

Nanobiosym is an innovative, high-tech company that is developing novel technologies at the nexus of physics, nanotechnology, and biomedicine. Founded by MIT/Harvard alum and located in Cambridge, Massachusetts, Nanobiosym was awarded the first X-Prize to be given for healthcare.

## **Technical Supervisor, Lab Operations**

### **Position Summary:**

The Technical Supervisor of Lab Operations is responsible for the technical components of the Molecular Lab within clinical business.

### **Job Responsibilities:**

- Provides technical oversight of protocol execution and hands-on training for the molecular team by developing technical training program modules for current and new assays. Ensures that all team members are provided with complete process and theory training.
- Works closely with the molecular team, quality assurance team as well as external vendors to provide support in technical troubleshooting on instruments and testing protocols.
- Works closely with cross functional team members during new product transfer to ensure that all quality and operational details are discussed and implemented during validation.
- Focus on the maintenance and operation of protocols and instrumentation as well as planning the arrival and placement set up of any new or relocated equipment.
- Work closely with the quality and regulatory teams to performance qualify any new or relocated equipment.
- Support compliance to all applicable regulatory and standard requirements (CLIA, NYS, CAP, ISO, etc.).
- Consult with the Laboratory (Medical) Director and other professional on staff, as needed.
- Make recommendations regarding hiring, discipline and promotion of subordinates; authorizes leave and overtime; evaluates and rates employee performance.
- Maintain confidentiality of all patient information in accordance with federal, state and local guidelines and regulations.
- Develop, train and mentor staff.
- Accepts other duties as assigned.
- Supports the general supervisor in achieving compliance with CLIA, CAP, NYS DOH and ISO 15189 2012.

- This position has been delegated the responsibility of assessing employee competencies.

### **CLIA/NYS/CAP/ISO 15189 2012:**

Each individual performs only those high complexity tests that are authorized by the laboratory director and require a degree of skill commensurate with the individual's education, training or experience, and technical abilities.

Each individual performing high complexity testing must:

- Follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results;
- Maintain records that demonstrate that proficiency testing samples are tested in the same manner as patient specimens;
- Adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed;
- Follow the laboratory's established policies and procedures whenever test systems are not within the laboratory's established acceptable levels of performance;
- Be capable of identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify the general supervisor, technical supervisor, clinical consultant, or director;
- Document all corrective actions taken when test systems deviate from the laboratory's established performance specifications; and
- Perform high complexity testing under the onsite, direct supervision of a general supervisor as defined in the CLIA regulations.

### **Required Qualifications:**

- Demonstrate clear ability to explain previous molecular assay experience; including the function of positive/negative controls, sample results, and data interpretation.
- Must possess relevant molecular skill set consisting of molecular fundamentals such as: RNA and DNA extraction, PCR, reverse transcription, and gel electrophoresis.
- 3+ years of experience managing Molecular department operations in a CLIA, NYS, CAP, ISO regulated environment.
- Knowledge of laboratory safety and quality control procedures and regulations.
- Proficient in Microsoft Office Suite and Internet for business use.

### **Preferred Qualifications:**

- Experience with real-time PCR, microarray, fragment analysis, Sanger sequencing, and Next Generation Sequencing preferred.
- MB(ASCP) certification preferred.

- Bachelors or Master's degree in a science field preferred. Minimum of three years post-graduation experience for a Bachelors, or one year post-graduation experience for a Masters, working in a laboratory (clinical preferred).
- However, it is also acceptable to meet one the following high complexity requirements:
  - Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution **or**
  - Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or have the equivalent education and training that includes:
    - At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either 24 semester hours of medical laboratory technology courses or 24 semester hours of science courses. If the 24 semester hours were in science courses then that must include 6 semester hours of chemistry, 6 semester hours of biology and 12 semester hours of chemistry, biology, or medical laboratory technology in any combination **and**
    - Have laboratory training that includes either completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS or at least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing **or**
  - Have previously qualified or could have qualified as a technologist under CLIA on or before February 28, 1992 as defined below **or**
  - On or before April 24, 1995 be a high school graduate or equivalent and have either graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS **or** successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician).
  - In order to qualify as high complexity testing personnel CLIA prior to February 28th, 1992 the individual must have met or could have met the following qualifications for technologist.
    - Have earned a bachelor's degree in medical technology from an accredited university; **or**
    - Have successfully completed 3 years of academic study (a minimum of 90 semester hours or equivalent) in an accredited college or university, which met the specific requirements for entrance into a school of medical technology accredited by an accrediting agency approved by the Secretary, and has successfully completed a course of training of at least 12 months in such a school; **or**

- Have earned a bachelor's degree in one of the chemical, physical, or biological sciences and, in addition, has at least 1 year of pertinent full-time laboratory experience or training, or both, in the specialty or subspecialty in which the individual performs tests; **or**
- Have successfully completed 3 years (90 semester hours or equivalent) in an accredited college or university as follows:
  - For those whose training was completed before September 15, 1963 at least 24 semester hours in chemistry and biology courses of which at least 6 semester hours were in inorganic chemistry and at least 3 semester hours were in other chemistry courses and at least 12 semester hours in biology courses pertinent to the medical sciences; **or**
  - For those whose training was completed after September 14, 1963, 16 semester hours in chemistry courses that included at least 6 semester hours in inorganic chemistry and that are acceptable toward a major in chemistry; 16 semester hours in biology courses that are pertinent to the medical sciences and are acceptable toward a major in the biological sciences; and 3 semester hours of mathematics; and has experience, training, or both, covering several fields of medical laboratory work of at least 1 year and of such quality as to provide him or her with education and training in medical technology equivalent to that described in this section; **or**
- With respect to individuals first qualifying before July 1st, 1971, the technologist was performing the duties of a laboratory technologist at any time between July 1st, 1961, and January 1st, 1968, and has had at least 10 years of pertinent laboratory experience prior to January 1st, 1968.

### **Core Skills & Competencies:**

- Ability to multi-task and work in a fast-paced, deadline driven environment.
- Effective verbal and written communication skills. Proven attention to detail with effective organizational skills.
- Effective interpersonal and team skills.
- Drive for Results (Service, Quality, and Continuous Improvement) - Ensure procedures and processes are in place that lead to delivery of quality results and continually reassess their effectiveness to achieve continuous improvement.
- Requires a high degree of care and attention with strict adherence to defined clinical testing protocols.
- Communication - Proficient verbal and written communication skills. Willingness to share and receive information and ideas from all levels of the organization in order to achieve the desired results.
- Teamwork - Commitment to the successful achievement of team and organizational goals through a desire to participate with and help other members of the team.

- Customer Service Focus - Demonstrate a focus on listening to and understanding client/customer needs and then delighting the client/customer by exceeding service and quality expectations.

### **Physical Demands**

- Must possess ability to sit, stand, and/or work at a computer for long periods of time.
- May have exposure to blood-borne pathogens, extreme temperatures, high noise levels, fumes and bio-hazardous material/chemicals including formalin in the lab environment.
- Visual acuity and analytical skill to distinguish fine detail. Ability to pass a visual color discrimination test.

### **Required Training**

- All job specific, safety, and compliance training are assigned based on the job functions associated with this position

### **Other**

- This position requires periodic travel and some evenings, weekends and/or Holidays.

This job description reflects management's assignment of essential functions. Nothing in this job description restricts management's right to assign or reassign duties and responsibilities to this job at any time.