



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

We are hiring for **Regulatory Compliance Specialist** in **Halma Company Perma Pure**

Location	Business Unit	Report to
Bengaluru	Healthcare	VP, RA/QA

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.



Detailed job description

<p>About Halma Company Perma Pure</p>	<p>Perma Pure LLC was founded in 1972 and is headquartered in Lakewood, New Jersey and operate facilities in Lakewood and in Salt Lake City, New Jersey. Perma Pure Lakewood facility manufactures components and devices primarily designed to dry and humidify gas streams and Salt Lake facility manufactures components and devices supporting mixing, blending, sensing and analyzing medical gases.</p>
<p>Position Objective (The purpose of role in current business/market scenario)</p>	<p>As the Regulatory and Quality Systems Specialist, you will drive the safety and efficacy of our products by ensuring that the organization follows industry specifications, standards, regulations, and laws. You will support top management with driving compliance with all elements of the quality management system and the applicable regulatory requirements and standards to support the design, and manufacturing of Class I and Class IIA & B (per the United States FDA Classification and European Union Medical Device Regulation) devices.</p>
<p>Responsibilities (KRAs / deliverables / job expectations)</p>	<ul style="list-style-type: none"> • Support the health of the Quality Management System to identify areas of weakness and coordinate activities to improve regulatory or quality system compliance including but not limited to EN ISO 13485:2016 certifications through the MDSAP program. • Provide RAQA support across sites working in partnership with other functions including Regulatory Affairs, Operations, Engineering, Supply Chain, Finance, HR etc. • Influence and mobilize key stakeholders toward desired results and future-state. • Maintaining a deep understanding of new and existing regulations that may impact their organization’s products and processes. • Utilize regulatory and standard understanding to standardize all business operations and establish clear, documented procedures. • Explain regulations, procedures, and policies to employees and stakeholders as necessary. • Prepare for and facilitate third-party audits as necessary. • Act as a liaison between the Perma Pure Group and state, local, federal, and international agencies to submit required forms and paperwork. • Escalate risks to top management. • Escalate regulatory risks to top management. • Partners with the Person Responsible for Regulatory Compliance and the Management Representative to ensure customer complaint adverse events are identified, investigated and reported in accordance with applicable international and federal guidelines. • Work with the Management Representative to coordinate company Management Reviews. • Identify state, national and international licensing for the shipment of medical devices. • Coordinate and complete reports required by US and International regulatory bodies. • Track US and international licensing to ensure renewal applications and updates are completed in the timeframes defined. • Compile licensing application to ensure that the specific international,

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	<p>national and state requirements outlined.</p> <ul style="list-style-type: none"> • Support the execution of Post Market surveillance / Vigilance activities. • Support and lead projects, as assigned, related to the implementation of new regulatory requirements as issued by FDA, Health Canada or EU Governing Body. • Provide approved regulatory documentation to internal and external Customers as requested. • Manage the adverse event reporting program for the Perma Pure Group in compliance with the applicable regulations as outlined by (but not limited to) international regional competent authorities, notified bodies, and Customer agreements. • Manages the review of each Maxtec complaint to determine if it is a reportable event in accordance with the applicable regulations including but not limited to US FDA 21 CFR Part 803, EN ISO MDSAP countries. • Other duties as assigned. • Maintain a deep understanding of the products or services offered by our company and the broader medical device industry in which we operate and the agencies that regulate it.
<p>Critical Success factors (critical / high impact aspects of role)</p>	<ul style="list-style-type: none"> • Working knowledge of 21CFR Part 820, 803, 801, EN ISO 13485:2016, MDSAP, EU Medical Device Regulation. • Competency in Medical Device Quality and Regulatory Systems for a global company including but not limited to the US FDA's Quality System Regulation, ISO 13485, The European Union Medical Device Regulation and the international Medical Device Single Audit program and the applicable regions.
<p>Academic qualification</p>	<ul style="list-style-type: none"> • Bachelor's degree in Bio-Medical Engineering, Life Science, Business or related field of study or equivalent experience.
<p>Experience (exposure)</p>	<ul style="list-style-type: none"> • 5-10 years' experience in a regulatory support role, preferably in a medical device manufacturing environment. • ASQ and/or RAPS Certification a Plus.
<p>Key attributes (critical functional competencies)</p>	<ul style="list-style-type: none"> • Analytical skills: Strong ability to collect and analyze 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 travel to work with customers and suppliers. • Computer proficiency in Microsoft Office products (Excel, Outlook, PowerPoint, Word, Teams).
	<ul style="list-style-type: none"> • 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.

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Competencies (fundamental skills and attitudes)

- 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

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