



Director of Manufacturing

About Leuko - www.leuko.com | careers@leuko.com

Leuko is an MIT spin-out developing PointCheck™, the world's first non-invasive white blood cell monitoring device. White blood cell assessment is a first-line indicator for multiple medically relevant situations, ranging from cancer chemotherapy management to the detection of life-threatening infections worldwide. Leuko is re-imagining the way to perform these tests without extracting blood and in a portable device. Leuko's vision is to empower patients and their loved ones, and make their lives better and safer by providing them with broad and immediate access to blood testing. Our groundbreaking technology has been awarded multiple awards including 1st prize at MassChallenge HealthTech and M2D2 Medical Device competitions. Leuko is a VC-backed (Series A) company and the recipient of a number of grants including a prestigious SBIR award from the National Cancer Institute.

Role Summary:

The Director of Manufacturing is a key role responsible for all facets of manufacturing, including elements of design transfer. Responsibilities include leading the organization to execute manufacturing operating plan milestones during the current high growth phase. This position is responsible for productivity innovations, product quality, stability of processes, and compliance with relevant regulatory standards. The overall responsibility is to lead the creation and execution of manufacturing strategies, long-range capacity planning, cost improvement, inventory management, and the building of future talent.

Job Responsibilities:

- Lead, plan and direct PointCheck™ product manufacturing transfer activities.
- Hands-on hardware engineering (CAD / prototyping) to refine the product for manufacturing transfer.
- Define and execute manufacturing strategy, aligned with regulatory requirements and company objectives.
- Develop strategic partnerships with medical device contract manufacturers and distributors.
- Provide vision, strategy and leadership across key engineering and product development functions including disposables, new product development, and manufacturing operations.
- Use of metrics with budgets, quality, product availability, cost of goods, safety.
- Implement Lean, Six Sigma, & Validation initiatives to support key business objectives.
- Achieve continuous improvements in assembly, processes, capacity and cost profile.
- Talent management, mentoring and developing staff and adding key hires as required.
- Identify current and future capabilities required to support long-term growth plans.

Job Requirements:

- Bachelor's or Master's degree in Engineering, or Operations Management required.
- Advanced prototyping, CAD (SolidWorks, etc.) and design review skills.
- Strong network of operations and manufacturing contacts across the healthcare industry.
- Experience in or previous work with medical device or healthcare-related companies.
- 10+ years of experience in a medical device manufacturing management position.
- Entrepreneurial experience, including closing of manufacturing and distribution deals for medical devices.
- Proven track record of success in closing partnership deals in the medical device industry.
- Expert knowledge and understanding of compliance regulations that apply to Quality, Regulatory Compliance (21 CFR Part 11), Environmental Health and Safety, as well as knowledge of standards related to equipment design and implementation into global medical device manufacturing.
- In-depth knowledge of the medical device industry, particularly in the areas of patient monitoring solutions and cancer patient care.
- Thorough understanding of the various types of partnership agreements, including OEM, distribution and strategic alliance.
- Excellent written, interpersonal, and presentation skills. Ability to interact with all levels of internal and external customers.
- In-person position at Boston office. Ability to travel nationally and internationally, as needed.

Additional Skills and Competencies Required:

- Proven ability to evaluate manufacturing processes and automation technologies and develop strategies for application of these systems adding high value to the business.
- Ability to work and excel within a fast-paced, dynamic, and constantly changing work environment.
- Strong ability to communicate complex matters effectively and in a succinct and organized manner.
- Demonstrated ability to effectively work across various functions and ensure deliverables against timelines.
- Ability to prioritize tasks in real time and exercise judgment in a high-stakes environment.
- Ability to quickly establish credibility, trust and support with both internal and external constituents.
- Demonstrated ability to hire, develop, and manage employees.
- Strong quantitative, modeling and negotiations skills and experience.
- Demonstrated strong time management and project management skills.
- Ability to interface effectively with all levels and functions both inside and outside of the organization.
- Self-motivated, and results oriented with the entrepreneurial spirit needed to excel in a small-company.

Equality and Diversity Policy:

Leuko is an Equal Opportunity Employer and our employees are people with different strengths, experiences and backgrounds, who share a passion for improving people's lives. Diversity not only includes race and gender identity, but also age, disability status, veteran status, sexual orientation, religion and many other parts of one's identity. All of our employee's points of view are key to our success, and inclusion is everyone's responsibility.