Job Title: Sterility Testing Scientist II, QC Microbiology
Location: US-NJ-Lakewood

Overview:
The purpose of this role is to test and report cGMP test results for the Quality Control Microbiology Laboratory. This role also provides training and support for less experienced members of the laboratory.

Responsibilities:
• Follows current GMP requirements and complies with company safety and controlled substance handling policies.
• Performs sterility testing as per compendial requirements in an isolator setting
• Participates in repair and maintenance of lab equipment and lab housekeeping (disinfection and cleaning).
• Initiates, documents and performs microbiological analysis on received test samples (including raw materials, bulk, final product, stability, water) as per USP, in-house or customer methods. Evaluates, records and reports data under minimal supervision.
• Performs environmental monitoring, as required; Evaluates, records and reports data.
• Performs quality control testing of media, reagents, and identification materials.
• Maintains adequate inventory of media and materials required for testing.
• Initiates proper documentation upon discovery of deviations and out of specification results, completes Trackwise write-up for deviations and out of specification results.
• Performs special projects as assigned including testing, compiling and trending of data and report generation.
• Performs data entry for tracking and generates trend analysis reports for EM program, etc.
• Revises SOPs, forms, protocols and other controlled documents.
• Performs micro identifications using manual testing and automated systems.
• Maintains lab stock cultures for evaluative testing and make dilutions of stock cultures as required by procedure, protocol, or USP requirements.
• Maintains intradepartmental communication to support company goals.
• Reviews laboratory logbooks to ensure compliance with good documentation practices.

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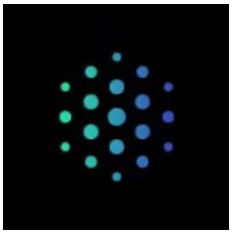

• Releases manufacturing areas after recovery using the ASCN in Trackwise. Writes Trackwise notifications and deviations and completes CAPAs. Creates and completes Trackwise change controls. Writes and revises SOPs, forms, risk assessments and other controlled documents.
• Interact with Operations staff to facilitate data and documentation corrections. Interacts routinely with departments such as Production, Quality Assurance and Regulatory Affairs.
• Creates purchase orders as needed.
• Flexibility in schedule is required.

Qualifications:
Bachelor's degree in biology, health science or microbiology.
2-5 years' experience in cGMP micro expertise.