JOB DESCRIPTION: EXEMPT	DATE:
Title: Principal Manufacturing Engineer	**Reports to:** Director of Operations

POSITION SUMMARY

This role is responsible for the following areas: In-house and contracted manufacturing, Process Development, New Product Introduction, equipment and process controls/qualification, and ensuring all activities follow GMP guidance and are compliant to the Inquis Quality Management System. This position will ensure that projects/products/processes are designed to facilitate manufacturability and will be responsible for technology transfer to manufacturing and scalability. The Principal Manufacturing Engineer will be a key contributor on Inquis' Manufacturing team, developing thrombectomy medical devices. We are seeking a Principal Manufacturing and Process Engineer with Medical Device Experience to support our new products. This individual must have a comprehensive understanding of the manufacturing operations and have a desire to provide equipment, fixturing, and process parameter solutions. Act as Manufacturing Technical Leader (SME) for new products, key contributor for Process Development activities. Main interface between R&D, Pilot/Commercial manufacturing line: act as a liaison between R&D, Supplier, Quality, and Operations team. This individual must have a proven track record for scaling production for a catheter based medical device from early clinical to commercial launch. A successful candidate will take the initiative, display a positive attitude, and have exceptional communication skills.

ROLES AND RESPONSIBILITIES

- Support operational transitions through development, clinical, and commercialization phases and ensure completion of Design Transfer and New Product Introduction (NPI)
- Support as Subject Matter Expert (SME) for Pilot/Production Line equipment and process status for new products processes
- Responsible for manufacturing process development, implementation, and continuous improvement to enhance yield, reduce cost, and improve productivity
- Responsible for performing manufacturing processes validation and equipment validation. This includes developing preparing master validation plans, drafting protocols, analyzing test results, and drafting/routing technical reports.
- Own Design Transfer Phase Activities: Evaluate current catheter manufacturing practices and Lead manufacturing to increase production capacity and implement new efficient processes.
- Initiate and lead lean manufacturing process improvement projects
- Initiate, Review, and Approve Document Change Orders
- Communicating with cross-functional internal team as well as Vendors, Suppliers, and Contract MFGs for purchasing and getting supports, etc.
- Support R&D Pilot/Production Line Support and Engineering
- Create/Own manufacturing documentation MPI, DMR, FMEA, & Protocols/Reports (IQ/OQ/PQ)
- Deploy manufacturing risk assessment and mitigations, including hands on and resourceful action plans
- Responsible for part/drawing release, and accuracy of the Bill of Materials (BOM).
- Drawing (SolidWorks) skills to design fixture and tooling to assist with manufacturing needs and process improvements
- Review engineering product specifications, CAD data/drawing, as part of design review process to ensure they meet industry and manufacturing standards and practices.
- Ensure DFM, Six Sigma, and LEAN considerations are incorporated into product and process designs.

- Mentor Junior Engineers and train Engineers/Techs/Assemblers and other associates as needed
- Collaborate with cross functional teams including QA, RD, Mfg., Marketing, and CA

REQUIRED EDUCATION/TRAINING and/or EXPERIENCE

- Bachelor's Degree or Master's degree in Biomedical, Mechanical, or Industrial Engineering or a related Engineering field
- Required: BS 8+ years or MS 6+ years of Manufacturing and Process Development experience (at least 6 years of it in relevant experience as job description in medical device industry)
- Required: BS 8+ years or MS 6+ years of Manufacturing and Process Development experience (at least 6 years of it in relevant experience as job description in medical device industry)
- Track record for New Product Introductions of medical devices scaling from clinical manufacturing to commercialization
- Experience with manufacturing catheter or intravascular delivery systems utilizing large bore reinforced shafts (12F+)
- Familiarity with FDA regulations and ISO quality standards
- Demonstrated experience leading devices from concept to launch
- Experience in manufacturing and controlling sterile product
- Experience in manufacturing catheter and delivery systems
- Experience with procuring and working with braid, coiled, and laser cut hypotube reinforced polymeric shafts.
- Excellent verbal and written communication skills

KNOWLEDGE, SKILLS AND ABILITIES

- Ability to solve problems and innovate solutions
- Ability to manage project timelines to execute deliverables in a timely manner
- Knowledge of and experience in pilot/production line set-up and validation in Controlled Environments (CER)
- Able to work in Cleanroom
- Knowledge on governmental regulations such as FDA QSR, ISO 13485, the MDR, and knowledge of relevant standards
- Knowledge of Good Manufacturing Practices (GMP) and Good Documentation Practices (GDP)
- Strong written and verbal communication skills and work cooperatively as part of a team
- Familiar with developing Master Validation Plans & executing operational and performance validations
- Familiar of GMP, GDP procedures and requirements
- Familiar with Design Control procedures and requirements