

SCIENTIST

Professional Summary

Extensive experience in immunoassay method platforms, including ELISA, ECL (MSD), Luminex, and Flow Cytometry. Directs and hands on involvement with method development, validation, optimization and troubleshooting of cytokine, clinical biomarker and PK assays. Oversee the technical transfer, development, and validation of outsourced immunoassays. Cross-functional team member for pre-clinical to clinical transition. Team lead with outsourced production and program management of polyclonal and monoclonal antibodies against drug product. Provide support and expertise to clinical teams regarding the measurement of biomarkers in support of clinical trials. Proficiency with cell culture techniques, transfections, protein production and purification. Cell based and in-vitro assay development, validation, and screening for drug discovery. Responsible for 1.5M dollar budget for Reagents driving key therapeutics. Understands and complies with Safety, Good Laboratory Practices (GLP), Good Manufacturing Practices (GMP) and Standard Operating Procedures (SOP) and Policies. Excellent communication, data analysis, and presentation skills.

Skills

ELISA

MSD

Luminex

Flow Cytometry

Multiplex

Assay Development

Assay Validation

Work History

Scientist 04/2013 to Current

Aaipharma â€“ Morrisville , NC

- Team lead for ELISA assay development and optimization of metabolic hormone panels in support of stem cell diabetes program.
- Managing CRO transfer of biomarker assays for preclinical and animal tox study.
- Investigating new strategies to advance drug discovery objectives: evaluated potential new biomarker assays, new technologies, addressing questions related to physiological responses to candidate therapy Multicolor surface and intracellular Flow Cytometric analysis of stem cells.
- Qualifying and validating Flow Cytometry and ELISA based Assays under GMP regulations.

Research Scientist II 01/2006

Exact Sciences â€“ Albany , NY

- Operations team lead with outsourced production of polyclonal and monoclonal antibodies against drug product.
- Involved in scheduling, data review, screening and overseeing projects to support studies in Pharmacokinetics, Immunogenicity and Biomarkers.
- Develop, optimize and troubleshoot new and existing biomarker and PK assays using ELISA and Multiplexing platforms including MesoScale and Luminex.
- Evaluate and implement new technology to improve laboratory efficiency and expand in-house assay portfolio.
- Coordinate method transfers, testing, reporting schedules and prioritization across multiple nonclinical and clinical programs, compounds, and collaborations.
- Exert scientific leadership to the technical staff and devise methods, formulas, and processes for the solution of technical problems that may arise.
- Provide support for in-house and CRO outsourced projects and personnel.
- Continuous improvement of laboratory compliance with GLP, regulatory guidance, industry best practices, and scientific reasoning.

Research Scientist 08/2004 to 01/2006

Danaher â€“ Carlstadt , NJ

- Expanded responsibilities included assay optimization, tissue culture, cellular differentiation, antibody staining and Flow Cytometry (FACS) analysis of cells for clinical assays.
- Responsible for the pneumococcal vaccine programs Opsonophagocytic Bioassay to test for Antibody dependent activity in Human Serum.
- Participated in scientific projects supporting existing techniques which included assay troubleshooting and streamlining current protocols.

Associate Scientist 09/1998 to 08/2004

Apex Systems â€“ Lansing , MI

- Daily work included method and assay development and validation of clinical and pre-clinical flow cytometry based assays, including those for viral gene therapy, cytokine, receptor, expression and binding assays.
- Developed and authored validation protocols, TPs, and SOPs.
- Evaluated experiments to optimize and test existing and new techniques and technologies.
- Participated in scientific projects supporting existing techniques, working independently as well as in a team.
- GLP/cGMP biotechnology committee member.
- Performed Microbial limits testing, Tissue culture, ELISA and Immunohistochemistry.

Graduate Research Assistant 05/1996 to 09/1998

University Of Kansas â€“ Lawrence , KS

- Performed microsurgery and analyzed various injected agents on chick embryos.

- Prepared slides and performed immunohistochemical analysis of tissue.
- Performed cell culture of mammalian tissues.

Education

M.S : Biology 1998 Seton Hall University - City , State Biology

B.S : Biology 1 1996 Seton Hall University - City , State Biology

Affiliations

American Association of Pharmaceutical Sciences (2006-Present)

Skills

Continuous improvement, ELISA, GLP, GMP, leadership, Team lead, Managing, optimization, personnel, processes, protocols, reporting, scheduling, scientific, TPs, troubleshoot, troubleshooting, validation

Additional Information

- AWARDS Janssen Encore Award (2014) Bristol-Myers Squibb R&D Triumph Award (2010) Bristol-Myers Squibb R&D Galaxy Award (2010) Bristol-Myers Squibb R&D Star Award (2007, 2008, 2009, 2010, 2011, 2012)