Laboratory Manager

OncoTracker, a West Hollywood based biotechnology company affiliated with a research institute (IMBCR) with proprietary intellectual property (IP) for an oncology biomarker seeks an ELISA (competitive binding solid-phase sandwich format) subject matter expert (SME) to lead assay development and validation efforts. OncoTracker is currently negotiating with pharmaceutical companies regarding BCMA licensing, CLIA and companion diagnostic assay opportunities. A GLP compliant quality management system is being established to support the integrity of data generated from research and development activities.

Data generated to date has used a commercially available ELISA kit (R&D Systems Duo Set BCMA ELISA) for which the research institute does not have IP licensing rights nor guaranteed supply chain control of the kit.

OncoTracker has three (3) strategic imperatives listed in order of their priority:

1. Validation of the R&D Systems assay
2. Development and validation of the R&D Systems assay substituting a custom made BCMA specific monoclonal antibody or antibodies.
3. Development and validation of OncoTracker's own BCMA ELISA format including formulation of buffers, reagents, detection systems, solid-phase methodology, etc.

Ethics Statement

To best serve customers, stakeholders, and employees, OncoTracker's managers and staff need to be free of undue internal and external pressures that may adversely affect the quality of their work. Ethics standards promote and strengthen confidence in the integrity of OncoTracker data. This position must ensure that federal, departmental, and FDA ethical standards are understood and followed by the incumbent and OncoTracker employees.

Role and Responsibilities:

- Applies strong technical expertise and serves as the assay development SME in leading all technical research and development activities.
- Develop development plans and schedules
- Assists the GLP Study Director to define and execute the requirements for test study project planning, protocol development/approval, procedural approaches, and conduct of GLP studies. Note that activities conducted as a GLP study or as part of a GLP study are to be planned and conducted according to Good Laboratory Practices as described in 21 CFR Part 58 and OncoTracker laboratory policies and procedures.
- Support GLP through adherence to procedural requirements including those associated with experimental design and data integrity.
- Support GLP auditing requirements as defined in standard operating procedures.
- Assign, guide and review experimental work performed by internal scientists and staff
- Perform bench work as necessary
- Review experimental data (antibody characterization, development data, validation data, etc.) and draw conclusions that drive progress towards achievement of strategic imperatives.
- Review lab notebooks maintained by junior staff to ensure compliance with data integrity procedures.
- Provide input and effort to continuously improve the quality management system.
- Oversee testing activities currently in place to support IMBCR requirements including ensuring that test specimens are procedurally controlled and secure.
- Proactively provide regular updates, reports and other communications to the management team.
- Escalate issues as necessary to the management team.

- Develop and either execute or oversee the execution of assay validation protocols.
- Establish stability studies using pre-approved protocols.
- Work with CMOs and/or other suppliers of critical reagents, intermediate and raw materials to ensure quality and availability requirements are met.
- Identify equipment, materials, skill sets necessary to achieve strategic objectives
- Mentor junior staff
- Other tasks as necessary to achieve the strategic imperative business priorities.

We are an equal opportunity employer and all applicants will receive consideration for employment without regard to race, color, religion, sex, national origin, disability status, protected veteran status, or any other characteristic protected by law. We will consider for employment qualified applicants with criminal histories.