

## **JOB DESCRIPTION**

### *Senior Consultant, Analytical Services*

#### **Essential functions:**

- Manages multiple analytical projects related to the development, qualification and/or troubleshooting of sensitive, efficient, and reliable assays for a wide class of biological molecules simultaneously.
- Prepares, reviews, and edits analytical method development, transfer, qualification, and validation protocols and reports.
- Writes CMC regulatory documentation for analytical methods.
- Provides technical expertise and advises project representatives/teams on topics pertaining to biopharmaceutical analysis and CMC development, including: assay development and selection, structure-activity relationships, product characterization and comparability strategies, impurity identification, Quality-by-Design, Process Analytical Technology, product quality attribute classification, and study design. Often presents findings and/or results to client senior management.
- Communicates effectively in a timely manner with external and internal clients regarding technical, scientific and other project related issues and progress.
- Provides technical guidance to others in resolving challenging issues relating to analytical methods
- Supports marketing efforts by participating in new client pitches and actively seeking repeat business opportunities
- Keeps current with technical developments in the industry and regulatory agency thinking.
- Types of Projects: Recombinant proteins, peptides, oligonucleotides, cell and gene therapies

#### **JOB REQUIREMENTS**

##### **Competencies (“soft skills”, traits, behaviors):**

- **Self-motivated**
- **Results oriented**
- **Detail oriented**
- **Shows initiative**
- **Creative thinker**
- **Focused on continuous development**

##### **Knowledge/Skills/Abilities:**

- Thorough understanding of a wide spectrum of analytical technologies, method development, method qualification/validation, and global regulatory analytical requirements
- Laboratory experience performing method development, transfer, qualification, and validation activities
- Experience with multiple compendial methods such as pH, endotoxin, and UV assays
- Experience with chromatographic assays
- Experience with bioassay and/or potency assays a plus
- Regulatory experience preferred
- Proven ability to successfully work in a team environment
- Excellent oral and written communication skills
- Ability to make independent decisions
- Willingness to travel (up to 50% once deemed safe to travel again)

##### **Education/Experience:**

- PhD in Analytical Chemistry, Biochemistry, or related discipline, with 4+ years relevant experience