POSITION DESCRIPTION

Job Title	Process Quality Engineer Supervisor	**Reports To**	Quality Leader
Department	Quality Assurance	**Location**	Gurnee, IL

GENERAL SUMMARY

The Process Quality Engineer Supervisor is responsible for the Quality Assurance and aspects of the Quality Management System. The Quality Engineering teams include:

- Product design controls (e.g., development of the Design History File (DHF) and the Device Master Record (DMR)) and
- Process controls (e.g., transfer-to-manufacturing, process validation).

The team drives process and system development to support daily operations and production. Note: The Quality Control team supports day-to-day production and verification of Device History Records (DHR).

KEY RESPONSIBILITIES *(Include but not limited to)*

- Responsible for providing both strategic and day to day leadership for the promotion of a "Culture of Quality" establishing and maintaining a high degree of quality awareness and continuous improvement throughout the organization.
- Leads the company's efforts for GMP including their implementation and auditing to ensure the company is always compliant and continually improving.
- Manages and leads a team and ensures that all direct reports are familiar with, trained on and follow all Quality System procedures related to their jobs.
- Sets clear quality standards and works closely and collaboratively with the organization and customers to ensure incoming parts and components meet and/or exceed expectations.
- Success and results driven; ask's "what else can I do" to move a process along thoroughly and quickly. Equally comfortable with "the way we do things" as well as promoting new ideas.

REQUIREMENTS FOR THIS POSITION

I. Professional Experience

- 2-3 years of progressive Quality experience in various sized medical device organizations.
- Preferred experience with direct reports
- Working knowledge of ISO13485
- Lead Auditor / Medical Device Auditing an advantage.
- Lean Six Sigma training a distinct advantage.

II. **Education**
- Bachelor's Degree Required (Life Sciences, Engineering or Business)
- Master's Degree a plus

III. **Language**
- English
- Spanish a plus

IV. **Travel (estimated % of time)**
- Domestic approximately 5%

PERSONAL TRAIT PROFILE

- Experience with implementation of a Quality Management System or management of a transformation of a quality management system.
- Excellent communication skills, both verbal and written, and the ability to interface effectively with internal departments; engineering, manufacturing, sales and marketing, administration and external customers and suppliers.
- Excellent at moving from conceptual, analytical, and problem solving, to execution and deliverables.
- A "hands-on" highly accountable individual who enjoys challenge and is capable and dedicated to getting the job done.
- A proactive, results driven leader with a positive "can do" attitude and a sense of urgency to getting things done.
- Well-organized, detail oriented and accustomed to maintaining excellent records.

KEY RELATIONSHIPS

a. **Internal**
- Reports directly to Quality Leader
- Direct Reports include:
  - Quality Production Leads
  - Quality Production Testers
- Manufacturing and Engineering Associates

b. **External**
- Customers
- Auditor

This job description in no way states or implies that these are the only duties to be performed by this employee. The incumbent is expected to perform other duties necessary for the effective operation of the department or unit. This job description may be changed at any time.

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