
July 29, 2010

Position Title: Director of Assay Development

Integrated Biotherapeutics, Inc. (IBT) is seeking a highly motivated, skilled and interactive individual to lead an Assay Development group. The successful candidate will serve as both the technical and administrative lead for IBT's program responsible for development, optimization and execution of analytical methods supporting the development and characterization of IBT's vaccine candidates.

Duties:

- Individual will lead a team of 4-6 scientists to support IBT's vaccine development activities by designing and executing proper assays for lot release, product characterization and product stability.
- Provide technical guidance on development activities and coordinate all analytical development activities.
- Oversee generation of Assay Development Reports and operating procedures and perform comprehensive reviews of all documentation to ensure they are comprehensive, accurate and acceptable for ultimate submission to funding or regulatory agencies.
- Prepare monthly Assay Development Status Reports
- Ensures completeness and content of assay transfer packages to CMO in support of upstream and downstream process development. Conducts site visits at CMO ensure successful assay transfer.
- Work with Project Manager to develop and maintain activity plans and schedules.
- Working with senior management, the Director of Assay Development will use his/her scientific expertise and insights to weigh in on strategic decision-making regarding company's product portfolio and will represent IBT at technical meetings with clients with focus on analytical development activities.
- Clearly and appropriately communicate with internal colleagues and direct reports, as well as external subcontractors or collaborators regarding analytical assay development.
- Perform all responsibilities in accordance with company guidelines and Standard Operating Procedures and appropriate industry and regulatory standards, guidelines, rules and regulations.
- Perform activities and duties using proper documentation and records towards Good Documentation Practices.

***Required Qualifications:**

- PhD in Molecular, Cellular Biology or related disciplines
- 10+ years experience in biotechnology or pharmaceutical industry with primary focus on assay development, as well as experience in assay transfer, and assay validation for GMP/GLP testing of products manufactured for human use.

- Demonstrated ability to lead team in designing experiments, setting milestones and meeting objectives.
- Excellent knowledge of vaccine product development and experience with regulatory requirements
- Excellent organizational, problem-solving, technical writing and verbal/written communication skills

Qualified candidates should contact:

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