



Position Description

Overview

Manager of Sterilization Technology
Libertyville, IL

Details

(Primary Qualification: 7-10years experience in microbiology)

A leader in the medical devices industry is looking to hire a Sterilization Manager as part of the Global Quality Management Microbiology/Sterilization Department. This position will manage the Sterility Assurance program for medical devices manufactured by the company. Position functions as the technical expert in sterilization and microbiological control issues.

Primary Responsibilities

Manage Development and Sterilization Validation for New Products – Perform testing and data collection for internally manufactured products sterilized with gamma radiation, ethylene oxide, or electron beam to meet current recognized standards. Coordinate sterilization validations of outsourced-manufactured products to ensure current standards are met. (20%)

Manage Sterility Assurance for Current Sterile Products – Perform testing and data collection for revalidation assessments and dose audits to allow Client to continue to market sterile products. Review sterilization standards and perform required testing to support authorized changes to processes, packaging, or sterile product to ensure the sterilization validation and requirements of current standards are met. Identify opportunities for cycle time reduction. (20%)

Support Clean room Operations – Review specifications for clean room operations, maintenance, and construction to ensure current standards are met. Assist in development of test plans, audits, and corrective actions for clean room functions. Provide training to associates working in and around the clean room environment. Trend clean room data and product bioburden data (20%)

Support Manufacturing Sites – Assist in investigations related to microbiology/contamination control/microbiology issues. Provide expertise to support ideas for improvement. (10%)

Manage Auditing Responsibilities– manage, schedule and perform plant independent audit of sterile products and clean room operations, audit clean rooms for outsourced-manufactured products, and audit contract sterilizer and laboratories to verify compliance to GMPs, current ISO standards, and Client specifications. (10%)

Microbiology Testing –Manage and oversee microbiology related work performed at contract laboratories. Assist in maintaining the in-house microbiology laboratory to provide in-house testing resources necessary to support the sterilization and microbiology testing of new products. Clean, sanitize, and dispose of returned products to support the Product Performance group. (10%)

Training/Educational Seminars – Provide training on clean room operations, sterile product handling, sterilization documentation review, and sterilization validations at all facilities. Coordinate tours of contract sterilizers and laboratories for associates from all facilities. Answer customer questions concerning sterilization of Client products. (5%)

Qualification and Management of Vendors and Contractors - Identify and technically qualify outside ETO, electron beam, and gamma irradiation processing contractors, testing laboratories, clean room support/supplies, and consultants as needed to insure the successful completion of scheduled events. Develop processing and testing agreements for new or improved products. Work with other functions as needed to resolve vendor problems related to sterile products. (5%)

Basic Position Requirements

- Academic/Credentials/Certifications: Degree in Microbiology, Biology, or equivalent (Masters preferred)
- 7-10years experience in microbiology area
- Minimum of 7years experience in sterilization technology with ethylene oxide and gamma radiation including validations and routine processing
- Experience in microbiology and sterility testing.
- Knowledge of standards including ISO 11135, ISO 11137, ISO 11737, and ISO 14644.

Physical Position Requirements

- Lifting – up to 50 lbs.
- Physical dexterity – for aseptic handling and computer keyboard
- Immunization VS Hepatitis B virus – biohazard control
- Ability to drive and have a functional vehicle - for travels to contract laboratories and sterilizers
- Ability to stand for long periods of time – for laboratory work
- Walking

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Cutting Edge *Connect* is a wholly owned subsidiary of Cutting Edge Consulting, Inc., an executive consulting firm with the goal of bringing talented individuals into quality organizations.

To speak with us directly, please contact:

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Partner

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To be considered for this position, please register with Cutting Edge *Connect* by completing the inquiry process. You will be notified by email when registration is complete.

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