Job Description		
Title Research Associate/Senior Research Associate, Reagent Formulation		
Department Reagent Formulation	***Reports to: EVP, Research & Development***	
	Supervises: No	
Effective Date: ***July 11, 2018***	*Page: 1 of 3*	***FLSA: Exempt***

Position Overview

Pierian Biosciences is an emerging biotechnology company specializing in cutting edge technologies utilizing molecular and immunology based clinical diagnostic assays to generate actionable data for improved patient outcomes. We are currently focused on the ChemoINTEL and ImmunoINTEL technology platforms for use in our clinical assay development, pharma development, and laboratory support services with the primary emphasis being oncology.

Under the direction of the Executive Vice President (EVP) of Research and Development (R&D), the Research Associate (RA)/ Senior Research Associate (Sr. RA) will:

- *Perform reagent formulation and quality testing*
- *Provide support to continuous improvement efforts in reagent formulation and respective quality processes, equipment and materials*
- *Assist in the maintenance and troubleshooting of reagent formulation processes, including participation in technical investigations, identifying process improvements, and designing/implementing corrective and preventive actions (CAPAs)*
- *Train personnel on the operation and safety of reagent formulation processes*
- *Ensure reagent formulation processes are functionally effective, safe, and meet any code or Occupational Safety and Health Administration (OSHA) regulations for design and safety*
- *Interface with all functional areas such as Research and Development, Quality, and Operations during development of new processes and lead cross-functional teams*
- *Establish International Organization for Standardization (ISO)/QA compliant documentation for reagent formulation processes and appropriate procedural or troubleshooting references for the operation of equipment*
- *Design and execute experiments to improve process control and process capability on new existing processes*
- *Assist with new product/process development*

Essential Job Functions

- *<u>Reagent Formulation and Quality Control (QC) Processes:</u>*
  - *Manage resources for maintaining, calibrating, and validating Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ) reagent formulation and QC test equipment as required by documented procedures*
  - *Initiate and drive equipment utility change controls to ensure equipment is implemented or repaired within required timeframe*
  - *Provide technical guidance on change controls and how they might impact the process/product specifications*
  - *Ensure that equipment is running reliably with minimal downtime*

  - *Train reagent formulation technicians in the proper and safe use of equipment*
  - *Author supporting manuals and procedures*
- *Product Development/Transfer:*
  - *Work closely with R&D, and Quality during the development of new products to ensure a smooth transfer of products into reagent formulation*
  - *Lead cross functional teams and equipment projects to implement new equipment*
  - *Plan and track progress, contribute to testing and validations plans; IQ, OQ, PQ*
  - *Establish preventive maintenance plans for equipment*
- *Reagent Formulation:*
  - *Maintain accurate and up to date reagent formulation procedures, Master Process Instructions, and Standard Operating Procedures; maintain familiarity with department procedures*
  - *Initiate changes in procedures where appropriate according to ISO standards*
- *Quality Assurance:*
  - *Maintain accurate and up to date reagent formulation procedures, Master Process Instructions, and Standard Operating Procedures; maintain familiarity with department procedures*
  - *Initiate changes in procedures where appropriate according to ISO standards*
- *Cost Reduction:*
  - *Support cost reduction programs by implementing process automation and material improvement*
  - *Collect data to monitor the process flow to help support cost reduction opportunities*
- *Job Scope:*
  - *Able to interact regularly with Reagent Formulation employees*
  - *Interact in both written/oral with all departments within the organization*

Non-Essential Job Functions

- *Quality Responsibility*
  - *Maintenance of quality systems and Regulatory compliance for the business by ensuring that all team members comply with processes, procedures, and instructions for all activities in which the team participates*
- *Safety Responsibility*
  - *Is knowledgeable and complies with all pertinent safety policies, rules and regulations*
  - *Ensure that all team members comply with safety rules and regulations*
- *Leadership Responsibility*
  - *Provide appropriate coaching and performance feedback to all direct reports and assures that all team members are being developed*

Experience Requirements

- *5+ years of direct laboratory experience in product or process development in IVD, Food or Pharma*
- *2+ years direct or indirect experience with pilot production or manufacturing environment in IVD, Food or Pharma*
- *Familiarity with current Good Manufacturing Practices, ISO regulations, and US / EU regulations*
- *Knowledgeable in biopharmaceutical techniques such as lyophilization, formulation, filling operations, biochemical assays, cell culture, cell isolation, sterile manufacturing, media powder and liquid composition, automated manufacturing, packaging, labeling, and aseptic technique*

Education Requirements

- *Bachelors in Science with emphasis in Chemistry, Biology, Immunology, or Engineering*

Knowledge, Skills, and Abilities (KSAs)

- *Proficiency with MS Office (Excel, Power Point, Word)*
- *Must possess excellent communication skills (written and verbal) and be capable of effectively conveying technical concepts to both technical and non-technical audiences*
- *Self-motivated with demonstrated leadership experience and the ability to work individually and within a team in whatever capacity may be required to ensure timely delivery of assignments and/or resolution of current issues*
- *Proven leadership ability, especially with indirect reports*
- *Ability to coordinate, facilitate and organize resources*
- *Experience in leading development projects and training technicians*
- *Team player, collaborative*
- *Effective time management*
- *Analytical problem solver*
- *Detail-oriented*
- *Organized*
- *Patient*
- *Pro-active*

NOTE: This job description is not intended to be all-inclusive. Employee may perform other related duties as negotiated to meet the ongoing needs of the organization. Pierian Biosciences is an Equal Opportunity Employer with a strong commitment to the achievement of excellence and diversity.