MANUFACTURING SUPERVISOR

Employment Type: **Full-Time / Exempt**
Department: **Technical Operations / #260**
Effective: **November, 2020**

Position Summary:

The Manufacturing Supervisor is responsible for all phases of production and/or packaging of all products (per instructions and specifications) and for operating production equipment within a fast-paced, regulated manufacturing environment.

Education and Experience:

Bachelor's degree in a biological science related field or equivalent required with specialized training certificates in materials and manufacturing preferred. 2+ years of previous assembly/packaging experience in a medical device environment preferred. Must have knowledge of material flow concepts and experience creating and implementing written Standard Operating Procedures. Must possess basic computer literacy and data entry skills. Experience operating under GMP compliant regulations. Good written and verbal communication skills are necessary. Ability to speak and/or read Korean is helpful, but not required. Experience with ERP system transactions.

Essential Functions/Major Responsibilities:

- Supervise assemblers for the assembly of molecular diagnostic PCR kits for Covid-19 while enforcing manufacturing procedures.
- Review completed production documentation.
- Maintain accurate records/documentation related to quality, work in-process, test results and special projects.
- Maintain production metrics.
- Plan and schedule weekly production and process development assemblies.
- Work with all departments to resolve issues and drive improvements to quality, cost and delivery.
- Ensure Manufacturing Department conditions (temperature, humidity and cleanliness) are maintained through proper attire and adherence to controlled room environments practice and procedures.
- Able to operate and train new associates on the following processes and attention to details:
  - Kit solution filling operation
  - Kit box labeling, kitting, and packaging
  - QC testing operation
  - Thermal cycler (PCR) amplification operation for QC testing
- Provide support to all departments as needed.
- Communicate with parent company on manufacturing processes and procedures, and technical troubleshooting.
- Manage all training for assembly workers using the Master Control system.

- Establish and maintain awareness and knowledge of Good Manufacturing Practices (GMP), ISO13485 and Standard Operating Procedures (SOPs); follow implemented procedures.
- Responsible for compliance with the company's quality system requirements through training and adherence to policies, procedures and processes.

Scope:

Works on problems of moderate scope where analysis of situations or data requires a review of a variety of factors. Exercises judgment within defined practices to determine appropriate action. Applies company policies and procedures to resolve a variety of issues. Normally receives limited instructions on routine work and general instructions on new projects or assignments.

NOTE: The above Job Description is intended to communicate the general function of the mentioned position and by no means shall be considered an exhaustive or complete outline of the specific tasks and functions that will be required. Additionally, specific tasks and duties of the position are subject to change as the Company, the department and circumstances change. All employees are expected to perform their duties within their ability as required by the job and/or as requested by management.