**nature and scope of position**

Responsible for the design and execution of pilot and plant level process development from prototype, cycle development, validation batches and scale-up/tech transfer of commercial batches. Leads improvement projects associated with company strategic goals in the areas of focus on process improvement, increased efficiency, optimization of total output capacity, and facility/product line expansion.

**Primary functions and core competencies**

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| **Process / Cycle Development** |
| Responsibilities: |

* Utilize expertise in experimental design for process development, data analysis and recommending data driven results.
* Effectively scale up new Projects from bench top through Pilot, Clinical and Commercial batches using appropriate experimental design, data analysis methods and compliant documentation.
* Assists teams, Quality Assurance or representative in development of appropriate analytical method development.
* Collaborates with Compliance, Manufacturing, Quality and Engineering Teams in equipment design Installation, Operation, Performance Qualifications (IQ/OQ/PQ).
* Formulation chemistry, experimental design, analysis, and reporting on individual and collaborative development projects per annual plan.

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| **Commercial / Scale Up** |
| Responsibilities: |

* Responsible for accurate, timely completion of commercialization projects (plant scale ups).
* Responsible for reporting status for accurate, timely, completion of projects and communication with Sales, Manufacturing, and Quality.
* Effectively scale up new products from Commissioning, Qualification and Validation of Commercialization batches.
* Provides technical direction and support on plant process development and commercialization teams with VP Pharma Development and Technical Innovation.
* Collaborate with cross-functional teams to enhance manufacturing processes.
* Analyze data, identify trends, and propose process improvements to optimize product quality.

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| **Collaboration & Communication** |
| Responsibilities: |

* Leads teams to maintain OFD’s leadership in the area of lyophilization technology and alternative preservation technology.
* Assists in continuous improvement of LyoLock as recognized process system platform for internal process and marketing activities
* Cultivates an environment where employees respect and follow company values.
* Establish and sustain effective relationships within team in order to foster an environment where innovation, continuous improvement, and cooperation are used to solve problems.
* Facilitate effective sharing of information across work teams, business areas, and functional areas.
* Function as a technical and business resource in areas of operations and product requirements.

**required knowledge, skills, and abilities**

* Knowledge of lyophilization and/or other preservation technologies with an understanding of how this translates to defining critical drying parameters for retaining critical properties.
* Understanding of statistical analysis methods and applications.
* General knowledge of Lean Six Sigma and ISO concepts.
* Demonstrated good verbal and written communication skills through positive and effective information sharing.
* Ability to interpret information received and adjust approach to meet company and department goals.
* Ability to maintain confidentiality.
* Ability to participate in continuous improvement of department procedures and processes.
* Ability to use all tools and resources available and apply to decisions made.
* Ability to work both independently and as part of a Team.

**core competencies**

* **Continuous Learning –** Taking initiative to regularly learn new concepts, technologies and/or methods.
* **Creativity and innovation** – Creating new approaches, designs, processes, technologies and/or systems to achieve the desired result.
* **Employee Development/coaching** – Facilitating, supporting and contributing to the professional growth of others.
* **Futuristic Thinking** – Imagining, envisioning, projecting and/or creating what has not yet been actualized.
* **Influencing Others** – Personally affecting others’ actions, decisions, opinions or thinking.
* **Interpersonal Communication** – Effectively communicating, building rapport and relating well to all kinds of people.
* **Problem Solving** – Defining, analyzing and diagnosing key components of a problem to formulate a solution.

**minimum qualifications**

* Bachelor in Engineering or Science degree in closely related fields. Equivalent work experience will be considered in lieu of degree.
* Minimum of 2 year of experience in related field.
* Experience in GxP environments and ISO 13485/14644.
* Demonstrated strong computer skills including proficiency in Microsoft Office applications.
* Demonstrated independent ability to analyze data & statistics, draw conclusions, and present results.
* Demonstrated experience working with cross-functional teams on projects impacting multiple departments preferred.

# REQUIRED OFD TRAINING

* The employee shall receive New Hire Orientation, including applicable CFR SOPs, to perform duties associated with product and process regulatory requirements, and this Job Description.

### Working Conditions / PHYSICAL REQUIREMENTS

* Normal office environment, periodic exposure to plant conditions (varying temperatures, wet, dry, high noise).
* Ability to work in a cleanroom environment with varying levels of personal protective equipment.
* Occasional use of a respirator may be required for safe exposure to certain materials.
* Ability to lift up to 40 pounds repetitively required.

**Expectations for All Employees**

Supports the organization's mission, vision, and guiding principles:

* GET IT DONE TOGETHER
* CARE FOR EACH OTHER
* PASSIONATE AND PROUD
* DARE TO MAKE A DIFFERENCE
* HELP OUR CUSTOMERS WIN
* DO THE RIGHT THING