

# MANUFACTURING ENGINEER

We are a manufacturer of orthopedic components/materials manufactured to high specifications for the medical industry. Our main focus is to supply high quality medical products to exacting customer and international specifications, supported by our technical department which is capable of testing polymeric materials to the highest standards. We are looking for a highly motivated individual to join our Technical Department.

### **KEY ACCOUNTABLE AREAS:**

- Adheres to Orthoplastics Core Values and all safety and quality requirements including, but not limited to: Quality
  Management Systems (QMS), Environmental Management Systems (EMS), U.S. Food and Drug Administration (FDA)
  regulations, company policies and operating procedures, and other regulatory requirements.
- Develops and Executes Process and Test Method Validations (IQ,OQ,PQ,PPQ) in accordance with Orthoplastics Medical's procedures and guidelines.
- Prepares or reviews documentation with a high degree of accuracy, completeness, and effectiveness using common engineering tools and templates.
- Creates and implements lean processes in a cellular environment utilizing appropriate methods such as machining, welding, Finishing, Cleaning, Assembly, and Inspection.
- Communicates ideas, information, and recommendations clearly, effectively and frequently within Orthoplastics, with outside suppliers or partners and with Orthoplastics customers during formal and informal interactions.
- Assists Quality with the execution of CAPAs pertaining to their areas of responsibility, including detailed Root Cause investigations and corrective/preventative actions.
- Defines, produces and implements documents including standard operating procedures and process work instructions.
- Creates, reviews and approves engineering drawings, equipment layouts, change orders and specifications.
- Uses structured Quality tools and techniques including statistical methods for data driven analysis and decisions, Appling DMAIC-Six Sigma approaches to solve issues and reduce variation in all manufacturing and business process.
- Develops tooling, fixtures and equipment used in manufacturing to optimize productivity and cost.
- Creates, schedules, conducts and/or coordinates detailed project plans for engineering work.
- Plans and executes project activities within a cross functional team. Project types can include new product development and introduction, manufacturing transfers, continuous improvement and cost reduction initiatives.
- Investigates, develops and implements new process technologies using Lean Manufacturing techniques to continuously improve cycle times and process flows.
- Collaborates with development, programmers, machinist and suppliers to evaluate designs for manufacturability and cost reduction.
- Demonstrates leadership through mentoring of peers and responsiveness to business needs to achieve positive results.
- Ensure internal Orthoplastics and external customer expectations are met or exceeded.
- Creates and executes validation protocols, processes and material evaluations.
- Supports maintenance team as needed to troubleshoot equipment issues.
- Drives Operational Excellence (OPEX) initiatives to improve efficiency, reduce waste, and enhance overall
  performance.
- Liaises with customers as required on complaints, process improvement activities and change management initiatives

## THIS EXCITING POSITION REQUIRES A PERSON WHO HAS:

- Close vision, distance vision, colour vision, etc. to inspect parts, blue prints
- Statistical knowledge and understanding of CNC machining principles is preferred
- Demonstrated proficiency in Solid Works and Minitab
- Knowledge of PLC programming
- Good problem-solving skills
- Strong written and oral communication skills
- Ability to work in a team environment



Must be able to work with minimum supervision

# REQUIRED QUALIFICATIONS/KNOWLEDGE:

- Engineering or Bachelor's degree in a technical field
- Proficient in Microsoft office suite (Word, Excel, Outlook)
- Six Sigma trained to Green or Black belt would be advantageous
- Experience with Operational Excellence (OPEX) tools and methodologies such as Kaizen, 5S, Value Stream Mapping, and Continuous Improvement
- Lean manufacturing and new product development or launch support experience is highly desirable
- Experience in medical devices preferred
- 3-5 years of experience in regulated industry

### **HOURS OF EMPLOYMENT**

Duties and hours may vary dependent upon workload

Please forward your CV and salary expectations to Tandy Kehoe, HR Business Partner via E-mail: <a href="mailto:kehoe@orthoplastics.com">kehoe@orthoplastics.com</a>.

We will be reviewing all applications on an ongoing basis and candidates may be asked to attend an interview whilst the vacancy is "live".