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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