SCIENTIST I
Professional Overview

Combines a unique combination of hands-on skills in manufacturing, automated systems, research and development, with highly advanced documentation skills, to help bio-pharmaceutical companies develop and produce quality products quickly and efficiently. Strong bench and equipment management skills. Leverages IT experience to drive accurate data collection, reporting, archiving and control.

Core Qualifications

- Research and Development
- cGMP Documentation
- Equipment Management
- Trackwise
- IQ / OQ / PQ
- Data Analysis
- SOP Creation and Management
- LIMS / VelQuest
- MAXIMO
- 21 CFR Part 11

Accomplishments

- Basic Lean Six Sigma Certified within Bristol-Myers Squibb.
- Saved $20,000/year for the company by enhancing the outsourcing of water samples.
- Worked with IT team to develop a new trending tool which extracts the data from LIMS which saved significant time in graphing all the data for investigations and studies. This project was submitted to BMS continuous improvement team for year 2013.
- Channelized the ordering of lab supplies and media by reaching out to vendors and placing standing orders for frequently used media. This saved lot of time and resources by not having to growth promote media as often.

Education
Bachelors of Science : Medicinal & Pharmaceutical Chemistry. Minor in Chemistry 2010 State University of New York City , State
Experience
Scientist I 04/2013 to Current Thermo Fisher Scientific Inc. Richardson , TX

- â€¢Manage and conduct multiple projects within tight deadlines.
- â€¢Use TrackWise to initiate an investigation and include those investigations in the quarterly and yearly trend reports.
- â€¢Institute CAPAs to close investigation within required time frame.
- â€¢Managed change control activities and successfully led implementation of chances to be compliant with SOP (Standard Operating Procedure) to reflect changing industry standards.
- â€¢Develop and recommend test strategies to verify the product performance and functionality and provide suggestions for future upgrades.
- â€¢Provide regular test status reports during the Project schedule. Complete the required final test reports necessary for release of the Product.
- â€¢Review peer-generated data for accuracy, completeness, and compliance with methods, SOPs and provide to the management to return the system to operation status after annual shutdowns.
- â€¢Schedule the IQ/OQ/PQ for the new instruments acquired by the Microbiology group.
- â€¢Review the IQ/OQ/PQ of the instrument prior to sending it to Quality Group for approval.
- â€¢Help in temperature mapping of the CTSU (controlled temperature storage unit) during the re-qualification process.
- â€¢REES (automated temperature monitoring) administrator for the Microbiology group. Monitor the temperature of all the Incubators and Refrigerators (CTSU's) on daily basis and initiate work orders to facility in case of any alarms.
- â€¢Designed and executed a Graph Generating System which gathers data from LIMS which is 21 CFR Part 211 compliant, working closely with the IT group, which reduced the work of trending by 20% on quarterly basis for the Microbiology group. This project was evaluated and rewarded by â€œContinuous Improvement Teamâ€ of BMS
- â€¢Use MAXIMO (asset management) system to initiate work order for the calibration of the instruments within the group and to print out calibration certificates for re-qualification protocols.
- â€¢Developed a new process for the archival of the lab notebooks, equipment manuals and qualification protocols of instruments in SharePoint.
- â€¢Go to weekly Facilities meeting to analyze the impact assessment on the laboratory by any changes and/or new implementation that are proposed by facilities.
- â€¢Contact facilities for equipment repair, follow up and host vendor presentation to maintain laboratory inventory and consignments.
- â€¢Conducting monthly lab inspection and following up with EHS (Environmental Health and Safety) for any safety related issues within the laboratory.

Technical Writer 06/2011 to 04/2013 Two95 International Inc. Richland , WA

- â€¢Working in a cGMP lab environment complying 21 CFR Part 211 with Analytical and Bio-analytical Research (ABD) Microbiology group.
- â€¢Provide environmental and water monitoring of the sampling done within the Parenteral and OSD area.
- â€¢Trending of the water samples for WFI (water for injection), WFO (water for operation) and CS (Clean Steam) systems and doing monthly review for tests such as TOC, Endotoxin, Heterotrophic Plate Count, Nitrates and Conductivity.
- â€¢Provide monthly analysis on the basis of trending, and report to management if any adverse trend or out of ordinary specs are observed.
- â€¢Write the quarterly and yearly trend reports of the individual areas. This includes Water as well as the Parenteral and OSD trend

reports.

- â€¢Keeping track of the manufacturing of various drug products for writing their individual Batch Reports and Media Fill Reports.
- â€¢Reviewing data for the non-viable and flex room areas and also the For Information Only (FIO) sites.
- â€¢Use LIMS and VelQuest (electronic notebook) for gathering the data for monitoring.
- â€¢Maintain calibration of the equipments and send out instruments to the vendors for re-calibration.
- â€¢Perform data mining and all the required trending for the Microbiology group during the FDA audit.
- â€¢Perform QC of the lab, lab instrument calibration and validation and document it accordingly in the lab notebook.
- â€¢Place standing orders using the SAP ERM system for the media and lab supplies needed for the routine testing within the laboratory.

QA/QC Analyst I 07/2010 to 06/2011 Bickford Senior Living Saginaw , MI

- Conducted testing of incoming Raw materials for their release.
- Worked in accordance with cGMP and GLP following the SOP.
- Sample preparation following official methods and company/laboratory SOP's, including wet chemistry, extractions and quantitative measurements.
- Wrote the quality investigation reports for the experiments performed and documented it using TrackWise.
- Performed the DI Waters test for the water used for the production in Manufacturing, Micro- Biology Lab and QC Chemistry Lab.
- Performed troubleshooting and initial investigation work related to OOS and OOT.
- Shipping and receiving of the raw materials that were tested at the contract laboratories.
- Tested the samples under the guidelines of USP, FCC, EP, BP, Japan Pharmacopeia and company methods.
- Performed impurities test using HPLC and GC using Empower II software.
- Operated analytical instruments such as pH meters, Viscometers, Karl Fischer and UV-Vis.
- Good experience with GC, FTIR analysis and wet chemistry.

01/2008 to 01/2009 Undergraduate Research, University At Buffalo

- Analyze organic and inorganic compounds to determine chemical and physical properties, compositions, structure by utilizing chromatography and spectroscopy techniques.
- Induce changes in composition of substances by introducing heat, light and energy for quantitative and qualitative analysis.
- Analyzed samples from various sources to provide information of compound present using analytical instruments like HPLC, pH meter and spectroscopy techniques.

Skills

â€¢ Expertise in MS Office Suite including PowerPoint, EXCEL, WORD, Outlook, One Note.

â€¢ Expertise in TrackWise (Quality Management Software)

â€¢ Expertise in LIMS (Lab Information Management Software)

â€¢ Expertise VelQuest (Electronic Lab Notebook)

â€¢ Expertise in MAXIMO (Asset Management)

â€¢ Expertise in REES (Automated Temperature Monitoring)