeling, packaging, IFUs), adjustment of QM system on FDA and GMP requirements,. • Support on Complaint Handling and CAPA System. • Support on design, conduction and documentation of preclinical and clinical trials. • Execution of Internal Audits. • Participation on External Audits: Notified body, customers, legal authorities, FDA. • Development of Risk Assessments (RIS) and Risk Management Plans (RMP) according to ISO 14971. • Execution of trainings, especially on RA and QM relevant topics.
Skills / Competencies	• Good knowledge about Medical Device Directive as well as general regulatory standards and regulatory guidelines. • ISO 13485, ISO 14971 and ISO 10993-ff experiences. • Experience in the field of class III and/or drug device combination products. • Experience in class III CE applications and key international players (USA's 510(k), PMA, Canada) as well as experience in registrations in Asian countries (especially China) are advantageous. • Well organized and good spelling style. • Regulatory experience in preclinical and clinical studies. • Skills in product and process qualifications, verifications and validations. • Experience with invasive catheters and implants are advantageous, as well as experiences in biodegradable implants. • Project planning and execution.
Working conditions	QualiMed, Winsen, Germany. Traveling related to the projects. Represent the company if necessary on conferences and exhibits. 40 hours/week
Any specific skill requirements	N/A

For more enquiries, please contact:
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