

JOB DESCRIPTION

POSITION TITLE: Project Manager, Research and Development

DEPARTMENT: Research and Development

POSITION REPORTS TO: Director, Research and Development Program Management

FLSA: Exempt

POSITION PURPOSE

The Project Manager, Research and Development works within R&D function to support & execute internal & contract product development & research projects. This position is a key role within the R&D organization ensuring innovative and quality products are delivered in a timely manner while maintaining compliance with industry standards and regulations.

ESSENTIAL FUNCTIONS AND RESPONSIBILITIES

- Champion new product development projects: developing and securing regulatory approval for new regenerative medicine products.
- Actively engage and collaborate on global cross functional product development teams.
- Project management
 - Scopes and prepares project plans and budgets.
 - Actively manages project timelines and budgets, ensuring projects are delivered on time and within budget.
 - Actively manages and mitigates project risks.
- Partner closely with commercial team to assess and to develop client proposals and quotations.
- Medical Device Design Control and Risk Management.
- Prepare documentation in accordance with relevant internal SOPs.
- Author engineering reports and presentations as required to document and communicate results.
- Ensure compliance with regulatory and industry standards (FDA, MDD/MDR, ISO, ASTM, etc.) as appropriate.
- Support sustaining and process engineering efforts during process scale-up and manufacturing improvement initiatives.
- Maintain a safe work environment.
- Other duties as reasonably assigned by the management team.

QUALIFICATIONS

- Minimum bachelor's degree in Material Science, Bioengineering, Chemistry, or related technical discipline.
- 3+ years of medical device and design control experience.
- Minimum 3 years of project management experience, PMP certification is a plus.

KNOWLEDGE & SKILLS

- Thorough understanding of the medical device industry. Working knowledge of other related disciplines.
- Experience in tissue engineering and biomaterials is a plus.
- Ability to travel as needed (<20%) within the US and globally.
- Exceptional organizational, communication (verbal and written) and interpersonal skills.
- Work under minimal supervision.



- Attention to detail, effective problem solving and decision-making skills.
- Knowledge of MS project software, Outlook, MS Excel, MS Word, MS PowerPoint.

INTENT AND FUNCTION OF JOB DESCRIPTIONS

Job descriptions assist organizations in ensuring that the hiring process is fairly administered and that qualified employees are selected. They are also essential to an effective appraisal system and related promotion, transfer, layoff, and termination decisions.

All descriptions have been reviewed to ensure that only essential functions and basic duties have been included. Peripheral tasks, only incidentally related to each position, have been excluded. Requirements, skills, and abilities included have been determined to be the minimal standards required to successfully perform the positions. In no instance, however, should the duties, responsibilities, and requirements delineated be interpreted as all-inclusive. Additional functions and requirements may be assigned by supervisors as deemed appropriate.

Job descriptions are not intended as and do not create employment contracts. The organization maintains its status as an atwill employer. Employees can be terminated for any reason not prohibited by law.