

Job Description		
Title Research Associate/Senior Research Associate ImmunoINTEL		
Department Research & Development	Reports to: Director or Scientist Level	
	Supervises: No	
Effective Date: January 30, 2017	Page: 1 of 2	FLSA: Exempt

Position Overview

Pierian Biosciences is an emerging oncology focused 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 and ImmunoINTEL technology platforms for use in our clinical assay development and FDA validation studies with the primary emphasis in oncology.

Under the direction of an assigned Director or Scientist, the Research Associate/Sr. Research Associate will perform all Immuno Oncology associated assay development experiments and process improvement activities in accordance with established procedures to meet all Good Laboratory Practices (GLP) regulatory requirements set forth in the FDA guidelines. She/he will work closely with development, manufacturing, clinical and quality staff to foster a team atmosphere striving for continued technical innovations, process improvement and centers of excellence.

Essential Job Functions

- Actively participates as part of the assay development, laboratory operations and manufacturing teams, following Good Laboratory Practices as defined in approved SOPs
- Performs assay development tasks independently
- Performs all aspects of assigned technical processes
- Performs instrument QC and preventative maintenance
- Assists with assay development process improvements coordinated with heads of Development, Manufacturing, and Quality Assurance
- Participates in drafting and execution of study plans to optimize assay/reagent parameters and product configuration
- Participates in experimental data analysis, interpretation, and study report writing
- Presents data for review and discussion at individual and group laboratory meetings
- Follows laboratory protocols rigorously to execute experiments, thoroughly documents all activities and maintains formal notebook
- Understands the experimental goals and results and provide feedback and basic troubleshooting as necessary
- Demonstrates training and proficiency in clinical sample processing for all assay development and FDA clinical trial validation studies
- As part of ongoing technical growth, gains further understanding of experimental principles by reading appropriate literature
- Demonstrates good laboratory practices in the handling of clinical specimens, cell culture, and other reagents, including antibodies, modulators, drugs and small molecule inhibitors
- Works cooperatively in a team environment; supporting senior scientific staff and co-workers
- Provides training to laboratory and manufacturing lab staff on technical tasks and

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- *compliance-related activities*
- *Prepares and qualifies research buffers and other reagents*

Non-Essential Job Functions

- *May be required to review and update SOPs, tracking logs, and material/reagent specifications under design control processes*
- *Material ordering, receiving and inventory control processes*

ImmunoINTEL Assay Technical Experience Requirements

- *Research Associate: B.S. with minimum of two (2) years relevant laboratory experience*
- *Senior Research Associate: B.S. with minimum of eight (8) years relevant laboratory experience or M.S. with minimum of two (2) years relevant laboratory experience*
- *Prior experience with molecular based clinical assays with an emphasis on fluorescent/luminescent based platforms (flow cytometry, IHC, ELISA and Luminex experience a definite plus)*
- *Prior experience operating under GMP, GLP, and GCP regulated environment desired*
- *Prior experience conducting clinical validation studies, clinical trials, and/or submissions for FDA 510k and PMA clearance is desirable*

Education Requirements

- *Bachelors or Masters in one of the Life Sciences; immunology, cell biology, genetics, molecular biology, biomedical engineering, or biochemistry preferred*

Knowledge, Skills, and Abilities (KSAs)

- *Leadership, integrity and initiative abilities*
- *Excellent written and oral communication skills*
- *Essential reading, research and writing skills*
- *Critical thinking, judgment and decision making skills*
- *Competency in MS Office products and ability to quickly learn other software applications*

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.