





Did you know ...

there is company that is essential to healthcare worldwide?

Develop your career at a company that is dedicated to improving people's health across the world

BD Biosciences (BDB) is a worldwide technology leader producing instrument and reagent products for customers in research and clinical markets. BDB currently enjoys a leadership position in its primary business of clinical and research flow cytometry instruments and reagents. The Rouge Project serves the research arm of BDB called Life Science Research Reagents (LSRR) based in San Diego. The Rouge Project will establish a Process Center for the manufacturing of stable, mature research reagent products in Tatabanya, Hungary.

QUALITY CONTROL LEADER

Main Purpose of the Position

IAs directed by the Quality Manager, the QC Leader:

- Responsible for supervising quality control staff and for the development, implementation and maintenance of quality control systems/activities.
- Is accountable for management of the QC laboratory.
- Demonstrates to be highly proficient in all applicable QC techniques in the area, operation of relevant equipment and software packages associated with testing, data analysis and interpretation, and data reporting.
- Actively participates/supports in quality experiments, analysis/troubleshooting and investigation of anomalies and make recommendations/decisions for corrective/preventive actions and for customer feedback purposes.
- Set up operations, support/coordinate in product/technology QC transfer including document review, QC plans/specifications setup and writing new documentation, arrangement of training and sample testing, calibration/maintenance of laboratory instruments and completion of validation if needed

Primary Responsibilities and Duties

Plant start-up:

- Plant Start-up activities require the supervisor to set up the laboratory plan and product testing plan, per schedule and assignments.
- Establish and ensure proper maintenance of the cell bank.

QC activity:

- Responsible for implementation of QC tests, standards, methods and procedures for inspection, testing and evaluating the precision, accuracy and reliability of company products.
- Provide expertise on all aspects of QC testing and procedures for products and transfer of test procedures and methods.
- · Provides supervision to quality control staff with responsibilities for results in terms of cost, methods, and EH&S.
- · Ensure the routine, accurate and timely completion of all assigned QC tests. Ensures release of product on time to schedule.
- Coordinate the analysis of data, review/report test results including completion of all required documentation and database entries.
- · Provides technical and hands on support for the product analysis.
- · Provides technical guidance to resolve issues. Investigates testing anomalies and implements corrective actions.
- Responsible for providing the data for the department budget and management of its execution.
- Support analytical method validation efforts.
- Leads Continuous Improvement Projects.

Equipment & Material:

- Ensures that cleaning, maintenance and calibration of QC equipment take place according to schedule.
- Ensure the required documents/records are available.
- · Take lead for writing equipment approval protocol, coordinating the implementation and completing the report.
- Coordinate the purchase of equipment and supplies used in routine testing.

Vivarium Management

- Set up the Vivarium for plant start-up and ensure the relevant documents, procedures are in place and the required supplies available.
- Supervise vivarium associates and activities.
- Ensure the timely supply of animal tissues as requested by the departments.

People & Performance management:

- Executes assigned responsibilities related to hiring, job assignments, performance management, and employee motivation.
- Assures that Company policies and procedures are followed.

Training & Compliance:

- Managing/organizing/conducting the training of associates in required techniques, operation of equipment, or other relevant group or department procedures or practices and complete proper documentation.
- Maintain working knowledge of current industry and international standards.
- Promote a safe work environment.

Requirements (Knowledge, Skills, and Abilities)

- · Requires a Bachelor Degree in a related scientific discipline (such as biology, microbiology or immunology)
- Minimum of 6 years of experience in relevant industry including 3 years of experience in a supervisory role or equivalent combination of related education and experience.