**Date Prepared: October 20, 2014**

**Job Title: Project Engineer**

**Location: 888 E. Belvidere Road, Suite 212**

 **Grayslake, Illinois 60030**

**Status: Full time**

**Position Summary:**

This position is responsible for managing and technical review for new product development projects. This includes, but is not limited to activities related to project management, design history file development, technical review and writing.

**Reporting Structure:**

Reports to Manager, Manufacturing Operations

**Direct Reports:**

N/A

**Major Responsibilities:**

* **Design Control**:
	+ Responsible for the project management of new product development
	+ Responsible for the creation of Design History Files (DHF)
	+ Responsible for the creation of Technical Files
	+ Responsible for the development of Risk Management files
* **Manufacturing:**
	+ Development of manufacturing documentation development
	+ Technical review / approval for product design documentation, product and process verification / validation protocols, design changes, risk management files, and DCNs

**Secondary Responsibilities:**

* Perform special tasks per request of the Manager, Manufacturing Operations

**Experience & Skills:**

* A minimum of 2 years experience in the medical device industry desired.
* Excellent organizational skills and ability to multitask
* Experience with medical device product development process and associated documentation: (Design History Files, Technical Files, Risk Management Files).