



JOB DESCRIPTION

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POSITION TITLE: QC Microbiology Manager	DEPARTMENT: QC Microbiology
REPORTS TO: Quality Director	FLSA DESIGNATION: Exempt
DATE /WRITTEN/REVISED: 07/28/2020	HR APPROVAL/DATE: QA APPROVAL/DATE:

JOB SUMMARY:

QC Microbiology Manager is responsible for organizing and managing the Quality Control Microbiology Department and assuring that Microbiology Lab operations and testing are performed in compliance with applicable regulations, company specifications, procedures, and policies and current industry practices. The QC Microbiologist Manager is also responsible for leadership in all microbiological aspects relevant to manufacturing of product at New Vision Pharmaceuticals, alongside training and qualification of all QC Microbiologist personnel.

CORE DUTIES AND RESPONSIBILITIES:

The QC Microbiology Manager contributes to proper control of all aspects of the New Vision manufacturing facility that may impact microbiological quality including; manufacturing processes and equipment, materials utilized, physical facilities, environmental conditions, specifications, cleaning and sanitization, sampling and testing, employees, personnel practices and procedures, etc.

Must maintain proficiency in all Microbiology laboratory methods, processes, and procedures.

- Understands and complies with SOPs, Environmental, Health, Safety, and Quality requirements and applicable regulations. Maintains awareness of industry best practices.
- Monitor sampling and testing as required for environmental and personnel monitoring, samples of raw materials, in-process product, and finished product.
- Monitor sampling and testing as required for monitoring of critical systems; Purified Water, Clean Steam, Clean Compressed Air, etc.
- Monitor testing apparatus, solutions, media, cultures, and reagents as required.
- Monitor quantitative and qualitative microbiological tests such as for media controls, enumeration, sterility testing, absence of index organisms, classification and speciation, antimicrobial effectiveness, etc. performed by all QC Microbiology personnel.
- Trains and qualifies personnel for Aseptic Operations, Microbiological Sampling and Testing, and associated documentation. Trains Microbiologists, assigns tasks, monitors their performance, and reviews their testing and documentation.
- Reviews Laboratory Notebooks and Logs as detailed in applicable procedures. Produces periodic reports for tracking, evaluation of trends, associated metrics, etc.
- Monitor calibration checks and performance checks of instrumentation and devices such as RCS, pH meters, balances and refrigerators.
- Provides support of product development projects, investigations, monitoring of utilities systems, and the stability program.
- Reports out of specification results to the Quality Control Director as required under established procedures.
- Provides support for all testing, tasks, and documentation in support of Validation Studies including Process Validation, Media Fills, Method Validation, and development of analytical methods.

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- Writes and proposes revisions to Standard Operating Procedures, Analytical Methods, Lab Reports, and related Forms.
- Performs reviews in support of Validation, Document Control and Change Control systems.
- Responsible for co-coordinating and maintaining the stability program supporting new product development and existing products.
- Tracks and reports Quality System Metrics relevant to testing, OOS Investigations, and training in support of Quality Systems Reporting to management.
- Provides QA Support for Audits and Inspections.

SUPPORTIVE FUNCTIONS

In addition to performance of the essential functions, this position may be required to perform a combination of the following supportive functions, with the percentage of time performing each function to be solely determined by the manager based upon the particular requirements of the plant:

- Responsible for participation in internal plant audits.
- Functions as a technical advisor and problem solver for Microbiology related issues.
- Participates in cross-training in QA and QC areas of responsibility.
- Participates in the Safety Program to evaluate microbiological aspects of safety.
- Promotes safe operating and working procedures. Counsels and trains QC Microbiology employees in safety awareness, ensuring that safety devices, equipment and personal protective equipment are used as required.
- Provides support for process improvement teams and capital projects.

SPECIFIC JOB KNOWLEDGE, SKILLS AND ABILITIES

The individual must possess the following knowledge, skills and abilities and be able to explain and demonstrate that he or she can perform the essential functions of the job, with or without reasonable accommodation, using some other combination of knowledge, skills, and abilities:

- Must be proficient in analytical techniques and methodologies including membrane filtration methods, pour plate methods, gram stains, colony counting, and aseptic techniques.
- Experience in antimicrobial effectiveness testing, sterility testing, method validation, cleanroom practices, and equipment qualification preferred.
- Must be able to effectively communicate with large groups and work collaboratively.
- Excellent oral and written communication

PHYSICAL DEMANDS

- Must be flexible in terms of working hours to meet the requirements of the position.
- Must be willing and able to travel moderately for business purposes.
- Must have the manual dexterity to install and operate sensors, devices and instruments as required to perform duties and assignments of the position.
- Must be able to lift up to 35 pounds.

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- Must be able to wear respiratory, hearing, and other personnel protection as required for entry and work in New Vision facilities. Must be able to wear cleanroom attire as required for entry and work in the New Vision cleanroom facilities.
- Must be able to sit and/or stand for a minimum of 10 hours per day. Must be able to speak clearly on the telephone, sit at a desk, and work on a computer as needed
- Must be able to exert well-paced ability in limited space and to reach other locations of the plant on a timely basis.
- Must be able to bend, stoop, squat and stretch to fulfill cleaning and repair/maintenance tasks.
- Vision occurs continuously with the most common visual functions being those of near and color vision and depth perception. Must be able to tell color differences/have normal color vision.

CRITICAL TASK

- Performs laboratory investigations for out of specification (OOS) microbiological testing results, and other microbiological laboratory non-conformances using established procedures under the direction of the Quality Control Director.

QUALIFICATION STANDARDS

Education: BS degree in Microbiology, Biology, or related Science is required. Master's degree in Microbiology, Biology, or related science or an equivalent level of education, training, and experience is preferred.

Experience:

A minimum of 7-10 years of experience performing testing in a Quality Control Laboratory supporting FDA regulated manufacturing operations or equivalent level of experience. Excellent knowledge of FDA, USP, and cGMP requirements in a pharmaceutical quality control laboratory preferred

Grooming:

All employees must maintain a neat, clean and well-groomed appearance per Company standards.

This job description is not an exclusive or exhaustive list of all job functions that an employee in this position may be asked to perform from time to time.

Relevant position titles:

Senior QC Scientist

QC Senior Manager