



Analytical Development Scientist: Cell Therapy, Molecular & Cell Biology Potency Assays
Location: Worcester, Boston areas

We are seeking a highly motivated Analytical Development Scientist, Cell Therapy to join our Analytical Development team. The successful candidate will have a background in virology, immunology, molecular and cell biology, and will be a part of our analytical development group focusing on design and development of molecular and cell-based methods for the characterization of cellular therapeutics before and post treatment to support process development, manufacturing, correlative sciences and clinical development of drug products at all stages.

Responsibilities:

- Apply expertise in virology, immunology, cell biology or molecular biology, to analytical design and development, establish new analytical methods and standard procedures for product characterization, product release and clinical assays.
- Lead the technology transfer of analytical methods to QC and support analytical method qualification and validation.
- Lead clinical assay development and transfer to CRO and support assay validation and clinical correlative data analysis.
- Support process development for the design and development of new cell and gene therapy products.
- Support clinical manufacturing for product characterization.
- Author and review technical documents such as methods, qualification/validation protocols and reports.
- Serve as analytical subject matter expert to solve technical challenges and support laboratory investigations.

Qualifications:

1. BS with 5-10 years, MS with 3-5 years relevant experience, or PhD in virology, molecular biology, immunology, biochemistry, cellular biology, pharmaceutical sciences or a closely related field.
2. Extensive knowledge and hands-on experience in the following areas:
 - Must have experience in PCR, qPCR, virus titration assay, immune cell subsets; experience with bioinformatic analysis is preferred.
 - Experience designing and developing molecular and cell assays.
 - Experience with primary cell culture and cell functional characterization assays.
 - Critical thinking, scientific reasoning and problem-solving skills required.
 - Knowledge of cGMP pertaining to the pharmaceutical and biological industries is a plus.