Quality Management | Process Planning & QA | Experienced

Sr. Manager- Regulatory Affairs

Bengaluru, India

MOTHERSON HEALTH & MEDICAL is focused on helping people become and stay healthy by enabling access to high-quality and affordable care. As part of the Motherson family, we draw upon decades of expertise in innovation, product design, engineering, software, and supply chain. Motherson Health & Medical leverages the vast resources of the Motherson Group, which includes over 180,000 employees and more than 350 manufacturing facilities in 41 countries. This enables us to substantially impact the healthcare industry by creating access to quality and affordable healthcare worldwide.

We continuously expand our core capabilities by collaborating with universities, hospitals, research groups, startups, and healthcare companies. By staying at the forefront of scientific and technical developments, we deliver cutting-edge products to our customers. We believe in attracting talented individuals, investing in their development, and providing equal opportunities for success. We actively recruit talent with core healthcare capabilities from diverse geographies to join our inclusive team. Together, we aim to revolutionise the healthcare industry and make quality and affordable healthcare accessible to all. Join Motherson Health & Medical and be part of our mission to make a positive impact on global healthcare.

What you'll do

Key Position in Central Team of Motherson Health & Medical to shape, plan and execute Regulatory strategies for Products as part of Organic growth as well as interfacing with Inorganic growth opportunities to assess regulatory risks and build a mitigation plan to enable the company scale up the business. Closely work with top management at Motherson Health & Medical Corporate for Regulatory Affairs & Quality Management Systems deployment and adherence at various locations of Motherson.

Provide Leadership and coordinate with cross functional teams to deliver Safe,Effective & Regulatory compliant Products to customers following the QCDMSES (quality, cost, delivery, development, management, safety, environment & sustainability) process.

Ensure right level of Processes, training and personnel are placed to support all Regulatory deliverables from Product Development, Go to Market, Product Certifications & Post Market Regulatory expectations. To be one point of contact for all communications for internal and External regulatory bodies to obtain and maintain Certifications for Site and Medical devices and components.

What we are looking for

• At least 15-20 years' experience in relevant industry like Medical Device OR Healthcare with ISO 13485, 21CFR 820 or cGMP regulated environment with Experience in Regulatory certifications & bodies that include but not limited to FDA 510(k), MDD/MDR CE Marking, CDSCO and various other market needs. • Proven problem solving, trouble shooting and Outcome focused Mindset. • Experience with leading Medical devices Cross functional teams in regulatory filling and certification activities. • Experience in New products Go to Market Regulatory Planning & working with Regulatory bodies to submit required documentation to enable product certifications.

Knowledge and educational level:

• BE or BTech. or high or equivalent Degree. MBA is added preference. • Working Knowledge of Regulatory Resources & Added certifications – Ex: RAPS, regulatory trainings and certifications. • Working knowledge & experience of regulatory requirements pertaining to Medical devices. • Should have excellent People management & Communication skills.

What we offer