ANALYTICAL RESEARCH SCIENTIST

Summary

Ready to assume the leadership responsibilities of a fast-paced high pressured environment, to serve and improve product quality and turnaround time. To direct the process improvement initiatives of a global leader, design, implement and support the adherence to corporate goals, collaborating with employees, customers and suppliers, insuring continuous improvement of process, products and services.

Highlights

- Data analysis
- Perform timely reviews
- Prioritize tasks
- Conduct lab investigations
- Participate in audits
- Prepare SOP's
- Knowledge of cGMP's
- Trouble-shooting issues

Professional Experience

06/2013 to 01/2016

Analytical Research Scientist Emd Millipore - Santa Fe De Bogota , CO

- Develop and initiate analytical assay plans for novel and routine customer products.
- Demonstrate the ability to be flexible to adapt to shifting project time lines.
- Establish benchmarks for on-quality technology transfer to GMP QC/Manufacturing.
- Demonstrate the ability to maintain customer focus of multiple projects.
- Demonstrate the ability to effectively execute and communicate assigned tasks and conduct complex assignments.
- Assist in the development of new products by providing analytical support as required for all assigned projects.
- Generate written and oral reports (e.g.
- progress reports, experimental results, marketing data, etc.) and effectively present the information.
- Support and coordinate analytical testing needed for successful transfer of products and manufacturing processes to the Transfer group and Operations.
- Develop appropriate analytical specifications, experimental design, method development and documentation required for successful transfer of products.
- Assist in the development of new assays for Quality Control/Analytical Services.

07/2007 to 12/2012

Senior Associate Scientist Emd Millipore - Schnelldorf , DE

- Spearhead sample testing primarily by HPLC, SEC-MALLS and capillary electrophoresis in support of Biologics Process
- Development and DAI studies Instrumental in performing routine testing and participate in activities such as assay troubleshooting and assay optimization
- Analyze level of impurities in newly patented drugs prior to their release into the market
- Research and develop new analytical models in chemical composition, organization, properties, and the processes and transformations which transpire
- Demonstrate the ability to effectively execute assigned tasks and conduct complex assignments i.e. determination of metal residue substance levels via ICP-MS in a timely manner.

03/2004 to 07/2007

Senior Associate Scientist Pfizer Inc - City , STATE

- Perform all work in compliance with GXP, company SOPs and regulatory standards.
- Conduct internal audits of laboratories and laboratory data.
- Perform timely data review to ensure accuracy, completeness, cGMP compliance, and applicable regulatory requirements.
- Document and report results in accordance with GMP.
- Reconcile Quality Control laboratory workbooks and logbooks.
- Assist in the review and approval of GMP documents such as SOP's and associated forms and initiate revisions.
- Assist in preparing internal scientific reports and testing of GMP manufacturing and release of clinical API, DP, in-process controls and intermediates.

04/2000 to 02/2004

Science Associate II Pharmacia Inc - City , STATE

- Work alongside scientists in discovery, biomarkers and clinical to design experiments, analyze and interpret data, and effectively communicate results
- Perform and develop cGMP SOP's for cleaning process.
- Revise and review various cGMP documents that focus on the determination of the efficacy and safety of compounds, the impact of dose decisions, selection of novel indication for targets and compounds, the biological interpretation of results, and the identification of prediction biomarker.
- Develop and maintain a strong professional network with the Internal and External scientific communities.
- Conduct internal audits of laboratories, laboratory data, and computer systems.

Education
2012
Masters of Science : Clinical Research Management Washington University - City , State Clinical Research Management
1995
Bachelors of Science : Chemistry Chicago State University - City , State Chemistry
Bachelor of Arts : Curriculum & Instruction Chicago State University - City , State

Curriculum & Instruction Grade K-12 Chemistry Teacher for 4 years

Certifications

Certified Lead Auditor of Quality Systems (BSI), QS 9000 Certified Auditor/ BSI Certified ISO 13485:2003 Lead Auditor, BSI Certified ISO 18001:2007 Auditor

Skills

Communicate effectively with colleagues across functional areas, as well as with team members, managers, suppliers/vendors

Develop, document and enforce Operating Procedures as they relate to departmental laboratory processes; knowledge of cGMP guidelines

Strong skills in conducting a variety of USP assays, HPLC, Atomic Absorption, Capillary Electrophoresis, UV, Atomic Absorption (AA)

Strong computer proficiencies, Windows, Microsoft Office Suite, Chromeleon, and Empower.