Vaishnavi Kommareddy

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Professional Summary

With 10 years of extensive experience in advancing novel scientific technologies and bringing therapy to life, I am highly skilled in developing and commercializing the therapeutic discoveries, allowing the patients to benefit from life-saving and life-enhancing treatments. With extensive experience in Research, quality control and manufacturing I am adept in navigating regulatory requirements ensuring compliance with 21 CFR Part 11, 21 CFR Part 820, and other GxP (GMP, GLP) regulations, as well as Good Documentation Practices (GDP). My expertise includes the design, development, optimization, and validation of immunoassays, and I am proficient in producing high-quality technical documents that meet rigorous standards. Known for effectively resolving complex problems in deadline-driven environments, I play a critical role in both collaborative team settings and independent roles, where my strong interpersonal skills and scientific acumen support successful project execution.

Work Experience Scientist, Bioassay services, 03/21/2022 to present

Lonza, Houston, Texas

- Specialized in leading and managing technical projects that bring cutting-edge therapies to life. My expertise lies in ensuring compliance with stringent FDA regulations and industry standards, particularly in medical device and therapeutic development, to guarantee patient safety.
- Lead and managed technical projects and met project timelines including but not limited to process development, qualifications, characterization studies, validation and post commercialization support.
- High skilled in assay qualifications and validations while maintaining compliance with FDA regulated GMP and GDP requirements.
- Responsible for developing assays, optimization and evaluating methods received from clients for gaps prior to starting transfer activities.
- Interact with clients in Joint Project Team meetings regarding method development , optimization, qualification, validation and technical challenges.
- Cross train analysts and and manage technical team as well as train QC Analysts on new methods during Assay Tech Transfer.
- Serve as SME for assays including but not limited to Flow cytometry, qPCR, cell culture techniques, ELISA, Potency and other quantitative assays.
- Interact with QC on equipment platform alignment and assay qualification or validation strategies.

Senior Research Scientist, 01/01/2018 to 03/18/2022

Ansh Labs, Houston, Texas

- Designed, Optimized, Documented and Validated Immunoassays to quantify biological markers for predicting pregnancy associated disorders and metabolic disorders.
- SME for ELISA, cell culture and western blot with 8 years of development experience.
- Manufacturing lead for large scale operations including commercial ELISA kits.
- Adept in developing and documenting Validation Summary Report (VSR), Standard Operating Procedures (SOPs) and Work Instructions (WIs).

- Prepared documented procedures for validation of assays to ensure compliance with FDA regulations.
- Skilled in Design Of Experiment (DOE) methodologies for multiple research and development projects and actively involved in reviewing and evaluating experimental data.
- Developed customized assays for clients based on their specifications and provided technical support for newly developed assays.
- Good Knowledge in developing, executing and reviewing IQ/OQ/PQ test scripts, Risk Assessments, Regulatory Assessments.
- Investigated and initiated nonconformance reports for reagents that do not adhere with the quality control specifications and presented CAPA as per regulatory guidelines.
- Interacted with Research Organizations and other testing facilities to provide support and drafted necessary documentation for appropriate transfer of scientific knowledge.
- Responsible for drafting batch summary reports for executed manufacturing campaigns to support client needs.
- Collated data to create summary reports and revised procedures and protocols to support manufacturing activities.
- Independently worked on root cause analysis and provided scientific justifications in deviation assessment.
- Trained and supervised the manufacturing team with the work protocols, proper equipment handling and good documentation practice.
- Developed multiple novel immunodiagnostic kits and presented a consolidated Poster Abstract at the annual congregation for American Association of Clinical Chemistry, 2018 : Preeclampsia 1

Research Scientist, 01/2015-12/2017

Ansh Labs, Houston, Texas

- Developed customized assays for clients based on their specifications and provided technical support for newly developed assays.
- Developed protocols and reports for routine methods used in the laboratory.
- Drafted as well as reviewed Standard Operating procedures (SOP's) for the various functions of the systems.
- Authored and reviewed user manuals and summary reports.
- Established the manufacturing procedures for the monitoring, operation, and control of the devices and equipment.
- Performed and implemented peer reviews of product documentation.
- Updated support documents for utilizing the functionalities of the equipment and support.
- Conduct literature reviews on materials used in device for biocompatibility evaluation.
- Adept in handling customer complaints and managing after sales processes.
- Skilled in analyzing and applying scientific theories, techniques, and regulatory requirements in bioanalytical studies for developing scientific approaches in product development.
- Developed Novel assays as well as Co-Authored and presented the following posters in the 98th Annual Meeting of the Endocrine Society, April,2016.
    - IGFBP1
    - Inhibins and activins 1

- Website published :
- ENDO 2016: The 98th Annual Meeting & Expo
- ENDO 2016: The 98th Annual Meeting & Expo

R & D Manufacturing Intern, 04/2014 to 12/2014

Ansh Labs- Houston, Texas

- Prepared and validated critical assay reagents and buffer solutions in adherence to ISO and FDA guidelines in a GMP environment.
- Generated reports and technical protocols, SOPs/ test procedures, for reliable, sensitive, and validated methods of analyses to meet Good Documentation Practices (GDP).
- Hands on training in Cell culture basics including cell counting and viability determination, development of growth curves, growth of adherent and suspension cells, transfection technologies for recombinant protein expression in animal cells, cryo-preservation and cryo-thawing of animal cells, cell cloning and primary cell culture.

Teaching Assistant-Quantitative Analysis Lab, 08/2013 to 12/2013

University of Houston-Clearlake-Houston, Texas

- Develop analytical methods for quantitative and qualitative analysis of ionic compounds.
- Training and tutoring undergraduate students in the instrumentation and their analytical methods to enhance their laboratory skills.
- Maintain lab equipment and aid in troubleshooting process.

Intern, 03/2012 Pharma-Train

- Underwent training of the instruments like Reverse Phase HPLC and GCMS for Quantitative and Qualitative Analysis of the drugs.

Intern-Lab Technician, 06/2011

Yegna Manojavam Drugs and Chemicals, LTD.,

- Underwent training in Quality Assurance and Quality Control departments using HPLC analyzing technique involved in chemical laboratories.

Education

- Master of Science, Chemistry, December 2013
  University of Houston-Clearlake-Houston, Texas
- Bachelor of Pharmaceutical Science, June 2012
  Jawaharlal Nehru Technological University-Hyderabad, India
- Harvard University , CRISPR Gene Editing applications- Certification Course, 2019