



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

We are hiring for **Executive - Regulatory Affairs** in **Halma India Hub**

Location	Business Unit	Report to
Bengaluru	Halma India Hub	Lead - Regulatory Affairs

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 $\geq 5\%$ 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.



Detailed job description

About Halma Company	The role of the India hub is to catalyze the growth of Halma companies in India. The India Hub provides business services including Infrastructure, marketing, trading, compliances, talent, finance & accounts to Halma companies. The India Hub has been operational since 2008 with around 26 of the Halma companies investing in local resources currently. The employees can be broadly divided into 4 groups – Sales, Digital, BSG and Core Support.
Position Objective (The purpose of role in current business/market scenario)	Halma India with several diverse group companies operating independently has grown into a multi-location hub office entity with major digital operations in Bangalore. With the Introduction of INDIA MDR regulatory licenses are mandatory for selling Medical Devices in India. This position as part of Core Support in Halma India hub should be able to adequately support, manage and execute effectively regulatory and licensing requirements of Halma Operating Companies dealing in Medical Devices in India. This position is expected to utilise the understanding of India MDR to support Halma Companies operate in India in compliance to all the local regulations across multiple medical devices and risk classifications. We expect the individual to independently support and proactively develop regulatory management for an agile and collaborative work environment at Halma India Hub in its growth journey.
Responsibilities (KRAs / deliverables / job expectations)	• Have regular meetings with international Regulatory Teams of Halma Companies to understand their evolving business needs wrt Indian market. • Assist them in understanding the India MDR with clarity. • Serve as a consultant, advisor and guide to the International Regulatory team with a solution orientation. • Reach out to CDSCO or travel to Delhi for mtg with regulatory officers to seek clarification. • Tap into External expertise/Consultant as and when required in some new areas. • Evaluate, Recommend, Implement and Use technology and platforms to manage licences and process flows for multiple Operating Companies within the Group • Minimise risk to business disruption from regulation. • Agile and responsive to changing regulatory environment and evolving business needs. • Manage LMPC & NPPA requirements along with labelling requirements for the import of medical devices. • Use MTAI membership effectively for advocacy as well as position Halma's point of view whenever required. • In addition, there are regulatory license applications for PESO to be also managed with a list of documents. • GEM portal registration for Halma companies based abroad including providing checklist, outlining process, following-up for documents, submission of the same, and facilitating online video audits of the factories.

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Critical Success factors (critical / high impact aspects of role)	• Executorial Rigor, Due diligence wrt to Documentation, and Process Oriented for day-to-day MDR Licensing requirement. • Understands varying needs across diverse stakeholders – especially different types of medical devices. • Transparent and effective communicator with all stakeholders, and commercially savvy when recommending solutions • Deep and Clear understanding of evolving India MDR
Academic qualification	• Degree in Regulatory Management
Experience (exposure)	• Minimum 1-2 years of relevant experience • Core end-to-end experience in India MDR • Experience in Regulatory License platforms. • Exposure to Legal Metrology & Labelling, UDI, MRP/Pricing/Trade Margins, Customs and other related operational issues • Exposure to European MDR and FDA would be advantageous.
Key attributes (critical functional competencies)	• Understanding of India MDR • Hands on experience with online applications with CDSCO for various MDR Licences, device risk classification, Product Family Grouping. • Experience with understanding of basic license management and alerts. • Basic understanding of International Regulatory Principles and evolving changes esp. wrt software in medical devices • Ability to understand an issue & escalate to International Regulatory Teams in a timely manner.
Competencies (fundamental skills and attitudes)	• Takes ownership and is proactive with challenges. • Detailed and Systematic Documentation • Organised and Process Oriented • Responsible (overcomes challenges to make things happen) • Transparent Communicator with listening skills • Keen sense of anticipation

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