# Director of Engineering

DesignPlex is specialized in development of electrical and electro-mechanical products for the medical field – specifically in the cardiovascular and neuromodulation areas. Join us to be part of a world class team located in Fort Worth, Texas. This is a fun and exciting time for DesignPlex as we grow and make the newest products in medicine a reality.

If you've spent at least 10 years as a leader in the medical device field, enjoy the challenges and opportunities of growing an entrepreneurial organization, this role is for you!

The person that takes this role will be mission critical for our organization and will be expected to take a leadership role in driving product development. You will lead a team of highly experienced engineers who value integrity, work-life balance, and find true happiness in bringing ideas to life.

**A Day in the life:**

- As the Director of Engineering, your primary responsibility will be to lead the engineering department.
- Mentor and guide the team for successful development and product launch.
- Grow the team through technical development of existing team and hiring new team members.
- Lead the creation of the Design History File to meet FDA and EU requirements.
- Design and develop text fixtures and apparatus for testing sub assemblies and final assemblies of developed products.
- Review CAD models, drawings, schematics, and integration of mechanical and electrical systems.
- Coordinate with electrical team for mechanical fit and functionality of electronics with the mechanical design.
- Lead risk analysis to ISO 14971
- Develop product/component requirements, source components and work with quality to develop incoming inspection requirements.
- Ensure that DHFs are accurate, complete and well organized.
- Lead and participate in concept generation activities, including brainstorming sessions. Refine, rate, rank and/or otherwise assess concepts.
- Manage development projects. Prepare project plans that specify project phases, tasks, task interdependencies, durations, resource assignments, and costs. Proactively communicate task assignments to responsible individuals and ensure that tasks are completed within the planned time. Track projects to project plans. Proactively report project status to personnel and to the project's client company daily via phone calls and Smartsheet an online project management software.
- Prepare budgets and quotes for new projects and track current project actuals against budget.
- Proactively communicate with client companies to ensure an ongoing two-way exchange of information.
- Verify the functionality of product design by developing design test methodology and specifications to ensure product designs meet applicable performance requirements.

**Required:**

- **Minimum Master's degree, PhD preferred, in Engineering is required.**
- **Minimum of 10 years of Class 3, AIMD, medical device product design** and development experience is required.
- Experience in leading a team of engineers.
- Must have strong working knowledge of 60601-1, 60601-1-2, 60601-1-6, 60601-1-8, 60601-1-11, IPC 610, EN 45502 and verification testing needed for approval of a medical device.
- Knowledge and practical experience with integration of mechanical design and electronics including PCBs, cabling, connectors, batteries, battery charging, power supplies and development of testing apparatus.
- Deep knowledge of manufacturing techniques and how to transition a model/assembly into physical components including machining, injection molding, sheet metal and assembly techniques.
- Ability to prepare requirements documentation, risk analysis per ISO 14971, and formalize the development plan, schedule and resources.
- Ability to lead a team of engineers and integrate mechanical and electronic elements into the product design.
- Ability to contract outside engineering, manufacturing and other required services.
- Demonstrated ability to bring products from concept to market with target budget and timeframe.
- Practical experience in sourcing required services or components.
- Familiarity with FDA QSR and ISO 13485 medical device regulations.
- Depth of knowledge in one or more clinical areas;  cardiovascular or neuromodulation
- Flexibility, persistence, resourcefulness, a drive to succeed, and an entrepreneurial spirit.

The above statements are intended to describe the general nature and level of work being performed by employees assigned to this position, but they are not an exhaustive list of all the required responsibilities and skills of this position.

Salary commensurate with experience.

This job is located in Fort Worth, Texas.