



**Job Title:** Manufacturing Lead

**FLSA Status:** Non-Exempt

**EEO Category:** Technician

**Management Level Position:**  Yes  No

**Reports to:** Manufacturing Supervisor

**Department or Division:** Manufacturing

**Job Description Effective Date:** 1.1.21

**POSITION DESCRIPTION:**

A Manufacturing Lead produces standard and/or custom medical devices to meet customer requirements by following standard work instructions and company policies while manufacturing Argen products in a team environment.

**ESSENTIAL DUTIES AND RESPONSIBILITIES:**

- Follow department SOPs and work instructions and adhere to customer and Argen standards for manufacturing products.
- Adhere to work instructions to properly operate and maintain equipment as needed.
- Visually inspect product quality, troubleshoot and escalate issues when necessary.
- Report & escalate equipment per work instructions.
- Ensure team meets daily Service Level Agreement (SLA) expectations.
- Identify and recommend disposition of defective items for rework or scrap.
- Understand the product manufacturing process from initial steps through final inspection.
- Make line balancing personnel adjustments as required to maintain production flow and communicate all adjustments to the Supervisor.
- Clearly communicate instructions and operational expectations to team members.
- Periodically inspect product to ensure quality levels are maintained.
- Complete all documentation and training as required.
- Assist in authoring and/or revising SOPs and work instructions as needed.
- Support R&D Engineering products as requested by supervisor.
- Maintain a safe and clean work area, wear appropriate PPE, and adhere to safety standards.
- Ensure safety guidelines are followed by all team members.
- Train all manufacturing associates on all SOPs and work instructions in area.
- Serve as a subject matter expert in area.
- Other duties as assigned.

**EXPERIENCE & QUALIFICATIONS:**

- High school diploma or equivalent required.
- **Five** plus years of experience working in a manufacturing environment preferred.
- Strong knowledge of all manufacturing procedures with the ability to train others.
- Possesses leadership qualities and leads a manufacturing team in achieving results in a high-volume manufacturing environment.

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- Possesses leadership qualities such as self-awareness, team focus, ability to translate learning into action, and train others to do so, as well as drive success.
- Ability to work in a team environment.
- Ability to follow instructions and readily accept additional responsibilities.
- Attention to detail and quality focused.
- Passionate about industry and desire to contribute where needed.
- Schedule adherence and dependability.
- Ability to meet tight deadlines and meet production goals.
- Ability to learn technical concepts by reading work instructions and standard operating procedures, and completing on-the-job training.
- Ability to effectively communicate in both written and verbal form.
- Ability to follow detailed directions in a Good Manufacturing Practices (GMP) environment required.
- Knowledge of cGMP regulations ISO 13485, 21CFR Part 820, CMDR SOR/98-282, 93/42/EEC, RDC 16 2013, MHLW MO 169 and TG(MD)R Sch3 preferred.

Personal Protective Equipment Required  Yes  No

If Yes Describe: Eye Protection

| PHYSICAL REQUIREMENTS, ENVIRONMENT & WORKING CONDITIONS  |           |            |              |
|--|-----------|------------|--------------|
| Description  | Regularly | Frequently | Occasionally |
| Sitting  | X         |            |              |
| Standing   |           | X          |              |
| Walking  |           | X          |              |
| Climbing/Balancing                                       |           | X          |              |
| Reaching-with arms & hands                               | X         |            |              |
| Stooping/Kneeling/Crouching/Crawling                     |           |            | X            |
| Talking  | X         |            |              |
| Hearing  | X         |            |              |
| Feeling/Touching   | X         |            |              |
| Vision-Close, Peripheral, Depth, Ability to Adjust Focus | X         |            |              |
| Light to moderate lifting (50lbs or less)                |           |            | X            |
| Moderate to Heavy Lifting (more than 50lbs)              |           |            |              |
| Travel Required  |           |            |              |

| Environment & Working Conditions                            | Applicable |
|---|------------|
| Loud noise level  | X          |
| Overtime  | X          |
| Working in a factory environment                            | X          |
| Ability to work in a confined area                          | X          |
| Ability to sit at a computer for an extended period of time |            |
| Exposure to airborne powder (non-toxic)                     | X          |
| Work near moving mechanical parts                           | X          |

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|   |   |
|---|---|
| Ability to sit and work on one machine for an extended period of time | X |
| Ability to stand for an extended Period of Time                       |   |

The intent of this job description is to provide a representative and level of the types of duties and responsibilities that will be required of positions given this title and shall not be construed as a declaration of the total of the specific duties and responsibilities of any particular position. An employee may be directed to perform job-related tasks other than those specifically present in this description.

#### Change History

| Version | Change Description   |
|---------|--|
| 1       | Initial Release  |
| 2       | Header and Footer, removed signature line, JD effective date CO# 201 |

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