Sr Director Director Regulatory Affairs

Hiring organization
Delfi Diagnostics Inc.

Job Location
Remote

Base Salary
$ 95000 - $ 125000

Date posted
May 22, 2024

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Description

The Director of Regulatory Affairs at DELFI Diagnostics will support the representation of DELFI with the FDA and other US and international regulatory agencies. Internally, this role will support and direct the regulatory function, regulatory activities within the company to ensure compliance with all applicable standards, regulations, and customer requirements. This position will communicate and collaborate across departments, including R&D, Assay and Software Development, Regulatory, Clinical Laboratory, Clinical Development, Quality and Commercial to ensure goals and strategies are met. nWhat you'll do Implement global Regulatory Affairs strategies, policies, objectives, and submissions in accordance with Company strategic plans, partnering directly with the VP of Quality and Regulatory Affairs, and indirectly with members of the product development and software teams.Lead the Regulatory function, to and including hiring, performance management, and career development; also implement regulatory operations SOPs, create functional excellence goals, etc.t.In partnership with the Quality team, support robust FDA quality systems including QMS documentation, internal audits & corrective/preventive actions, document/data control, material review (nonconforming material) and establishment and maintenance of quality records. Prepare, and coordinate the preparation of pre-submissions, sprints, and PMA modules, as well as Technical Files for CE marking. Build appropriate relationships with Operations, R&D teams, Technical teams, and Commercial, and provide on-going support as needed. Provide on-going support to the product development teams for regulatory issues and questions. Participate as an effective member of cross-functional teams. Work with cross-functional teams to develop technical strategies that support current and long-term business objectives. What youâ??ll have accomplished 12 months from nowFacilitate and support the achievement of key corporate goalsAchieve key milestones across multiple IVD product development projects, including sprints, pre-submissions, and/or module milestones with the FDAHelp implement systems and processes needed to develop and launch IVD productsWhat youâ??ll bring to DELFIRequiredBachelor's degree in Engineering, Technology, or other life science degree. 10+ years in regulatory activities, implementation, and compliance experience in the medical device industry. 5+ years of medical device software experience, preferred. Experience with PMA submissions Strong understanding of 21 CFR 820, ISO 13485, Good Clinical Practice, and other applicable global regulations related to in vitro diagnostics (IVD) and clinical studies.Working knowledge and experience in the following areas: Quality System Management, US and OUS Regulatory, Document Control, Design Control, Design V&V and Process Validation, Design Transfer, Risk Management, Complaint handling, Vigilance Reporting, CAPA management, Supplier Control, etc. Demonstrated ability to effectively lead facility inspections conducted by Regulatory Agencies.Demonstrated ability to effectively manage and lead a Regulatory functionDemonstrated ability to successfully work with individuals and in a cross-functional team environment. Strong ability to influence and work with personnel at all levels. PreferredKnowledgeable in CLIA/CAP and laboratory developed test (LDT) requirements.Expertise in next generation sequencing techniques in high-throughput settingsExperience with software in medical device settingsn$160,000 – $300,000 a yearWide range reflects from Director level to Sr Director level. Compensation packages at DELFI include annual salary, bonus, equity, and benefits. Actual compensation packages are based on a wide array of factors unique to each candidate, including but not limited to skillset, years & depth of experience, certifications & relevant education, geography.nPlease mention the word **EXCELLANT** and tag RNTQuMTYyLjIwOC4yMzc= when applying to show you read the job post completely (#RNTQuMTYyLjIwOC4yMzc=). This is a

beta feature to avoid spam applicants. Companies can search these words to find applicants that read this and see they're human.

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