

POSITION TITLE: Quality Control Technician

TECHNICIAN LEVELS / Level I

DEPARTMENT: Quality Control

APPROVED BY / DATE:

REPORTING RELATIONSHIPS:

POSITION REPORTS TO: Quality Manager POSITIONS SUPERVISED: None

POSITION PURPOSE:

The main focus of the role will be around laboratory activities relating to the validation and conduct of QC in process and release testing.

Additionally, assist in the ongoing maintenance and effectiveness of quality management system processes.

ESSENTIAL FUNCTIONS AND BASIC DUTIES:

- Contribute to implementation and compliance with the company's ISO13485 Quality System.
- Execute/oversee analytical methods (final product/incoming raw material testing) in line with GMP regulations and requirements, including Verification and Validation of QC release assays
- Schedule analyses in line with manufacturing schedules
- Inspection (including testing) and handling of incoming goods
- Compliance with laboratory safety (Such as COSSH, Health and Safety, Calibration, Raw material maintenance)
- Non-Conformances, Deviation, CAPA, OOS and Root Cause Investigation
- Develop laboratory protocols for lab equipment
- Perform IQ/OQ/PQ on new equipment
- General laboratory housekeeping and GMP activities
- Carry out process control procedures, e.g. environmental monitoring
- Contribute to the ongoing quality system improvements
- Work with other functions to resolve quality/process issues and ensure adequate control of materials and processes
- Writing and implementing procedures
- Assist in risk management processes
- Tracking calibration and maintenance requirements
- Assist in implementing and maintaining 5S within the Laboratory
- Any other duties reasonably requested by Senior Management or the Board of Collagen Solutions

QUALIFICATIONS

EDUCATION/CERTIFICATION:

BSc (or equivalent) is essential MSc desirable



QR-62-01-3

REV : 005

REQUIRED KNOWLEDGE:

Knowledge of ISO13485 and GMP is desirable

EXPERIENCE REQUIRED:

Laboratory experience is essential Industry experience desirable Experience of working in a GMP laboratory would be advantageous

SKILLS ABILITIES:

- Excellent attention to detail
- Demonstration of problem-solving skills

OTHER REQUIREMENTS:

PHYSICAL STRENGTH: Ability to lift and/or carry > 50 lbs./22 kgs.

LANGUAGE ABILITY: Proficiency in English

LEVELS DEFINED AS:

Level I: Laboratory experience required Level II: Minimum 1-2 years' experience as a level I quality control technician Experience of performing data checking of laboratory worksheets Experience of performing training for relevant QC technicians

INTENT AND FUNCTION OF JOB DESCRIPTIONS

Job descriptions assist organizations in ensuring that the hiring process is fairly administered and that qualified employees are selected. They are also essential to an effective appraisal system and related promotion, transfer, layoff, and termination decisions.

All descriptions have been reviewed to ensure that only essential functions and basic duties have been included. Peripheral tasks, only incidentally related to each position, have been excluded. Requirements, skills, and abilities included have been determined to be the minimal standards required to successfully perform the positions. In no instance, however, should the duties, responsibilities, and requirements delineated be interpreted as all-inclusive. Additional functions and requirements may be assigned by supervisors as deemed appropriate.

Job descriptions are not intended as and do not create employment contracts. The organization maintains its status as an at-will employer.