

The Senior Manufacturing Development Engineer will ensure that plastic consumables for the Savanna molecular platform are designed for manufacturability and can be successfully transferred from R&D to manufacturing. This position is also responsible for manufacturing process development, implementing pilot and high-volume production lines, and sustaining manufacturing per operational requirements

This is a cross-functional role that will manage contract service providers to support production line implementation and will provide technical assistance to others as needed related to manufacturing capabilities. This role is also required to demonstrate a heightened sense of urgency in resolving matters related to manufacturing and contribute positively in a fast-paced operations environment.

#### ESSENTIAL FUNCTIONS:

- Participate in product design efforts to ensure that design for manufacturability is incorporated into platform consumables and that selected raw materials are compatible with proposed manufacturing processes.
- Define manufacturing specifications and collaborate with contract service providers to develop manufacturing processes, define process specifications, and demonstrate process feasibility using prototype equipment.
- Generate manufacturing specifications to support production line implementation and scale-up.
- Develop scale-up strategies that leverage manual, semi-manual and fully automated equipment designs. Ensure equipment designs incorporate systems to ensure product quality.
- Collaborate with Operations management to identify, secure and sustain contract manufacturers for high-volume manufacturing of consumables. Generate work packages including product specifications, drawings, production and facility requirements to support request for quotes, scope of work and other contract documentation.
- Develop and lead initiatives to achieve manufacturing cost objectives including optimization strategies for production yield, material and labor usage, and implementation of factory metrics.
- Carries out duties in compliance with established business policies.

#### Education and Experience

- B.S. in Mechanical or Manufacturing Engineering- required
- 8+ years' experience in Medical Device high-volume manufacturing- required
- Minimum 3 years' experience in New Product introductions- required

#### Knowledge/Skills

- Must be able to resolve moderately complex technical problems independently and progressively gain the skills to solve complex problems with minimum supervision.
- Must have a thorough understanding of machine function, electro-mechanical and controls.
- Knowledge and ability to use computer applications that include Solid Works, MS Word, Excel and Project. May include Lab View and statistical analysis software
- Must be organized, detail oriented, and have strong verbal and written communication skills
- Must take a proactive approach to the performance of job assignments with minimal input from supervision. This position requires decision making to a level that can affect overall manufacturing efficiency, which may impact direct cost margins
- Basic knowledge of regulations governing medical device assembly and design.
- Must have experience with validations, technical writing, Six Sigma, 5S, OEE and DOE
- Must have knowledge of mechanical design and plastic injection molding.

Interested parties should send their resume to: [joshciardelli@peaktechnical.com](mailto:joshciardelli@peaktechnical.com)