

Company: Medical Device Manufacturing  
Job Position: Full time  
Job Location: Fremont, CA

We're seeking a full time Product Development Director.

**Job Summary:**

The Director of Product Development is an experienced person within the medical device industry with extensive knowledge performing their function with the Food & Drug Administration (FDA) Quality System Regulations (QSRs), International Organization of Standardization (ISO) 13485, Medical Device Directive (MDD) 93/42/EEC, and ISO 14971. As a member of the management team, the Director of Product Development participates in defining and executing the overall strategic technology roadmap that will drive the overall business growth in an increasingly competitive medical device environment. The successful candidate will be responsible for building a functional organization that has the capabilities and capacities to meet the business needs. In addition, the candidate will be expected to manage a group of talented professionals, including budget planning, staffing, training, performance evaluation and career development. The Director of Product Development will manage the design and development of new products as well as product changes and enhancements.

**Travel Requirements:**

This position may require 10-20% travel.

**Job Responsibilities:**

- Manage complex medical device development programs from concept through design, validation, clinical trial, product release, as well as sustaining engineering regarding post launch product management.
- Plan, schedule, monitor and complete projects in a timely manner as to contribute and assist in building a robust IP estate.
- Interface with Marketing, Quality, Engineering, Regulatory, Manufacturing, Clinical, outside vendors, partners and physicians to develop the next generation products.
- Manage a team including but not limited to managers, engineers (hardware/software) and technicians.
- Provide technical leadership to engineering staff.
- Coordinate and update staff on goals, objectives and time constraints of projects.
- Identify and establish departmental objectives and established procedure that are measurable such that outcomes can be quantified.
- Identify and ensure area of technical responsibility complies with the most current international technical standards.
- Ensure departmental staff is appropriately trained in current industry technology, US and International requirements and company practices and procedures.
- Take a leadership position in development processes, efficient use of prototyping resources, standards and methodologies, and prioritization of business objectives.
- Implementation engineering best-practices including appropriate tools and processes.

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- Track and evaluate the resource needs and development stage of new products to ensure appropriate characterization and specification development.
  - Prepare and give or facilitate technical reviews and discussions, technology demonstrations, and presentations to company internal or external organizations, teams, or individuals.
  - Prepare and participate in briefings, technical meetings, tactical or strategic planning with other functional areas and/or executive management.
  - Write or review proposals for prospective product development projects and ensure that they are professionally done, contain accurate technical content, costs and time estimates.
  - Constantly strive to build a world class engineering organization focused on technology and product development.

**Qualifications:**

- Minimum of 10 years experience in product development in the medical device industry with a strong background in design control.
- Four-year, accredited degree in Engineering or Physical Sciences.
- Strong leadership skills coupled with an excellent management history with multidisciplinary engineering teams.
- History of partnering with physicians and colleagues to identify unmet clinical needs and working with the engineering team to develop solutions.
- Experience advancing investigation products through research and development to commercialization.
- DOE and statistics methodology experiences are preferred.
- Presentation skills are preferred.
- Knowledge of Risk Management, Software Requirements, Good Manufacturing Practices (GMP) and applicable Quality System Standards.

**Curexo Technology Corporation** offers a fast-paced work environment, very competitive compensation, medical and 401K retirement plan benefits.

We are an equal opportunity employer and encourage diversity.

To apply: Please submit resume and Cover Letter to HR dept

**Company Overview:**

The Company is a pioneer in medical robotics and world leader in image-directed, robotic products for orthopedic applications. The Company's product allows surgeons to pre-operatively plan their surgery in a 3-D virtual space and then execute the surgery in the operating room, exactly as planned.