Title: **Operations Engineer**
Department: **Advanced Engineering**
Travel requirement: **Up to 30%**

Job Summary

The Onkos Operations Engineer is responsible for the mid and late stage development and implementation of new technologies, products, product improvements and value engineering to existing product lines through the use of scientific, engineering and manufacturing principles and internal customer input to achieve the project deliverables (ex. quality, cost, and delivery). The Operations Engineer leads the planning, creation and execution of statistically driven Design Verification testing of new technologies, and Designs of Experiment in both the Development and Process Validation phases of a program or project. They also lead the implementation and execution of the final Process Validations of new processes. In addition, the Operations Engineer supports FDA submission requirements, develops and implements testing procedures, supports and develops quality systems as they relate to manufacturing efforts and R&D, conducts product remediation exercises, root cause and engineering analyses, and works with R&D on design for manufacturability, quality testing, and inspection.

Responsibilities

- Ensures work output is compliant with all current regulatory and quality standards.
- Completes all required training in timely fashion.
- Works with multidisciplinary project teams to develop, implement, complete and facilitate the following for the launch of safe and effective technologies and products:
  - Design and development of working prototypes through manufacturing equivalent final products
  - Design for manufacturability
  - Designs of Experiment
  - Statistical process analysis
  - Design Verification testing
  - Internal / external communications with 3rd party vendors
  - Performance analyses of prototypes and final products
  - Performs and applies essential engineering and manufacturing rigor to all development of products and processes, such as;
    - Equipment Installation, Operational Qualifications
    - Materials performance, intended use, environment, cleanability, sterilization techniques
    - Material and chemical processing techniques
    - Risk analysis via FMEA.
- Performs and advises on equipment design and procurement
- Conducts Process Validations including Operational and Process Qualifications
- Conducts functional and performance testing of technologies
- Generates process quality requirements
- Creates Standard Operating Procedures and Material Specifications
- Generates Regulatory related documentation and testing protocols.
- Generates cleaning and sterility testing and documentation requirements

- Prepare comprehensive project timelines with technical objectives, milestones (timing, resource requirements, costs, etc.).
- Comply with Design Control and Stage Gate processes while testing prototypes and products.
- Assist manufacturing engineers in developing innovative manufacturing and processing techniques and/or seek out new technologies for materials and processing through 3rd party relationships.

Requirements

- A minimum of three years of successful advanced technology manufacturing or manufacturing scale-up accomplishments in the medical device filed, preferably orthopedic medical device development.
- Minimum of BS degree in scientific discipline, materials, chemical, biomedical, or other engineering science.
- Ability to apply analytical skills, in solving engineering problems and developing new technologies
- Demonstrated knowledge of statistically driven Designs of Experiment.
- Demonstrated knowledge of process scale-up and Process Validations.
- Demonstrated computer skills including spreadsheets, word processing, database and other applicable software programs.
- Excellent interpersonal skills; self-motivated and flexible to changing schedules.
- Strong attention to detail, good oral and written communication skills