

SENIOR SCIENTIST

Objective

A challenging opportunity in Assay Technology Assessment and Evaluation.

Skills

- Time Management and Organizational Skills.
- Quickly adapt to changes to realign
- Problem solving and analytical skills.
- Interpersonal and Leadership
- Project Planning and Scheduling
- Customer Service
- Quality Control/Assurance
- Clinical Trial Management
- Experimental Design, Data analysis, and Interpretation
- Understand FDA submission process (510K and CBE-30)
- Process Excellence Six Sigma Green Belt Certified (SIPOC, FMEA, Gage R&R, DOE; etc.)
- Immunodiagnostic Assays development (Infectious Disease, Cardiac, Sepsis; etc)
- Strong background with VITROS analyzers and assays.

Education and Training

Bachelor of Science : Medical Technology 2001 State University of Buffalo , City , State

Clinical Laboratory Technologist New York State Licensure (License No: 012588) 2007

ASCP certified Medical Technologist 2002

Process Excellence Green Belt Certification 2005

Good Clinical Practice Training 2007

Experience

Catalent Pharma Solutions, Inc. San Diego , CA Senior Scientist 03/2016 to Current

- Led and maintained multiple assay projects simultaneously for the Assay Architecture Team.
- Planned assay evaluations aligning to project timelines to meet strategic imperatives.
- Led assay assessment, analysis drawing, and conclusions to move forward the assay design.
- Performed research to assist with assay development to enhance or troubleshoot assay performance.
- Mentored other scientists to further their developmental growth.
- Wrote Technical Documents.
- Presented to cross functional teams.
- Presented project outcome to customer forum, such as AACC.

American Chemical Society Columbia , MD Scientist II 02/2005 to 02/2016

- As a Scientist II I have been requested to assist within many projects within multiple platforms from Assay Architecture (Phase 0 to Phase 1 assay assessment), Point of Care assay and system development teams, Assay and System development for Donor Screening, Immunodiagnostic Assays and Dry Slide Technology platforms, and Site Management for Internal and External Validation Trials for the VITROS 5600/3600 Platforms.
- Within these various roles my responsibilities included the following:
- Initiate experimental design and assisted with project planning to meet project goals.
- Execution of experimental design and Interpretation of data.
- Interfaced with cross-functional teams.
- Authored FDA submission documentation, Strategy documents, FMEA assessments, verification/validation/technical reports, and experiment summaries.
- Presented technical data to internal (i.e. Team meetings, Assay Review board) and external venues (i.e. AACC).
- Led various Assays and System assessments.
- Led laboratory test schedule and tasks.
- Site Manager for external trials.
- Prepared contracts, financial disclosures, and test protocols.
- Managed IRB submissions and sample collection.
- Conducted protocol training, site start-up/close-out visitation, and continued site supervision.
- Liaison between OCD lawyers and customer site to complete Trial Contracts.
- Established a refurbishment program for the 5,1FS (at the time there was no process in place).

Wuxi Aptec Natick , MA Scientist I 08/2003 to 03/2005

- Development of Infectious Disease/Transfusion Medicine/Immunodiagnostic Assays
- Maintained lab quality control
- Executed and documented experimental test designs for donor screening and diagnostic assays, feasibility of a new donor screening system

Peoples Bancorp Inc. Hillsboro , OH Technical Support Specialist I 07/2001 to 08/2003

- Provided customer assistance for the Clinical Chemistry and Immunodiagnostic Division
- Provided troubleshooting assistance and resolution for customer equipment and assay complaints/concerns for all

Chemistry/Immunodiagnostic analyzers (DT60, 250, 550, 750, 950, and ECI)

- Assessed chemistry issues for potential Health and Safety, and reported events to Quality Assurance/Customer Quality personnel following FDA required protocol
- Documented customer interaction and resolution within call management system

Computer Skills

- Proficient with Microsoft Office Word, Excel (Analyze-It), Outlook, and Power Point applications.
- Familiar with Microsoft Access and Project
- Proficient with the following data analysis tools: Statistica (CLIA), Minitab, Microsoft Excel Analyze-IT, OARS
- Certified Process Excellence Six Sigma Tools SIPOC, FMEA, Gage R&R, DOE design and analysis, in addition to other specific OCD analysis tools

Activities and Honors

ASCP

AACC