

Position Title: NPI Project Manager
Functional Group: New Product Introduction
Report To: VP of New Product Introduction (NPI)
Status: Exempt

PURPOSE OF POSITION: The NPI Project Manager position will be responsible for managing both new projects under development and directing the transfer of new products into manufacturing by working with all functional groups within a team environment. The position will complete assigned projects as required for New Product Introduction, Quality Assurance, and Production/Materials functional groups.

MAJOR DUTIES AND RESPONSIBILITIES:

QUALITY ASSURANCE

- Support Prospect goals and objectives, policies and procedures including maintenance of Good Manufacturing Practices, US and EU regulatory compliance.
- Support the timely processing of complaints, nonconformity, returned goods, corrective and preventive action (CAPA) activities.

NEW PRODUCT (INTRODUCTION)

- Direct the design development activities; prototype design/fabrication, design changes, design files.
- Direct the development of documentation for design verification and validation activities.
- Direct new product stage gate process; project plan, schedule, budget, phase design reviews.
- Direct the selection and management of third-party test labs.
- Direct the training of NPI engineers and technicians.
- Support the execution of design verification and validation; test plans, test protocols, test reports.
- Support the establishment of the Design History File for each NPI project, as required.

NEW PRODUCT (TRANSFER)

- Direct the development of device master record activities; specifications, manufacture process instruction, in-process test methods, lot history records.
- Direct the development of documentation for process validation (IQ/OQ/PQ) activities.
- Direct the establishment of equipment files; specifications, calibration, preventative maintenance.
- Support the establishment of suppliers; selection, approval, management requirements.
- Support the setup of new product bill of materials into Prospect ERP system.
- Support the assembly training of Production assembler(s).
- Support Client (customer) Service; communication, relationships at all levels, team meeting.
- Support the manufacturing line layout; design, specifications, equipment, tools, personnel requirements.
- Support procurement; component/equipment specifications, ordering, quoting, supplier research.

EDUCATION / EXPERIENCE REQUIREMENTS:

- Minimum Requirements: BSEE, BSME or related degree
- Minimum of eight (8) years medical device product development and/or medical manufacturing environment experience.

OTHER QUALIFICATIONS:

- Experience working within medical device quality systems including Quality System Regulation (QSR) and ISO 13485:2016 desirable.
- Must be detail oriented, and an effective communicator.
- Good interpersonal skills; verbal and non-verbal communication, listening, problem-solving, decision-making, assertiveness.
- Good technical writing skills.
- Strong computer skills, including Word and Excel
- Experience with ERP systems
- Detail-oriented and strong organization skills

Associate Signature

Date Reviewed

Management Signature

Date Reviewed