**MICHAEL OMOREGIE OMIGIE**

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**857-247-1481**

**SUMMARY**

Detail-focused Data Analyst with knowledge in data warehousing, process validation and business needs analysis. Proven to understand customer requirements and translate into actionable project plans. Dedicated and hard-working with passion for Big Data.

Competencies and Skills:

* Data cleaning
* Data collating
* Vlookup
* Data analysis skills
* Data review
* Data entry/verification
* Database Management
* Data Mapping
* Statistical Analysis
* Structured Query Language (SQL)
* Query Tools
* Data Visualization and Presentations
* Public Information Research
* Advanced Excel Spreadsheet Functions

**PROFESSIONAL EXPERIENCE**

**Amgen**

**Quality Stability Data Analyst January 2022 – Present**

* Build and maintain technical GMP documents and product stability studies
* Review, verify, report, and archive GMP data for clinical and commercial products
* Apply keen attention to detail to conduct data review and reports
* Execute transactions in relevant GMP computer-based systems (Change Control, LIMS, Veeva vault)
* Adeptly manage time-sensitive activities independently

Takeda Pharmaceutical, Lexington, MA

Quality Stability Data Analyst March 2021 – December 2021

* I support Specialists in the Project Management of Stability Studies for Drug Products, Drug Substances and Intermediates as well as associated Data Evaluations and Documentation.
* I support data analysis activities, including trending of stability data for multiple products and authoring of technical documents.
* I support ongoing activities in EQMS systems including (Veeva vault).
* I support ongoing stability programs and objectives.
* I support compilation and analysis of stability data for compliance to end of shelf life expectations.
* I support operational activities related to stability quality systems, including LIMS, JMP and other software applications like Minitab and Discoverant.
* I support the analysis of and detection of stability alerts (OOTs).
* I support the development and training initiatives of statistical applications for stability management.

Bristol Myers Squibb, Devens, MA

Quality Stability Data Analyst September 2019 – March 2021

I support all aspects of Global Biologics Stability data management program as necessary, including:

* Data entry and verification in the electronic Laboratory Information Management System (LIMS).
* Management of routine data table updates.
* Review of data to ensure compliance to cGMP and applicable stability protocols.
* I assist in data updates/ verification for Annual Product Quality Reviews, Annual Reports, filings and other ad-hoc requests.
* Archiving of electronic and paper data/information.
* Support activities of Stability Third Party sample storage facility including but not limited to inventory control, sample receipt support, labeling, sample destructions, sample pulls and oversight of sample deliveries, as needed.
* I ensure compliance with training requirements at all times.
* I maintain the office and stability facility in accordance with cGMP’s and good housekeeping practices.
* Initiate and promote change as part of operational excellence.

**Bay Cove Human Services, Boston, MA August 2018 – September 2019**

**Case Worker**

* Attend to the daily needs of persons served on an individual basis as well as foster increased independence and self-determination by teaching socialization skills and activities of daily living
* Assist in the development and implementation of Individualized Action Plans (IAPs) including implementation of behavioral objectives/plans.
* Participate in IAP meetings and other meetings as required by supervisor.
* Record and appropriately utilize necessary data, daily progress notes, staff log and complete all other IAP and program required documentation.
* Transport consumers to and from day programs, medical appointments and other activities as required.
* Provide opportunities for leisure time activities and foster independence in the choice and participation of those activities.
* Fulfill case management responsibilities as assigned by supervisor, including those related to medical and legal concerns.
* Ensure client safety and comply with program standards for staff coverage, including assistance to the Administrator-On-Call whenever possible.
* Communicate in a professional manner as well as acting as consumer advocate and role model.
* Provide a supportive environment that includes opportunities for consumers to determine, to the fullest extent possible, personal decisions for daily schedules and routines.
* Maintain knowledge of ongoing program issues and developments as well as informing supervisor of program issues and concerns.
* Perform duties consistent with program and agency policies and procedures thereby reflecting reasonable safety standards.

**Hoag Memorial Hospital Presbyterian, Newport Beach, CA April 2018 – May 2018**

**EMR/LIMS Support Specialist**

* I assisted in training and helping Lab Technicians and Phlebotomist to navigate the Epic Hyperspace LIMS using the Receiving, Scan, Collecting Order and sending packing list to another lab.
* Support the laboratory registration desk staff, Phlebotomist, Clinicians and physicians
* Training the Lab Technicians and Phlebotomist on efficient use of LIMS Hyperspace and Epic Beaker workflow.
* I assisted users with; specimen inquiries, transcribing orders, result entry, reports, workflow, and specimen transfer.
* Assisted nurses with documenting IVs and I/O in the doc flow sheet
* Assisted nurses in discharging patients and printing of after visit summary documents
* Assisted providers with creating progress notes using notewriter and smarttool
* Supported providers to set order set and single orders as favorite
* Assisted nurses to arrive, Transfer and discharge patients from the unit manager.

