

Operations Leader

Summary:

The Operations Leader is responsible for assuring that production/process and purchasing controls have been established and maintained to provide quality products and assist in the attainment of sales forecasts and profit projections. The Operations Leader works with the Management Team to assure compliance to customer requirements, external standards, and internal specifications/procedures.

Responsibilities:

- Leads the development of medical packaging processes
- Manages direct reports within the Operations Department (Supply Chain Coordinator, Operations Specialist)
- Provides input into Management Review and participates in meetings
- Participates in quality planning and the establishment of quality objectives
- Assures personnel are trained on relevant procedures, work instructions, and quality records (e.g. DHRs).
- Member of document Change Control Board which conducts the analysis & approval of document change requests
- Develops specifications pertaining to production and process controls
- Manages the purchasing process
- Responsible for the development of equipment installation/qualifications and validation protocols and the execution of these protocols
- Ensures that production schedules are consistently met to minimize backorders
- Manages production workflow and provides detailed capacity analysis planning
- Develops plans for efficient use of materials, machines, and personnel
- Reviews work order variances and develops plans to improve production costs and product quality
- Fosters a culture of continuous improvement of pre-packaging, assembly, labeling, and packaging methods
- Manages stock levels including components, in-process, and finished goods
- Ensures components/products are properly handled & stored in warehouse locations and production areas
- Ensures production personnel are trained on equipment work instructions & requirements contained in DHR
- Member of Material Review Board (MRB) conducting the analysis and disposition of nonconforming product
- Maintains departmental metrics to ensure business operations are efficient
- Utilizes structured problem solving techniques and lean principles to drive continuous improvement
- Manages preventive maintenance and calibration processes
- Contributes to the annual capital and headcount budgetary process
- Manages EHS program for company
- Follows established safety requirements and adheres to Fenner Framework HSE Management System.
- Performs other job related responsibilities as assigned.

Qualifications:

- 10 years' experience in class II or Class III medical device manufacturing
- 5 years' operations management or leadership experience
- 2 years' of medical packaging and labeling experience
- Bachelor's degree in (Biomedical Engineering, Materials Engineering) or related discipline
- Considerable knowledge of ISO 13485 and 21 CFR Part 820 requirements
- Ability to write procedures, protocols, and reports
- Experience in technical writing and use of statistical tools
- Experience in pFMEA, DOE, and process validations.
- Proficient with MS Excel, MS Word and MS PowerPoint

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