Job Title: Analytical Development Scientist

List Biological Laboratories, Inc. is a privately held company located in Campbell. The company specializes in the production of both native and recombinant bacterial toxins used for research purposes as well as GMP toxins and live biotherapeutic products, for exciting and emerging industry, for use in clinical trials use.

List Labs offers a congenial small company environment and the convenience of working in the South Bay Area.

We are seeking a talented and motivated Analytical Development Scientist to support our Quality and Compliance Department. This position is a key role within the Quality and Compliance Department. The individual will help define and develop the analytical method development function. This function develops and maintains in-depth understanding of the scientific principles associated with various analytical methods to support drug substance and drug product development at various clinical stages as per ICH guidelines and provides support to drug substance and drug product characterization, process development and stability assessments.

ESSENTIAL DUTIES AND RESPONSIBILITIES

- Analytical methods development, optimization, validation/qualification, and transfer to QC for routine release and stability testing
- Deep technical and scientific knowledge of analytical technique, software, and instrumentation, such as HPLC, spectrophotometric assays, immunochemical methods, titration assays, SDS PAGE, ELISAs, enzymatic assays, cellular cytotoxicity
- Apply scientific knowledge and/or with collaboration with technical subject matter experts develop separation methods, e.g. RP, IEX, HILIC, SEC and Protein A affinity chromatography for quantitative and qualitative analysis of impurities in drug products
- Adopts and develops next-generation analytical platforms for better characterization and extend our understanding of our products
- Serves as analytical lead in multidisciplinary project teams and/or sub-team meetings within the company or with clients
- Develop, qualify, validate assays/ methods with minimum supervision, write SOPs and transfer methods to QC department as needed
- Design experiments and write protocols for assay development and validation
- Perform assays or supervise other analysts for assay development and validation work
- Analyze experimental data with appropriate statistical tools and report scientific results
- Interpret data and adhere to strict guidelines on documentation when recording data
- Review and/or approve cGMP documentation generated by other analysts in the laboratory if necessary

- Contributes to building a culture that encourages continuous learning, improvement, and innovation, and encourages team members to expand their technical skill base

QUALIFICATION AND EXPERIENCE

- B.S. or M.S. preferably in biological sciences or related field
- A minimum of 5 + years of relevant experience in Biotechnology or Pharmaceutical industry

KNOWLEDGE, SKILLS AND ABILITIES

- Works on complex problems in which analysis of data requires evaluation of identifiable factors
- Exercises judgment within generally defined practices and policies in selecting methods and techniques for obtaining solutions.
- Is familiar with regulatory guidelines pertaining to assay development, qualification, and validation
- Understands analytical development and uses published literature to extend understanding, as well as consulting internal and external experts as needed
- Ability to generate new experimental proposal built on existing methods or techniques
- Highly independent and self-motivated and integrates well within a team
- Strong ability to trouble-shoot technical problems
- Good organizational skills with ability to meet deadlines and prioritize work on multiple projects
- Excellent oral and written communication skills
- Dedicated, hard-working and dependable