

Regulatory Project Manager

Kforce Professional Staffing has a direct hire/permanent position open at this time for a Regulatory Project Manager. Kforce delivers the right match, the right way: with personal respect, a disciplined process and exceptional service. For more general information please log on to www.kforce.com

Job Description: We are seeking a regulatory project manager (with 510k submissions) to join a focused on implementation of design control practices in the software and hardware engineering areas; as well as, in assay and applications development. The project manager will bring previous medical device experiences, work with groups to initiate design control practices consistent with FDA quality standards as defined by 21CFR, Part 820. Since design control is a new process to our client, the project manager's role is to identify necessary activities and results, and guide them in the process of completing design control steps. The goal of the regulatory manager's efforts will be to develop design history files and put procedures in place to support a pre IDE meeting with the FDA and to lay the ground work for a FDA 510k submissions for the T5000 system and reagents in 2009. The Regulatory Manager will be expected to perform the following tasks: Establish design control process and governing operating procedures compliant with FDA QSRs under 21CFR, Part 820. Drive the preparation of a quality documentation package with design plans, input requirements and specifications, and output artifacts Organize appropriate cross-functional reviews to support the design control process internally and externally with appropriate experts Train software and automation technical staff on design control methods and identify areas of improvement required Support communications with the FDA regarding device classification issues Participate in technical design processes to help focus efforts on regulated device(s). **Technical Skills Required:** Bachelors degree in biological sciences, physical sciences, mathematics or computer science, advanced degree preferred. Prior experience interacting with the FDA. Prior experience with successful FDA 510k submissions. 5+ years industry experience in medical devices through software or instrument systems related to assays which measure human clinical conditions. Previous project management experience. Strong oral and written communication skills. Ability to be successful in a fast-paced, team environment. Stable work history. U.S. Citizenship is required (government contracts requirement). For more information or to apply directly please contact David Schwarzenbek at: dschwarzenbek@kforce.com or 858-550-1663.