Job Description		
Title Manufacturing Science and Technology-Quality Assurance Scientist		
Department Manufacturing	***Reports to: Director of Manufacturing***	
	Supervises: No	
Effective Date: ***July 18, 2017***	*Page: 1 of 4*	***FLSA: Exempt***

Position Overview

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

Under the direction of the Director of Manufacturing, the Manufacturing Services and Technology Quality Assurance Scientist (MSAT-Quality Assurance Scientist) will:

- *Create processes and maintain procedures for the inspection of incoming materials, in-process materials and finished goods. Select appropriate inspection, test and measurement equipment, fixtures, and gauges*
- *Leads initial supplier approvals and the continuing evaluation of supplier performance.*
- *Communicates with customers and suppliers on issues related to product quality and performance*
- *Implement and manage MRP for use in inventory management and control*
- *Perform product manufacturing and quality testing*
- *Assist in development of performance measurements and reporting requirements that set quality metrics for each stage of the production process*
- *Provide support to continuous improvement efforts of manufacturing and respective quality processes, equipment and materials*
- *Assist in the maintenance and troubleshooting of manufacturing processes, including participation in technical investigations, identifying process improvements, and designing/implementing corrective and preventive actions (CAPAs).*
- *Works with MSAT team to develop process validation protocols, FMEAs, quality plans, manufacturing procedures, inspection plans, and specifications*
- *Interface with all functional areas such as Research and Development, Quality and Operations during development of new processes and lead cross-functional teams.*
- *Contribute to ISO/QA compliant documentation for manufacturing processes and appropriate procedural or troubleshooting references for the operation of equipment*
- *Execute experiments to improve process control and process capability on new existing processes*
- *New product/process development*

Essential Job Functions

- *Manufacturing Processes:*

  - *Works with MSAT to assure that process is capable of producing a quality product that meets established requirements; assures process changes made to improve product design, reduce costs or increase manufacturability do not negatively affect quality*
  - *Provide technical guidance on change controls and how they might impact the quality specifications*
  - *Author supporting manuals and procedures*
- *Product Development/Transfer:*
  - *Work closely with Engineering, Manufacturing, R&D, and Quality during the development of new products to ensure a smooth transfer of products into manufacturing*
  - *Plan and track progress, contribute to testing and validations plans; IQ, OQ, PQ*
- *Manufacturing:*
  - *Maintain accurate and up to date Manufacturing procedures, Master Process Instructions, and Standard Operating Procedures. Maintain familiarity with department procedures*
  - *Initiate changes in procedures where appropriate according to ISO standards*
- *Supplier and Inventory Control:*
  - *Perform purchasing for laboratory and manufacturing*
  - *Control and track inventory and materials throughout material and product lifecycle*
  - *Create metrics for measuring internal inventory efficiency*
  - *Onboard, validate and implement a MRP system*
  - *Implement and train appropriate personnel on use and management of system*
  - *Support cost reduction programs by implementing process automation and material improvement*
- *Job Scope:*
  - *Able to interact regularly with Manufacturing employees*
  - *Interact in both written/oral with all departments within the organization*

Non-Essential Job Functions

- *Quality Responsibility*
  - *Maintenance of quality systems and cGMP 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*
    - *Provides appropriate coaching and performance feedback to all direct reports and assures that all team members are being developed*

Experience Requirements

- *5+ years of experience in supplier, materials and/or process and product quality assurance*
- *2+ years direct or indirect experience with quality functions within a pilot production or manufacturing environment in Diagnostics, Medical Device 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*
- *Knowledgeable in cell and tissue culture techniques and molecular assays*

Education Requirements

- *Bachelors in Science with emphasis in Chemistry, Biology or Engineering*
- *CQPA or CSQP or Medical Technologist desired*

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.