

Company: Tata Elxsi Limited
Position Title: Regulatory Affairs Specialist
Location: 2701 Troy Center Drive, Troy, MI 48084 and unanticipated client locations throughout the U.S.

Position Responsibilities: Perform European Union Medical Device Regulations (EU MDR) labeling gap assessment and closure activities for different product families with the Vascular Therapies & Implants and Drug & Chemistry Technologies. Understand the products, customer codes and revalidating/re-verifying company's internal documents (SOPs, DOPs etc.). Provide technical expertise and assistance to the labeling team, in interpreting requirements. Lead assessment activities in packaging and labeling by identifying compliance gaps and support gap closure activities. Author and review gap assessment checklists and reports required for technical files and design dossiers updates for products. Devise and validate new strategies to mitigate risk identified during gap closure activities. Collaborate with subject matter experts (SMEs)/Managers to review gap rationales before routing it in change orders. Incorporate the feedback from Notified Body and content strategizing for client acquired companies. Review and advise team on what will be realistic prescribing information for the intended product. Supporting technical communication team on creation of "Instructions for use." Collaborate with SMEs/Managers to understand the functional and business needs while designing labels. Support a product family global launch: Involves working with cross functional teams, maintaining project management tracker, planning and prepare submissions, supporting addendum labeling, product release and launch activities. Provide onsite support for label print testing at design sites and production printing at manufacturing sites.

Position Requirements: Bachelor's degree (or foreign equivalent) in Biomedical Engineering, or a related field, PLUS three (3) years of experience in the job offered or a related position. Experience must include demonstrable knowledge: EU MDD; EU MDR 2017/745; Gap Analysis & Remediation; ISO 13485; ISO 15223-1; ISO 15223-2; ISO 14971; EN 1041; ISO 20417; TDS; GSPR; ERC; DoC; Adobe In-design; Photoshop; Prysm R3; Prysm 360; QMS Root Cause Analysis; MS Project, and; Smartsheet. Travel to unanticipated client locations throughout the U.S. approximately 30%, as required. May telecommute from any location within the U.S. Multiple positions available.

To apply, please email resume to nirbhayd@tataelxsi.com. Reference job code 57901.0417