



Job Title: Contractor (Scientist or Senior Research Associate level)
Job Type: Contract / Temporary
Job Hours: 40 hours per week, Monday through Friday
Reports to: Director, Analytical Development

Summary

In this hands-on temporary position, this person will develop analytical methods for characterization of products and provide analytical support for process development and manufacturing. When needed, this person will perform assays in compliance with cGMPs. Other responsibilities may include developing appropriate quality measures for Xcellerex's disposable products, developing, validating, transferring and executing assays, characterizing products and processes, work staffing, training and creation of documentation.

Essential Functions:

- Provide expertise in chemistry and analytics related to Xcellerex's products.
- Work with QA and Engineering to develop appropriate Quality systems for Xcellerex's products.
- Perform method development, assay validation and characterization for multiple projects.
- Coordinate outsourced testing.
- Actively participate on project teams
- Perform data reviews, prepare reports and quality documents.
- Prepare analytical sections of regulatory filings.
- Supervise additional personnel.
- Develop and implement rapid methods for process monitoring
- And any other duties assigned by management.

Knowledge, skills and abilities

- Extensive technical experience in analysis and development of pharmaceuticals, biologics and devices.
- Comprehensive understanding of protein chemistry. Familiarity with viral systems is a plus.
- Demonstrated knowledge of modern analytical techniques, including ELISA and cell-based assay experience, HPLC, capillary electrophoresis, mass spectrometry, quantitative PCR, gel electrophoresis.
- Experience in development & validation of methods destined for QC in the pharmaceutical industry.
- Understanding of current Good Manufacturing Practices (cGMPs).
- Proven team player with well-developed interpersonal and mentoring skills, excellent organizational skills, communication skills, including written documentation skills and presentation skills.

Working conditions

Most work will be performed in the Xcellerex Analytical Development/Quality Control laboratories.

Minimum Qualifications:

- Bachelor's degree in a scientific discipline with 10 years of experience; or a Master's degree with 5-7 years experience; or a Ph.D. with 3 years experience in analytics for products regulated by the FDA.
- Outstanding capabilities in fostering multi-disciplinary teamwork and adjusting priorities in response to changing conditions and schedules.
- Willingness to work in compliance with GMPs when needed.