

Director of Operations

PURPOSE OF JOB:

Directs and coordinates activities of manufacturing engineering department to achieve timely goals. Develops and coordinates the design, manufacture, testing, and validation for new or existing products personally or through subordinates. Proposes and executes broad product, process, and cost improvement projects requiring participation from multiple departments within the organization.

MAJOR DUTIES AND RESPONSIBILITIES:

- Establish and maintain a manufacturing facility which is QSR/MDD compliant.
- Hire, train, and manage engineers, technicians, supervisors, assemblers, leads, and other designated manufacturing staff.
- Participate in the creation and improvement of manufacturing processes for new products, product changes and enhancements, and related tooling and fixturing.
- Create and maintain production schedules which are consistent with Ardian goals and objectives.
- Participate in facilities engineering and planning as needed.
- Work with research and development staff to ensure that products under development are optimally manufactured.
- Lead and actively manage process validation, shelf life testing, etc. and continuously identify and implement process improvements.
- Procure and oversee outside suppliers and consultants as required.
- Develop and maintain departmental budget.
- Participate in the development and continuous improvement of manufacturing processes consistent with high quality and low product costs.
- Assist in the development of QSR/MDD systems in coordination with the Document Control, R&D, and Quality Assurance functions.
- Complete accurate and timely manufacturing documentation including manufacturing procedures, material records, employee reviews, etc.
- Document concepts, design, and processes in a manner that provides an accurate and complete intellectual property record for the company.
- Provide feedback to management regarding product status as well as other critical issues which affect the attainment of schedules or product quality.
- Facilitate regular line meetings.
- Support company goals and objectives, policies and ISO/MDD requirements, the Quality System Regulation, and other regulatory requirements.
- Fully embody & actively promote Ardian's Core Principles & Quality Policy.

EXPERIENCE REQUIREMENTS:

- 10+ years medical device industry experience.
- Director of Operations experience in a medical device company.
- Prior experience working with medical device catheters required.
- Design and development engineering in manufacturing or operations required.
- Experience with process improvements, assembly operations, tools design, ISO 9000, process capability design, and project management are required.

EDUCATION REQUIREMENTS:

- BS or MS in engineering

OTHER QUALIFICATIONS:

- Introductory knowledge of the medical device industry is required.
- Knowledge of GMP, FDA regulations, and LEAN manufacturing preferred.
- Introductory knowledge of Quality System standards & regulations & Quality Assurance.
- Ability to perform word processing & create spreadsheets.
- Values consistent with Ardian's Core Principles.