Halma
safer • cleaner • healthier

Join a high-performing group with a purpose: to grow a safer, cleaner, healthier future for everyone, every day.

We are hiring for **Regulatory Affairs Specialist** in **Halma Company IZI Medical**

Location	Business Unit	Report to
Bengaluru	Healthcare	Quality VP

About us

Halma is a global group of life-saving technologies companies, driven by a clear purpose. We are an FTSE 100 company with headquarters in the UK and operations in 23 countries, including regional hubs in India, China, Brazil, and the US

Our diverse group of nearly 50 global companies specialise in market leading technologies that push the boundaries of science and technology.

For over 50 years, the combination of our purpose, strategy, people, DNA and sustainable business model has resulted in **record long-term growth in revenues and profits and an increase in dividend by ≥ 5% every year**– an achievement unrivalled by any company listed on the London Stock Exchange.

Halma India fulfils the potential of the region by harnessing the diverse talents, expertise, infrastructure, and operational

We have a team of over 250 professionals representing commercial, digital and support functions across our seven offices in India, two in Bengaluru and one each in Delhi, Mumbai, Thanjavur, Vadodara, and Ahmedabad.

Halma India is a Great Place to Work® certified organisation, recognised for 3 consecutive years.

Here's why working with us is fulfilling:

We offer a safe and respectful workplace, where everyone can be who they 'REALLY' are, feel free to bring their whole selves to work and use their unique talents, knowledge, expertise, experiences, & backgrounds to create meaningful outcomes.

We nurture entrepreneurial spirits and empower them to think beyond the possibilities, to discover, shape and build their own unique stories. Our diverse businesses and operations provide fulfilling opportunities to grow as individuals and make an impact.

We are simple, humble and approachable, and we believe in leadership at all levels to bring our purpose to life. Everyone at Halma India makes an impact, and so do you when you join us!

Halma India is an equal opportunity employer, which means the base of our recruitment decisions is always on skills, competencies, attitudes, and values. We are committed to hiring from diverse backgrounds without regard to age, ethnicity, religion, marital status, disability status, sex, gender identity, or sexual orientation.

Great Place To Work. Certified DEC 2025-DEC 2026 INDIA

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Detailed job description

About Halma Company IZI Medical	Halma Company IZI Medical is a leading innovator, manufacturer, and distributor of quality medical devices, IZI Medical is a leading developer, manufacturer, and provider of high-quality medical consumable devices used in interventional radiology and oncology, radiation therapy, neuro-spine, and image guided surgery procedures. IZI Medical :- https://izimed.com
Position Objective (The purpose of role in current business/market scenario)	The Regulatory Affairs Specialist will support global regulatory activities for IZI Medical Products, with primary responsibility for preparing and maintaining EU MDR Technical Documentation and international regulatory submissions. The role will also support regulatory strategy, product lifecycle management, and global market expansion to ensure continued regulatory compliance throughout the product lifecycle.
Responsibilities (KRAs / deliverables / job expectations)	• Prepare and maintain EU MDR Technical Files including GSPR, risk management, labelling, UDI, verification/validation evidence, PMS and clinical documentation. Maintain consistency across Technical Documentation, Design History File (DHF), Risk Management File, Design Verification & Validation, labelling, and manufacturing documentation. • Support international registrations and respond to Notified Body, Competent Authority, and regulatory agency questions. • Support preparation and maintenance of CERs including literature searches, clinical evidence evaluation, state-of-the-art reviews, and benefit-risk analysis. Perform regulatory impact assessments for clinical literature, standards updates, and regulatory guidance changes. • Prepare and maintain PMCF Plans, PMCF Evaluation Reports, PMS Reports, PSURs, complaint trends, and vigilance summaries. Monitor complaint trends, post-market surveillance data, vigilance activities, and published literature to support continuous clinical evaluation. • Ensure consistency between CER, PMCF, PSUR, risk files, IFUs, SSCP/SSCR (if applicable), and Technical Documentation, adhering to all applicable regulations and terminology. Participate in Technical Documentation gap assessments and remediation projects to maintain MDR compliance. • Support regulatory assessments for design, supplier, labelling, and product changes among all IZI product families. • Monitor changes to applicable regulations, harmonized standards, MDCG guidance documents, and international regulatory requirements; assess impact on existing products and recommend implementation actions. Work closely with Quality Assurance, R&D, Operations, Manufacturing, Supply Chain, Marketing, Clinical Affairs, and external suppliers to support regulatory compliance throughout the product lifecycle.
	• Hands-on experience compiling EU MDR CER, PMCF Plans/Reports, PMS Reports, and PSUR documentation. • Experience with clinical literature search strategies, appraisal, and documentation.

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Critical Success factors (critical / high impact aspects of role)	• Experience supporting regulatory assessments for manufacturing, supplier, sterilization, and design changes. • Experience working with Notified Body questions regarding clinical evaluation, PMS/PMCF, PSUR, and Technical Files according to MDR regulations and guidelines. • Experience with Class IIa/IIb sterile devices, implantable devices, biopsy needles, fiducial markers, or surgical/interventional devices preferred. • Experience with sterile medical devices, EO sterilization, packaging validation, and shelf-life validation preferred. • Strong regulatory writing and project management skills.
Academic qualification	• Bachelor's degree in life sciences, engineering, regulatory affairs, or related field.
Experience (exposure)	• Minimum 3–5 years of medical device regulatory affairs experience, including hands-on preparation of EU MDR Technical Documentation, CERs, PMS/PMCF documentation, and international regulatory submissions.
Key attributes (critical functional competencies)	• Analytical skills: Strong ability to collect and analyse data to identify patterns and potential liabilities is still often a part of the job description for many. • Interpersonal skills to effectively interact across functions working in a highly motivated team atmosphere. • Strong written and verbal communication skills and proven ability to present to internal and external stakeholders. • Strong and proven problem-solving skills. • Ability to independently manage multiple regulatory projects and competing priorities with minimal supervision. • Ability to travel to work with customers and suppliers. • Computer proficiency in Microsoft Office products (Excel, Outlook, PowerPoint, Word, Teams).
Competencies (fundamental skills and attitudes)	• The ability to interact successfully across cultures. • Excellent English language communication skills, preferable with multiple languages. • Self-starter, able to work independently under tight deadlines. • Strong presentation skills and ability to conduct meetings. • You set high standards for yourself and others in the pursuit of excellence, honesty, integrity, and trust. • Be willing and able to operate in a lean environment and be creative and prudent in optimizing workflow. • Highly collaborative team player with the ability to engage quickly and help leadership Demonstrated ability to work effectively with global teams across multiple time zones.

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