SHURIG SOLUTIONS INC.

INTEGRA LIMIT UNCERTAINTY

Production Supervisor
Job Location: Boston, MA

Responsibilities

The Production Supervisor is responsible for performing the essential duties and responsibilities as listed below.

ESSENTIAL DUTIES AND RESPONSIBILITIES

To perform this job successfully, an individual must perform each essential duty satisfactorily.

Primary responsibilities are:

- Supervises the daily activities of the Assembly Team (approximately 15 people); provides clear direction to team.
- Sets assembly and packaging plan based on product schedule, equipment efficiency, materials supply, staffing resources and volume required to meet demand and to ensure maximum production quantity and quality.
- Expedites operations that delay schedules and alters schedules to meet unforeseen conditions.
- Ensures adherence to SOP and GMP are followed.
- Provides training, coaching and development to the team.
- Ensures Quality and Regulatory compliance (facilitates Non-Conformance/CAPA/Audit related investigations, system/tracking transaction).
- Generates progress reports on schedule status and keeps records of completed orders, batch records, or documentation files.
- Creates culture of “safety first” and identifies areas for improvement.
- Uses department systems and tools to track and manage production schedule.
- Reports on all resource issues such as personnel, material, and equipment.
- Effectively follows SOPs, policies, and ISO/QSR requirements.
- Delegates to, and provides direction and guidance to Lead Assembly Operators, and Assembly Operators.
- Communicates technical details of production schedule to Assembly Operators.
- Reviews & transacts Device History Record (DHR) Batch Records in ERP system.
- Manages inventory levels within all stages of department production and works with overall site inventory control team for accurate demand plan forecasting.
- Develops business continuity/resilience plan and methodically eliminates high risk single points of failure: people, equipment, suppliers.
- Responsible for people management of the Assembly team including but not limited to, interviewing Assembly Operator candidates, approving timecards, approving time off requests, scheduling, and with support from Human Resources and the Manufacturing Manager performance reviews and disciplinary actions.

- Represents Assembly Operations during corporate and external quality audits.
- Drafts SOP and Work Instruction (WI) revisions as necessary and works with Quality Compliance for proper document change control approval and implementation.
- Conducts training to new hires and existing team members as revised SOPs and WIs are implemented and new SOPs and WIs are implemented.
- Performs all steps and phases within the Assembly and Packaging operation at expert level with the ability to cross train Assembly Operators currently specialized in only specific steps.
- Conducts chemical/ solution application, formulation, and analysis as needed in the Production operation.
- Actively participates in department activities spending 40% of their time on the assembly and packaging floor for coaching and mentoring, Gemba/ working side-by-side with team members on the floor and ensuring quality and compliance requirements are being met to produce a safe and efficient medical device for our healthcare partners and their patients.
- Prepares materials to be sent to off-site 3rd party sterilization, including understanding and following relevant SOPs, processes, and requirements, and competing relevant documentation.

Qualifications

- Bachelor's degree or equivalent with 0-2 years of experience of leading a team
- Experience in medical device, pharmaceuticals, Quality/Regulatory Compliance, or another regulated environment.
- Familiarity with application of GMP, ISO, FDA quality standard in a Life Sciences industry, preferably medical device.
- Experience and/or willingness and capability of working in an ISO certified cleanroom with full gowning requirements.
- Must have a Patient Safety and Quality Compliance mindset to be successful in this role and at this site.
- Capable of supervising 15-17 direct reports while performing their own duties.
- Proficient experience with Microsoft Office software (Excel, Word, PowerPoint) to create reports, spreadsheets, analyze data and prepare presentations (Power BI experience is a plus).
- Ability to follow instructions precisely, recognize deviation, and recommend corrective action. Detail-oriented.
- Excellent communication and organizational skills, Strong in interpersonal skills and ability to work with a diverse team in a positive and collaborative manner.
- Experience working with an ERP system

TOOLS AND EQUIPMENT USED

This role routinely uses standard office equipment (i.e., computers, keyboards, phones, photocopiers, filling cabinets, as well as other general office equipment).

Below is a non-exhaustive list of equipment used for production operations:

- Heat Sealer
- Pneumatic Die Cutting Press
- Digital Thickness Gauge
- Meshing Machine
- Pump System
- Tray Sealer

PHYSICAL REQUIREMENTS

The physical requirements listed in this section include, but are not limited, to the motor/physical abilities and skills require of position in order to successfully undertake the essential duties and responsibilities of this position. In accordance with the Americans with Disabilities Act (ADA), reasonable accommodations may be made to empower individuals with disabilities to undertake the essential duties and responsibilities of the position.

While undertaking the essential duties and responsibilities of the position, the employee must repeatedly sit, listen. Speak and have the ability to move throughout all location of the building. The employee is required to go to all areas of the company. The employee may be required to periodically lift and/or move up to 25 pounds. Specific vision abilities required by this job include close vision, distance vison, Color vison, Peripheral vison, depth perception and ability to adjust focus. Ability to travel via car, train and/or airplane to domestic and international location as needed.

ADVERSE WORKING CONDITIONS

The adverse working conditions listed in this section include, but are not limited to, those environmental conditions to which the employee may be exposed while undertaking the essential duties and responsibilities of this position.
Adverse exposure may result form the handling of hazardous and bio-hazardous material the include, but not limited to, flammable and corrosive liquids, compressed gases, sharps, and medical wastes.

SELECTION GUIDELINES

Formal application, rating of education and experience; oral interview and reference check; job related tests may be required.

DISCLAIMER

The duties listed above are intended only as illustrations of the various types of work that may be performed. The omission of specific statements of duties does not exclude them from the position if the work is similar, related, or a logical assignment to the position.

The job description does not constitute and employment agreement between the employer and employee and is subject to change by the employer as the needs of the employer and requirements of the job change.

(Facility will be moving to Braintree in 2024)

In an effort to minimize the spread of the coronavirus and to protect our employees, all new hires in the US and Puerto Rico will need to be fully vaccinated for COVID-19 in order to be considered for employment with Integra LifeSciences, unless eligible for an accommodation as provided by law.