



Job Title: Sr. Director, Operations
Department: Manufacturing Operations, Coating Services Business Unit (CBSU)
Reports To: President & CEO
Direct Reports: Yes
FLSA Exempt: Exempt
Approved by:

Approved Date:

Job Summary

The Sr. Director of Operations is responsible for strategic planning, business plan deployment and operational excellence to meet our customers' needs. This position has responsibility for leading and developing the Coating Services Business Unit (CSBU) from the ground up. The scope of CSBU includes coating of medical devices with Biocoat's hydrophilic coatings under cGMP and ISO 13485 guidelines. He/ She will lead by establishing a culture of true continuous improvement environment and driving a high-performance culture based on honesty, integrity and respect.

Job Duties

- Serve as a key member of the executive team that sets the company's strategic direction.
- Accountable for business metrics – on-time delivery of customer materials, safety, quality, delivery, productivity, material variances, coaching and training of direct reports, inventory, as well as assuring personnel growth and development.
- Responsible for the overall manufacturing and supply chain inclusive of materials management, production, manufacturing engineering, receipt, tracking of materials and shipping.
- Plans and directs manufacturing activities across CSBU ensuring the effective use of material, equipment and personnel. Reviews and analyzes receipt, product tracing and tracking through process, manufacturing methods, systems and procedures to assure performance which meets or exceeds regulatory requirements such as cGMP's/ISO.
- Leads lean transformation activities and business process improvements.
- Responsible for operating the business unit under cGMP and ISO 13485 guidelines. Leads cross-functionally with QA/RA to address Non-conformances, customer complaints, supplier corrective action requests (SCARs) and corrective and preventive actions (CAPAs).
- Develops and implements operating methods and procedures designed to reduce or eliminate waste. Maintains continuous improvement process and champions lean six sigma initiatives. Facilitates structured, cross functional CIP project reviews.
- Responsible for leading increased production targets, and cost reduction related to achieving Annual Operating Plan and 3-Year Plan profitability targets.
- Assists in preparation of annual departmental budgets and provides input regarding functional objectives for annual operating plan.
- Provides recommendations to leadership team in selecting floor level and professional staff incentive metrics that provide organizational alignment with Biocoat objectives and goals.
- Provides manufacturing expertise in development of new CSBU sites and for accepting of new product assignments.
- Works closely with product engineering to design and develop machinery for maximum throughput at the highest level of quality/value.
- Collaborates with Business Development and Supply Chain to develop relationships with customers and our supply base.
- Responsible for developing strong leaders and hiring outstanding talent to support business growth.
- Responsible for establishing CBSU in Horsham, Pa, as well as future domestic and global locations including Europe and Asia.
- Domestic and international travel required.
- Other duties as assigned.

Impact

- Input to Operations/Manufacturing budget.
- Ensure cost containment levels are maintained.
- Design processes for streamlining work.
- Analyze potential areas for savings or efficiencies.

Independent Judgment

- Overall accountability and ownership of development, direction, coordination, and evaluation of direct labor and support employees in Manufacturing Operations.
- Recommend which projects are priority relative to company goals.
- Determine best in class frameworks, systems and processes.

Analysis/Problem Solving

- Ability to define problems, collect data, establish facts, and draw valid conclusions and take actions.
- Ability to develop and set up 'best in class' bar code scanning operations to receive, process and ship materials for entire business enterprise, as well as for CSBU.
- Ability to interpret an extensive variety of technical instructions in mathematical or diagram form and deal with several abstract and concrete variables.
- Ability to apply mathematical operations to such tasks as frequency distribution, determination of test reliability and validity, analysis of variance, correlation techniques, sampling theory, and factor analysis.

Communication

- Ability to respond to common inquiries or complaints from customers, regulatory agencies, or members of the business community.
- Ability to effectively present information to top management, public groups, and/or boards of directors.

Skills/Technical Skills

- Communication, process design & improvement, teamwork, delegation, motivation, judgment, quality focus, cost conscious, diversity, ethics, strategic thinking, innovation, safety, planning/organizational, and professional skills.
- Relationship building skills
- Working knowledge of cGMP and ISO standards.
- Working knowledge of traditional PC based software such as Microsoft Office.
- Requires an above average people skills ability and placing the customers needs on a high priority.

Knowledge

- Understands medical device manufacturing regulations.
- Knowledge of medical device manufacturer, chain of custody tracking methods, and supplies knowledge preferred.
- World-class manufacturing knowledge preferred.

Physical Requirements

- While performing the duties of this job, the employee is occasionally required to stand; walk; sit; use hands to finger, handle, or feel; and reach with hands and arms and talk or hear. Specific vision abilities required by this job include close vision, distance vision, color vision, peripheral vision, depth perception, and ability to adjust focus.

Education

- B.S. Engineering or Business Degree
- Master's Degree (M.A.) preferred

Experience

- 10-15 years related experience and/or training; including a minimum of 5 years in a leadership role.