1. Position Summary:

Responsible for supporting Operations, Engineering and Quality Departments in areas including Inspection, Logistics, Document Control, Calibration, Auditing, PDP Hand-offs and Special Projects.

2. Key Responsibilities/Duties:

- Manage incoming inspection process and assist and releasing materials from quarantine
- Manage final product inspection procedures and process
- Manage nonconforming materials and nonconforming material process
- Manage and maintain calibration process and procedures
- Support product complaint investigations leading to root cause determination.
- Engage in development and improvement of manufacturing process
- Identify and implement Corrective and Preventive Actions (CAPA) to improve QMS
- Interface with all departments in the organization in matters related to the quality system compliance.
- Engage and interface with external/internal audits as Subject Matter Expert (SME)
- Train employees on QA principles and practices
- Review documents, drawings, tool specifications, calibration requirements documents for QA/QC signoff
- Create/support test plans, validation plans and, product QA plans
- Participate as Quality Representative on development and operations projects
- Completes all administrative functions relating to business or quality requirements
- Comply with policies, guidelines and regulatory requirements per Ondine Quality System
- Maintain clean and organized work areas
- Monitor and analyze quality metrics to identify trends and drive continuous improvement
- Prepare, trend, and report quality metrics
- Serve as back-up for Change Analyst/Document Control function
- Participate in other projects and tasks, as required

Responsibility to Ondine's Quality Management System

- Know and understand the Ondine quality policy and relevant Quality Management System elements and how the job responsibilities support and achieve the requirements of the QMS.
- Be familiar with Ondine's annual quality system objectives and support the achievement of the quality objectives through individual and departmental action plans.
- Perform all assigned Corrective and Preventive Actions (CAPA's) according to the urgency set by QA, CEO or President that ensures the CAPA effectiveness and closure time performance meets the requirements.

3. Job Requirements:

- 8 years of experience working in regulated medical device industry preferred
    - Experience with medical device regulations 21 CFR 820, ISO 13458, MDD, EU MDR, TGA
- Bachelor's degree in mechanical engineering, biomedical engineering, process engineering or related technical discipline, preferred.
- Experience in Risk Management for medical devices ISO 14971
- Effective time/task management skills; excel working in a fast-paced environment

- Ability to adapt to frequently changing priorities.
- Fluent in English
  Effective and professional communication skills; Internal (engineering, operations, microbiology, R&D, etc.) and external (customers, auditors and suppliers) required.
- Software Application validation familiarity a plus
- IPC 610 Certification

4. Key Attributes:

- Detail oriented with good record keeping
- Organized and responsible
- Good manual dexterity and eyesight
- Self-motivated
- Self-sufficient
- Reliable, punctual
- Willingness to learn
- Ability to follow-through and follow-up
- Ability to work independently and with minimal supervision