

## Quality Control Technician with Advanced Skills

### SUMMARY

Responsible for assay assessment, development, implementation, and validation for use evaluating human biologic drug products manufactured in a cGMP environment. It is also the responsibility of this position to troubleshoot any problems that may arise and to be up-to-date on all methods applicable for QC testing. Set-up, organization, and day-to-day operations of a Quality Control Laboratory are also required.

**ESSENTIAL DUTIES AND RESPONSIBILITIES** include the following. Other duties may be assigned.

#### Responsible for QC assays as follows:

- Gel electrophoresis
- ELISA Assays
- HPLC Analysis of Plasmid iso-forms
- qPCR Gene Expression and Genomic
- Mammalian Cell Culture and Transfection
- Wet Chemistry Techniques

#### Responsible for Testing as follows:

- In-process testing
- Release testing
- Stability testing

#### Responsible for Method Qualification and/or Validation

- Qualification of USP/compendia methods
- Tech transfer of assays
- Test Method validation
- Qualification of new equipment

#### Responsible for documentation/administration as follows:

- Organize all accumulated data
- Keep notebook up to date and signed
- Write Protocols for test method validation and Qualifications
- Write development reports, validation and other relevant technical reports
- Writing SOP's, testing records and protocols

#### Responsible for QC analysis as follows:

- Spectramax software
- qPCR software
- HPLC software
- Gel imaging software
- Excel and word software

### REQUIREMENTS:

- Candidates should have a Bachelor's or Associate's degree and 3+ years of relevant experience and 2-5 years of assay development experience.
- Applicants must have a life sciences, molecular biology, microbiology or chemistry background.
- Experience with qPCR is a must.
- Experience with chromatography, gel electrophoresis and microbiology techniques are preferred.
- Method development and optimization experience in a cGMP environment is a plus.

Contract to hire position.

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