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2301 E 60th N, Sioux Falls, SD 57104
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# Research Associate (QC)

## JOB DESCRIPTION

JOB TITLE: Research Associate (QC)
RECORD:
FLSA STATUS: Exempt
LOCATION: Sioux Falls, SD

REPORTS TO: Quality Control Manager
UPDATED: 28 MARCH 2019
DEPARTMENT: QUALITY CONTROL

**Position Summary:**
The Quality Control (QC) Research Associate will be responsible for supporting and conducting analytical assays for clinical release and stability testing for all immunotherapeutic programs within the QC laboratory. This position will focus on the optimization, qualification, validation, performance and transfer of analytical methods. The scientist will execute these tasks within a matrixed team environment and support general day-to-day lab operations and maintenance of equipment in the QC laboratory.

**Essential Duties and Responsibilities:**
With moderate supervision while demonstrating independent ownership of key program tasks responsibilities will include but are not limited to:

- Performing QC analytical assays for release and stability testing in support of the immunotherapeutic programs using standard and specialized analytical methodologies for testing antibodies, including but not limited to: ELISA, PCR, HPLC, aseptic technique and physical property characterization.
- Working under GLP and/or cGMP laboratory guidelines.
- Maintaining accurate QC records, inventories and data spread sheets.
- Maintaining scientific Laboratory Notebook details as needed.
- Independently author and update related SOPs, data records, and development reports.
- Qualifying and/or validating analytical methods to support clinical product testing.
- Transferring analytical methods from R&D to QC laboratory and assist in optimizing and developing assays to support in-process, lot release and stability testing of clinical and/or commercial products.
- Maintaining equipment used in the QC laboratory.
- Supporting general laboratory operations including, preparing buffers, ordering and maintaining supplies as needed, and keeping track of samples.
- Scheduling and general cleaning of the QC laboratory and support cleaning of the cGMP facility.

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- Coordinating and communicating with third party laboratories and vendors.
- Reliably meeting project or initiative timelines and revise work plans as needed to address changes in project scope, priorities or timing.
- Participating in functional and cross functional team meetings and conferences to promote the advancement of product quality control scientifically and in compliance with cGMP.

**Qualifications:**
To perform this job successfully, an individual must be able to perform each essential duty satisfactorily. The requirements listed below are representative of the knowledge, skill, and/or ability required.

**Education, Experience and Certifications:**

- Bachelor's degree and 2-3 years of industry experience or associates degree and 6+ years of relevant experience.
- 1-2 year's experience in a cGMP laboratory highly desired.
- Background and familiarity in standard and specialized analytical methods for biologic product testing.
- Strong organization skills and/or experience with project management.

**Language Skills:**
Individual should possess strong communication skills and proficiency in Microsoft Office software (Word, Excel, PowerPoint and Outlook) as well as the ability to effectively present information in one-on-one and small groups.

**Mathematical Skills:**
Basic mathematical skills to consist of addition, subtraction, multiplication and division. Understanding of basic statistical analysis and capable of calculating concentrations, dilutions, molarity.

**Physical Demands:**
While performing the duties of this job, the employee is regularly required to walk, stand and sit. The employee must be able to move up to 50 pounds. Specific vision abilities required by this individual include close vision, peripheral vision, and the ability to adjust focus. The employee will view a computer monitor for long periods of time.

**Physical Requirements/Working Conditions:** Job requires good physical mobility. Ability to move over 50 pounds by mechanical means. Be able to sit for extended periods of time.

**Working Environment:**
Duties will be performed in both a standard BSL1 laboratory and a BSL2 laboratory.

**ADA:**
The employer will make reasonable accommodations in compliance with the Americans with

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Disabilities Act of 1990.

*This job description will be reviewed periodically as duties and responsibilities change with business necessity. Primary and additional duties and responsibilities are subject to modification.*

*I have read and understand the responsibilities of the position. I also understand changes can be made as needed.*

_____ _____

EMPLOYEE DATE

_____ _____

SUPERVISOR DATE