



SkylineDx is a commercial-stage biotech company based in Rotterdam, the Netherlands with both commercial and laboratory operations in the United States. Originally a spin-off of the Erasmus Medical Center in Rotterdam, the company specializes in the development and marketing of innovative gene signature-based diagnostic tests to assist healthcare professionals in making personalized treatment decisions for individual patients. These tests are designed to accurately determine the type or status of the disease or to predict a patient's response to a specific treatment. Based on the test results, healthcare professionals can tailor the treatment to the individual patient. The MMprofiler™ is the company's lead product. To learn more, please visit www.skylinedx.com.

Job Description

Laboratory Manager

Position Summary

The Laboratory Manager is accountable for the accuracy and reliability of all laboratory services provided by SkylineDx USA, Inc. The laboratory manager is responsible for day to day operational management and oversight of all laboratory operations, personnel, and for monitoring the production of medical diagnostic testing in the CAP certified CLIA lab performed by assigned clinical lab personnel. The laboratory manager will work closely with internal and external contacts including suppliers, physicians, and other healthcare providers regarding clinical laboratory testing, operations, and development of new tests. They will manage routine and complex molecular biology procedures including analyzing and interpreting results, and developing, validating, and implementing assays.

Duties and Responsibilities:

- The laboratory manager is responsible for leading the implementation of all procedures and operations as well as ensuring that metrics to measure quality, production, and efficiency are established and strictly followed. Under the direction of the Laboratory Director, the laboratory manager will ensure adequate performance of all laboratory procedures.

Core Responsibilities:

- Performs high complexity molecular diagnostic and clinical testing by following department procedures as needed.
- Presents data and/or information across all levels including the lab, department, division, and corporate, and proficiently answers questions from all groups of staff, managers, and clients.
- Recommends and endorses test methods to include validation, documentation, and implementation of all test systems.
- Develops and maintains detailed laboratory procedure manuals to meet CAP/CLIA accreditation and licensing requirements; ensures departmental SOPs accurately reflect current process and updates SOPs as needed.
- Provides direct management & supervision of the laboratory operation and personnel.

- Responsible for the selection, retention, and training of qualified laboratory personnel; ensures that Laboratory staff is trained and compliant with SOPs and skills checklists.
- Reports any problem cases and/or abnormal findings to the Laboratory Director to ensure timely resolution and/or follow up.
- Initiates and monitors QC programs for the department; assures compliance with regulations; monitors all quality metrics and ensures that corrective actions are documented and implemented.
- Resolves technical problems in accordance with established policies and procedures; remains available to testing personnel at all times that tests are being performed to provide on-site telephone or electronic consultation.
- Monitors test analyses and specimen examinations to ensure that acceptable levels of analytic performance are maintained.
- Assures that corrective actions are taken whenever test systems deviate from the department's established performance specifications.
- Ensures that all personnel meet the regulatory requirements and have adequate knowledge of the test systems for which they are responsible.
- Attends regularly scheduled laboratory management meetings and informs his/her staff of pertinent information.
- Ensures that technical personnel are responsive to client requests or problems.
- Actively supports and complies with all company, departmental, and safety policies and procedures.
- Prepares employees reviews, approves time and attendance records, maintains training files and performs other administrative duties as required.
- Monitors the preparation of solutions and reagents for laboratory procedures on a monthly basis.
- Monitors laboratory log books, specimen accession sheets, workflow drafts, etc., to ensure quality assurance of specimens.
- Monitors the performance of various housekeeping and/or maintenance tasks to keep the laboratory and equipment in clean and operable condition.
- Reviews and signs PO's prior to submission regarding supplies used by the laboratory staff in order to maintain sufficient inventory.
- Maintains advanced knowledge of CAP/CLIA requirements and is knowledgeable with the specialty requirements within those organizations for assigned discipline.

Other Duties:

- May head up the validation processes through documentation and development of procedural operations for both existing and new tests following instructions for use, manufacturer's guidelines, and/or established department SOP's.
- May serve as the Education Coordinator for assigned department's state approved training program.
- May serve as a technical resource for the department by investigating and resolving analytical testing problems, recommending a course of action in instances identified as

- beyond acceptable limits, and responding to non-routine/complex inquires and/or requests from clients and sales representatives.
- May assist in coordinating orientation and continuing education programs for all licensed departmental personnel.
 - May assist the Laboratory Director in establishing budgetary controls and maintaining cost at an acceptable level. May prepare reports detailing departmental activities, revenues, expenses and the like, as needed.
 - May serve as the Safety Officer.
 - Perform other duties as assigned by the Laboratory Director and/or head of commercial operations.
 - Achieves desired level of competency and accuracy for the main department processes and responsibilities of assigned position, as defined in established SOPs, within 6 months.
 - Reports quality results with limited errors.
 - Maintains satisfactory results on all department specific competency assessments.
 - Works productively and efficiently to achieve company and departmental goals.
 - Effectively schedules and manages resources to meet department goals.
 - Communicates effectively with all levels of staff.
 - Maintains thorough knowledge and shows demonstrated support of SkylineDx core values, safety, compliance, and Company policies and procedures.
 - Remains current on developments in field(s) of expertise, regulatory requirements, and a comprehensive knowledge of the company's products, markets, and objectives as well as industry trends.
 - Recommends and interprets policies and procedures to accomplish assignments and resolves a broad range of issues and problems.
 - Maintains a safe working environment and a strong customer focus.

The above duties & responsibilities represent the general duties considered essential functions of the Laboratory Manager role and is not to be considered a detailed description of all the work requirements that may be inherent in the position.

Required:

- Bachelors of Science degree in biological sciences, medical technology, or equivalent; advanced MS degree or PhD in molecular biology strongly preferred.
- Minimum of 8 years related clinical lab experience with 2 years of supervisory level in a clinical laboratory, with Molecular Biology experience.
- Current State of California supervisor level license to perform laboratory testing that includes Clinical Laboratory Specialist (CLS) license required (ASCP certification for assigned specialty).
- Compliance experience with regulatory agencies such as CAP, CLIA, and FDA that include accreditation inspections, writing, and editing laboratory Standard Operated Procedures (SOP).
- Demonstrated proficiency in computer skills including statistical analysis and laboratory information systems.

- Previous molecular diagnostics experience including DNA/RNA isolation, PCR, RT-PCR, Real-Time PCR, capillary electrophoresis and DNA sequencing highly desired.
- Must have a comprehensive working knowledge of frequently used personal computer programs and applications, such as, e-mail, Microsoft Office (e.g. word, excel, PowerPoint), etc.

Reporting:

- The laboratory manager is part of the leadership team and reports directly to the Head of Commercial Operations with a dotted line to the Laboratory Director at SkylineDx BV located in Rotterdam, The Netherlands.

Travel Requirements:

- Ability and willingness to travel by air, train or car may be required for internal and external business meetings in order to meet defined sales objectives. Must possess a valid driver's license and passport.
- May be required to spend time in the field calling on and working with customers and/or traveling with assigned sales representative(s).
- Expect some evenings/overnights, including weekends, and international travel as required.

Physical Demands:

- Standing, sitting, walking, bending, reaching, manual manipulation, and lifting up to 50 pounds may be necessary.

Work Environment:

- Must be able to work in a biohazard environment and comply with safety policies and standards outlined in the Safety Manual
- Adheres to department specific safety guidelines.

Primary Location:

- United States: San Diego, CA

Organization

- US Commercial Operations

Schedule:

- Full-time.

Employee Status:

- Exempt.

Job Posting:

- January, 2018

Contact:



- All inquiries should be addressed to Jeffrey Jones at j.jones@skylinedx.com.