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| Department: | **Production** |
| Reports To: | **Business Development Manager** | FLSA Status: | **Non-Exempt** |
| Employee Type: | **Full Time** |
| Prepared By: | **David Carty** |

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| Approved By: | **Kyle Furtak** | **Date Approved** |  |
| Reviewed By Human Resources: | **Isabel Peruyera** |

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| Job Description |
| * **SUMMARY:**
* Develops and engineers improvements in injection molding processes. Modifies injection molding machines, assists with set up and troubleshooting for equipment, and develops materials to be inserted into molds to create products. Assists with implementing new production and process technologies.
* Characterize, verify, and validate manufacturing processes to meet various regulatory requirements.
* **MAJOR DUTIES AND RESPONSIBILITIES:**
	+ Work with management to improve level of care, maintenance, and ensure continuous improvement.
	+ Follow our Safety Requirements & Safety Training Program Procedures.
	+ Coordinate activities to evaluate and resolve engineering related production problems encountered in assigned areas of molding and manufacturing.
	+ Responsible for lubing, cleaning, and daily mold maintenance in presses.
	+ Communicate with molding technicians to determine needs and gaps and communicate to management.
	+ Ensure mold maintenance logs are properly kept and maintained in compliance with Quality Management System.
	+ Inspect molds after set-up is completed for the following: water leaks, loose water hose clamps, improper knockout bars or any mechanical malfunction of the mold that may prevent a proper production run.
	+ Continuously perform checks and monitor mold surface temperatures and maintain cleanliness.
	+ Investigate and resolve processing problems affecting quality of the product.
	+ Identify problems, diagnose causes, and determine corrective actions.
	+ Process request for tool repair. (e.g., generate work orders for repairs)
	+ Confer with Management staff to implement plans and recommendations.
	+ Characterize, verify, and validate manufacturing processes to meet various regulatory requirements.
	+ Follow safety requirements & safety training program procedures.
	+ Work with cross functional teams, including design, operations, quality, reliability and tooling, to develop processes for manufacturing devices in regulated industry.
	+ Independently complete process feasibility, characterization, IQ/OQ/PQ plans and reports and process release activities.
	+ Use statistical methods to resolve technical challenges and evaluate capability of manufacturing processes.
	+ Understand final product and assembly specifications so that processes are created to achieve the specification.
	+ Coordinate activities to evaluate and resolve engineering related production problems encountered in assigned areas of molding and manufacturing.
	+ Ensure mold maintenance logs are properly kept and maintained in compliance with Quality Management System (QMS).
	+ Inspect molds after set-up for the following: water leaks, loose water hose clamps, improper knockout bars or any mechanical malfunction of the mold that may prevent a proper production run.
	+ Continuously perform checks and monitor mold surface temperatures and maintain cleanliness.
	+ Will be required to check wear and tear or any parts of the tool.
	+ Investigate and resolve processing problems affecting quality of the product.
	+ Identify problems, diagnose causes, and determine corrective actions.
	+ Process request for tool repair. (e.g., generate work orders for repairs)
	+ Confer with management staff to implement plans and recommendations.
	+ Recommend measures to improve production methods, equipment performance, and quality of product.
* **OTHER DUTIES:**
	+ Other duties may be assigned.

***The preceding functions have been provided examples of the types of work performed by employees assigned to this job classification. Management reserves the right to add, modify, change, or rescind work assignments and to make reasonable accommodations as needed.**** **QUALIFICATIONS**:
* To perform this job successfully, an individual must be able to perform each essential duty satisfactorily. The requirements listed below are representative of the knowledge, skill, and/or ability required.
* Computer knowledge (Excel, Word, etc.)
* Knowledge of IQMS ERP system a plus/preferred
* Ability to understand Good Manufacturing Practices (GMP) and Good Documentation Practices (GDP).
* Ability to multitask to fully carry out instructions.
* Maintain cleanroom, standard practices, housekeeping according to Standard Operating Procedures (SOP) and Work Instructions (WI)
* Ability to pay close attention to detail.
* Ability to read and understand simple instructions
* Must be a team player.
* Willing to submit to background/drug screen check.
* Able to communicate written and verbal communication to all.
* **SUPERVISORY RESPONSIBILITIES**:
* This job has no supervisory responsibilities.
* **PHYSICAL DEMANDS:**
	+ The physical demands described here are representative of those that must be met by an employee to successfully perform the essential functions of this job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.
	+ While performing the duties of this job, the employee is regularly required to stand, walk, use hands and fingers, handle, feel, and or reach with hands and arms, climb and balance, and be able to communicate.
	+ The employee is occasionally required to stoop, kneel, and crouch.
	+ The employee must to regularly physically lift, move and or pull up to 30 pounds (lifting more than 30lbs requires assistance).
	+ Specific vision abilities required by this job include close vision, distance vison, color vision, peripheral vision, depth perception and ability to adjust focus.
	+ Travel up to 10% when required.
* **EDUCATION AND/OR EXPERIENCE:**
* Bachelor’s degree with 2 years of experience or
* Master’s Degree with zero years of experience; prior plastics experience is a plus
* **DECISION MAKING:**
* Ability to define problems, collect data, establish, and draw valid conclusions.
* Ability to interpret an extensive variety of technical instructions in mathematical or diagram form and deal with several abstract and concrete variables.
* Ability to solve practical problems and deal with a variety of concrete variables in situations where only limited standardization exists.
* Ability to interpret a variety of instructions furnished in written, oral diagram, or schedule form.
* **MATHEMATICAL SKILLS:**
* Ability to work with mathematical concepts such as probability and statistical inference, and fundamentals of plane and solid geometry and trigonometry.
* Ability to apply concepts such as fractions, percentages, ratios, and proportions to practical situations.
* Ability to add, subtract, multiply, and divide in all units of measure, using whole numbers, common fractions, and decimals. Ability to compute rate, ratio, and percent and to draw and interpret bar graphs.
* **COMMUNICATION:**
	+ Ability to read and interpret documents such as Safety Rules, operating and maintenance Instructions, and Procedure Manuals. Ability to write routine reports and correspondence. Ability to speak effectively before groups of customers or employees of organization. Must speak, read, and write English, bilingual a plus.
* **WORK ENVIRONMENT:**
* The work environment characteristics described here are a representative of those an employee encounters while performing the essential functions of this job.
* While performing the duties of this job, the employee is frequently exposed to moving mechanical parts. The employee is occasionally exposed to high, precarious places; fumes or airborne particles; toxic or caustic chemicals; extreme heat and risk of electrical shock.
* The noise level in the work environment is usually loud.

***To perform this job successfully, an individual must be able to perform each essential duty satisfactorily. The requirements listed above are representative of the knowledge, skills, and/or abilities required. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.******I hereby acknowledge that I have read and understand the content of this job description. I understand that the job description may be revised from time to time in the future by the Company in its discretion. I understand and agree that nothing in this job description should be construed as a contract of employment, and that employment with this Company is at-will meaning that the terms of employment may be changed with or without notice, with or without cause, including, but not limited to termination, demotion, promotion, transfer, compensation, benefits, duties, and location of work.***Employee Print Name: **­­­**Employee Signature:  **­­­­** Date: |