



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 **Lamidey Noury Medical**

Location	Business Unit	Report to
Bengaluru	Healthcare	R&Q Manager

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 CERTIFIED AS A GREAT PLACE TO WORK.

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 Lamidey Noury	<p>Lamidey Noury French manufacturer of electrosurgical devices since 1947. Lamidey Noury is dedicated to enhancing surgical precision and patient outcomes. Its high-quality innovative electrosurgical devices are designed to improve the safety and efficiency of urological, gynaecological procedures and other surgical procedures. They are essential in minimally invasive procedures to contribute to improved outcomes for patients.</p> <p>Lamidey Noury - https://en.lamidey-noury.com/</p>
Position Objective (The purpose of role in current business/market scenario)	<p>The Regulatory Affairs Specialist will be responsible with development, management, and implementation of regulatory strategies to support new and existing medical devices globally.</p>
Responsibilities (KRAs / deliverables / job expectations)	<ul style="list-style-type: none"> • Plan, coordinate and prepare document packages for regulatory submissions and renewals with emphasis on EU Technical Files, MDSAP, and other regulated countries. • Perform MDR gap assessments and remediation of MDD technical files. • Author Regulatory department procedures, templates. • Maintain annual facility registrations, device listing, GSI, and GUDID as required by US FDA. • Carry out monitoring regulations and standards applicable to Lamidey Noury Medical's medical devices. • Conduct impact analysis of amendments to standards and regulations applicable to Lamidey Noury Medical's medical devices. • Manage the submission of export registration files by providing the information requested by distributors and/or authorities. • Respond to requests from distributors and/or authorities to follow up on the submission of files. • Maintain registrations by managing file renewals. • Follow registration certificates and quality contracts with distributors. • Collaborate with the export sales team to monitor registrations and prioritize them • Manage 510K files and communications with the FDA. • Perform other related duties as assigned.
Critical Success factors (critical / high impact aspects of role)	<ul style="list-style-type: none"> • Have significant experience in regulatory affairs applied to medical devices • Have knowledge of standards, regulations, and legal requirements applicable to medical devices: Regulation (EU) 2017/745, FDA requirements (510K, CFR 21 part 820), SFDA, MDSAP. • Experience in medical device development, quality assurance, or regulatory affairs is highly desirable. • Strong analytical and problem-solving skills with the ability to assess complex technical issues. • Excellent communication and collaboration skills to work effectively with cross-functional teams. • Detail-oriented and well-organized, with the ability to manage multiple

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.





	<p>tasks and priorities simultaneously.</p> <ul style="list-style-type: none"> Familiarity with documentation and submission requirements for regulatory bodies is an advantage.
Academic qualification	<ul style="list-style-type: none"> You have a master's degree in regulatory affairs, science, or equivalent.
Experience (exposure)	<ul style="list-style-type: none"> 3-5 years of experience in Quality or a regulated industry is preferred.
Key attributes (critical functional competencies)	<ul style="list-style-type: none"> Excellent verbal and written (including technical writing) communication skills with strong attention to detail is required. Proficient in Microsoft Office (Outlook, Excel, and Word) and ERP systems. Working knowledge of Quality System Software systems is preferred. Proficient in time management, multitasking, and organizational skills. Ability to interact with multiple departments, including Customer Service, Sales, Production, and Engineering. Comfortable working with and learning new products and technology.
Competencies (fundamental skills and attitudes)	<ul style="list-style-type: none"> Ability to plan, schedule and set personal and team priorities. 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.

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.