Quest Diagnostics, Marlborough, MA May 2016 – March 2018

Clinical Data Entry Steward

* Perform specimen handling, processing and quality control to ensure that specimens meet appropriate testing requirement.
* Carry out data entry of patient’s information into Quest Diagnostics LIMS system.
* Centrifugal separation of blood components and transfer of separated components into secondary containers.
* Ensure proper identification and labeling of laboratory specimen according to laboratory SOP
* Properly store laboratory specimen according to specific temperature stability requirement in order to maintain specimen integrity.
* Retrieval and proper disposal of laboratory specimen according to Quest Diagnostics SOP.
* Preparation of laboratory specimen for shipment to different testing sites across the country.
* Report to and help resolve issues of discrepancies with appropriate laboratory staff and ordering physicians.

Cambridge Biomedical, Brighton, MA August 2015 - March 2016

Clinical Laboratory Technician

* Preparation of Bacterial and Cell Culture Media according to Laboratory SOPs
* Preparation of Buffer Solutions and Standard Solution according to Laboratory SOPs
* Isolation of peripheral blood mononuclear cells (PBMC) from human blood
* Help to maintain and improve specimen management systems for clinical research and clinical diagnostic labs
* Specimen handling, processing, and preparing reagents.
* Communicating issues to Laboratory Management; reviewing test analyses with management.
* Analyzing, reviewing, and reporting test results and quality control results with management.
* Entering and releasing of test results through the LIS/LIMS system
* Reporting and maintaining records of test results according to GLP
* Compiling, coding, categorizing, calculating, tabulating, auditing, or verifying information or data.
* Troubleshooting test systems and taking appropriate action when indicated.
* Adhering to all Laboratory Safety Policies.
* Performing instrument calibration as well as routine, scheduled, and unscheduled preventive maintenance; maintaining equipment, temperature charts, and equipment logs according to GMP.
* Storage and disposal of specimens.
* Maintaining of stock inventory of reagents and materials for clinical diagnostics and research.
* Reviewing SOPs as assigned
* Identifying problems which may adversely affect test performance or reporting of test results and taking appropriate action including notification of Laboratory Management.
* Participating in laboratory QA programs and laboratory CE programs.
* Participating in proficiency testing and competency evaluation throughout the year.

Boston Medical Center, Boston, MA April 2013 - May 2015

Clinical Laboratory Technician

* Carry out batching and accessioning of laboratory specimen in order to prevent losses of specimens in transit to testing site.
* Perform data entry of patients’ information in the laboratory information system
* Perform data entry of patient’s laboratory requisition in the laboratory information system, as requested by patient’s physician.
* Collection of blood samples in appropriate containers for laboratory investigations for both inpatients and outpatients.
* Record and ensure proper documentation of medical laboratory data of outpatients and inpatients.
* Transport specimen from collection site to testing site in a timely fashion
* Effectively communicates between patients and physicians, nurses and laboratory staff to meet patients needs and ensure patients satisfaction
* Provide training and guidance to less experienced laboratory support technicians.
* Inventory Control of reagents, chemicals and supplies using proper labeling and computerized transactions
* Maintain general lab organization and availability of lab supplies.

Beth Israel Deaconess Medical Center, Boston, MA October 2010 - April 2013

Research Assistant

* Preparation of Bacterial and Cell Culture Media according to Laboratory SOPs
* Preparation of Buffer Solutions and Standard Solution according to Laboratory SOPs
* Ensures quality assurance and quality control according to cGMP and lab SOPs.
* Autoclaving of laboratory glassware and surgical instruments
* Sorting and proper placement of research materials in appropriate storage places
* Worked closely with principal investigators and other clinical research staff
* Performed calibration of equipments/devices

OPRI Medical Laboratory Services, Benin City, Nigeria March 2002 - February 2010

Laboratory Supervisor

* Ensured the implementation of project plans as assigned.
* Assisted with managing the scope of work, objectives, deliverables and financials and work orders.
* Performed calibration of laboratory equipments/devices.
* Preparation of buffer solutions and culture media according to lab SOPs.
* Performed laboratory investigations in the Chemical Pathology lab including:
* Liver function tests, total protein measurements, fasting and non-fasting blood sugar tests, Electrolyte, Urea and Creatinine level measurements.
* Carried out laboratory investigations in the Hematology and Blood group serology lab including:
* Blood grouping and cross matching, genotyping for identification of common mutations and polymorphisms, complete blood count, platelet count, erythrocyte sedimentation rates, clotting time, bleeding time (PT-INR).
* Recorded and ensured proper documentation of medical laboratory data for outpatients.
* Ensures quality assurance and quality control according to cGMP and lab SOPs
* Provided training and guidance to interns, less experienced laboratory technicians and new hires.
* Receiving, unpacking, processing, organizing, and storing of laboratory reagents and supplies.
* Inventory Control of reagents, chemicals and supplies using proper labeling and computerized transactions
* Maintain general lab organization and availability of lab supplies.

**CERTIFICATION**

Google Data Analytics

**EDUCATION**

MCPHS University, Boston, MA

MS in Clinical Research, 2016

MCPHS University, Boston, MA

Graduate Certificate in Regulatory Affairs, 2016

Ambrose Alli University, Nigeria

Bachelor of Science in Human Physiology, 2007

Credentials evaluated by World Education Services (WES)