R&D Project Manager

Biomedical company is looking for R&D Project Manager

Job description:

• Oversee and manage design-controlled product development efforts including definition of proper and testable product requirements, definition of product development milestones, conducting design reviews, and rigorous testing & analysis in support of verification and validation activities.
• Manage and lead teams of non-direct reports
• Create and manage project scope, schedule, and budget
• Monitor and maintain awareness of new and current product regulations and standards
• Manage a project within standardized methods and project models
• Ensure the timely release of critical deliverables within the project
• Schedule and lead meetings to coordinate inter-departmental project activities; including those necessary to resolve project issues
• Ensure all aspects of the project are in compliance to internal procedures
• Understanding of group dynamics to influence team members
• Effective communication with project stakeholders and management
• Communicate project status at defined intervals and meanings, and escalate any concerns to the Supervisor and associated Management representatives.
• Assure that all product and project deliverables (quality, performance, cost, schedule and revenue) are met

Experience/skills required:

• BS in Engineering discipline (e.g., Biomedical, Chemical or other relevant degree)
• Minimum of 4+ years of experience in medical device or other regulated industry
• Skilled in product development processes and a general business understanding, preferably in the highly regulated medical device industry
• Industry experience of 5 plus years including three years’ managing projects
• Ability to coordinate across disciplines and integrate all aspects of business as they impact development projects including negotiation of scope, roles and responsibilities, specifications, timelines, and resources - up, down and, across the organization
• Demonstrated effective written and oral communications skills
• Strong analytical skills to assess situations and drive decision making
• Capacity to achieve outcomes based on ability to facilitate and negotiate desired results
• Project Management Professional (PMP) certification not required but is a key differentiator.
• Prior history working in an FDA regulated development environment; specifically ISO 13485
• Knowledge of FDA 510(k)/PMA process strongly preferred
• Verification and Validation experience with FDA-cleared or approved IVDDs
• Experience with design of experiments, statistical analysis techniques, and data analysis tools
• Prior experience in interventional medical device is necessary

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