

Position Title: Director of Operations
Functional Group: Production, Materials, Manufacturing Engineering
Report To: CEO/President
Status: Exempt

PURPOSE OF POSITION: The Director of Operations will oversee production planning, material control, purchasing, equipment purchases and maintenance, facility layout and maintenance, engineering of manufacturing processes, resource management including hiring, allocation and termination.

MAJOR DUTIES AND RESPONSIBILITIES (not an all-inclusive list and subject to change):

- Communicate objectives and direct manufacturing engineering, material control, production, and warehouse activities to achieve company objectives for Clients.
- Ensure that Client finished products are of high quality, compliant to requirements, and available as required by Clients.
- Anticipate the need for changes within the operations areas and implement those changes.
- Identify contractors, equipment, technologies, and new processes to use in growing and developing operation capacity and capabilities.
- Provide purchasing planning and control of information to support production schedule through company ERP system.
- Manage and approve company suppliers which includes supplier selection, supplier audits, supplier performance assessments, and supplier improvement initiatives.
- Hire, train, motivate, and develop staff in assigned Functional Group(s).
- Participate and support company management reviews by collecting, analyzing, and summarizing data and trends.
- Support incoming inspection to resolve delivery and quality issues.
- Support Risk Management activities per EN ISO 14971 for the Client products, which may include process Failure Mode and Effects Analyses or other risk management tools.
- Support quality assurance activities to comply with regulations and standards; US FDA Quality System Regulation and EN ISO 13485.

EDUCATION / EXPERIENCE REQUIREMENTS:

- Minimum BSEE or BSME, preferred additional master's degree in business administration.
- Minimum of 12 years' experience in medical device industry.
- Working knowledge of Quality Systems pertaining to medical device development and manufacturing.

OTHER QUALIFICATIONS:

- Strong leadership, managerial and teamwork skills, including organizational abilities, project management, problem-solving, written and verbal communications.
- Skill in examining and re-engineering operations and procedures.
- Excellent communications, personnel management, and time management skills required.
- Ability to motivate teams and simultaneously manage several projects.

Associate Signature

Date Reviewed

Management Signature

Date Reviewed