About SQI Diagnostics
SQI Diagnostics is an innovative diagnostics and life sciences company that develops and manufactures clinical-grade multiplexed immunoassays and molecular assays that are run on its patented automated instrumentation platform. These assays have broad applications, including organ transplant and autoimmune clinical diagnostics along with pharmaceutical research diagnostics. SQI develops custom research and diagnostic assays that are multiplexed, which means simplification, consolidation, and automation of many individual tests into one.

Working at SQI Diagnostics

SQI Diagnostics offers a dynamic, stimulating, challenging, and supportive work environment with competitive salaries and generous benefits. SQI Diagnostics is ISO-13485:2016 certified.

We are a multi-discipline team supporting a variety of projects and technologies that allow continual learning and expansion of skills. The SQI management team is committed to fostering the growth and career development of its employees.

Develop experimental protocols and test procedures, perform experimental studies, analyze the data, evaluate the results, form conclusions with the ability to keep organized and comprehensive laboratory notebooks and data repository

· Develop reagent preparation and assay test protocols, characterization methodologies and acceptance criteria; optimize reagent formulations and demonstrate performance and stability prior to design transfer to Manufacturing

· Support the development of antibody, antigen and biomarker diagnostic assays from product concept through regulatory clearance, including initial research, feasibility activities, verification, validation, and design transfer within SQI's design control process and QMS

· Identify, test, and implement solutions to defined technical and project issues based on scientific knowledge through evaluating the scientific literature, intellectual property landscape and laboratory research

· Identify and propose opportunities to build the platform's assay portfolio

· Develop and write SOPs, work instructions, development reports and supporting quality documentation; serve as reviewer and Subject Matter Expert for documents, internal audits, design reviews, etc.

· Understand the fundamental analytical platform-assay relationships and lead root cause analysis, data reviews and technical discussions

Education, Qualifications, and Requirements:
· Graduate degree in Chemistry, Biochemistry, Immunology, or equivalent education program

· Masters with 2+ years or Doctorate with relevant project experience; regulated pharmaceutical, diagnostic, biotechnology, and/or medical device company

· Experience with product development for immunoassay, formulation design and optimization, data-driven improvement methodology

· Experience with multiplexed protein and molecular assays; exposure to flow cytometry, ELISA, or lateral flow is an assent

· Experience with fluorescence-based detection technologies and/or microscopy; understanding of image processing fundamentals is an asset

· Experience working with biological samples, handling blood, urine, and others in a CL-2 laboratory; ISO 13485, GLP or cGMP preferred

· Experience mentoring, teaching and training junior scientists and/or students in concepts, technical writing and laboratory techniques