POLYMATH
REGULATORY CONSULTANTS LLC

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SKILL SET

Regulations: 21 CFR 210, 211, FD & C Act, ICH, EudraLex Parts I, II, Annexes, Annex 1, GLP, GCP, CLIA

Quality Assurance: GMP Audits, Inspection Readiness, Sterility Assurance and Sterile Manufacturing, Gap Assessments, Quality Risk Management, Data Integrity, Audit & Inspection Responses, CAPAs, Quality and Performance Metrics Assessment, Training, QMS

Quality Control: Data Collection, Analysis, and Review, Microbiological Testing, UV/Vis, Chromatography, Spectrometry

Products/Services: Food, Raw Materials, Imports, API, Packaging, QC Testing, Clinical Materials, Biopharmaceuticals, Cell/Virus Banks, Gene Therapy, Viral Vectors, Biologics, Medical Devices

Applications: FDA applications, SAP, Microsoft Office, Waters Empower Chromatography Data System, Thermo Scientific Xcalibur LC-MS software, Analyze-It, SAS Visual Analytics, SPSS analytical software, CDC Epi Info, STARLIMS, Laboratory Information Management System (LIMS), eQMS

Certifications: MP324 Medical Products Data Integrity (2019), Former US FDA Certified Level I Drug Investigator

PROFESSIONAL EXPERIENCE

Polymath Regulatory Consultants, LLC
GMP and Quality Consulting
Independent Contractor

Sr. Quality Consultant
January 2025 - present
Atlanta Metro Area

Pfizer, Inc. **Regulatory Quality Manager, GMP Auditor**
Regulatory Quality Assurance August 2021 – August 2024
Corporate Compliance Division Atlanta, GA

- Led and/or participated in GMP audits and assessments.
    - Related activities included but are not limited to: scheduling audits, audit preparation, led audit execution, prepared audit reports, reviewed and evaluated the adequacy of the auditee responses to audit findings, and performed audit follow-up activities.
    - Initiated audit reviews through consultation with relevant departments, subject matter experts, and management.
- Assessed whether operations were executed in compliance with CGMP/GDP requirements and guidelines, Pfizer Quality Standards and Quality Agreement requirements, and SOPs.
- Interpreted regulatory requirements and industry best practices, reported risks that could lead to compliance issues and recommended improvements/solutions.
- Assessed quality and compliance risks and communicated potential non-compliance matters to senior leadership, vendor management, and technical staff.
- Communicated relevant quality and business information to the site, contract manufacturer, supplier, or service provider audited to maintain relationship between the auditee and Pfizer.
- Liaised between auditee and appropriate Pfizer groups, to ensure that all pertinent information that could impact the auditee or Pfizer (e.g., regulatory inspection activities or significant changes) are requested, provided, and documented.
- Led and participated in due diligence assessments to determine the auditee's quality compliance.
- Assisted auditee in preparing for regulatory inspections.
- Collaborated with leadership, site personnel, and subject matter experts, to enable a culture of excellence in objective audits and effective CAPAs.
- Developed cross-functional collaborative relationships to facilitate engagement, team building, best practice sharing, risk-based analysis, critical thinking, and innovative problem solving.
- Maintained audit databases
- Remained current on applicable laws, regulations, guidelines, internationally recognized standards and other pertinent policies, procedures, and standards that could impact the auditee's operations.

US Food & Drug Administration **Consumer Safety Officer/Investigator**
Office of Regulatory Affairs March 2015 – August 2021
Office of Medical Products & Tobacco Operations Atlanta, GA
Office of Pharmaceutical Quality Operations
Division II Investigative Operations Branch

- Conducted independent and team domestic and foreign GMP surveillance and pharmaceutical application inspections (i.e. Pre-Approvals; New Drug Applications; Abbreviated New Drug Applications) of human and animal APIs, prescription and over-the-counter (OTC) drug manufacturers, repackers, relabelers, distributors, and contract testing laboratories.
- Inspected procedures, polices, technical documents, CAPA, product recalls, design controls, quality unit responsibilities, and production and process controls of regulated drug firms.
- Evaluated product quality and medical complaints to ensure good documentation practices,

investigation in a timely manner, root-cause determination, effective CAPAs, and if when appropriate, reported to regulatory agencies.
- Collected and analyzed essential information of potential violations and objectionable conditions identified during an inspection or investigation (i.e. documents, photographs, documentary and physical samples).
- Ensured that all documents and records met the applicable regulatory requirements.
- Independently wrote establishment inspection reports and prepared other written materials, such as investigative memorandums, endorsements, recall audit checks, and sample collection reports.
- Used policies, guidelines and regulations to formulate clear and decisive recommendations of regulatory compliance.
- Independently planned, organized, and import program assignments.
- Conducted recall audit checks to verify the effectiveness of a recalled product.
- Conducted and led meetings with firm management and participated in regulatory meetings with relevant agencies, industry representatives, key stakeholders and state partners.
- Regularly served as the Acting Supervisor for the Office of Pharmaceutical Quality Operations, Division 2 in the absence of supervisor.

Quintiles Laboratories/Q2 Solutions **Global Senior Project Services Coordinator**
June 2012 – March 2015
Marrietta, GA

- Provided project support and site management to investigator sites of pharmaceutical sponsors and clients by assisting with the management of clinical pharmaceutical studies, including set-up, maintenance, study monitoring and close-out processes.
- Managed global and domestic clinical sites, CROs and vendors.
- Supported all phases of a project-specific protocol, including, but not limited to, the design of the monitoring plan to adequately managing the project; protocol review to ensure database accuracy; created protocol-specific laboratory manuals and flowcharts; managed project close-out procedures; and provided training for investigator sites and clients.
- Performed routine clinical research study tasks and including daily monitoring of projects, managing site list data, ordering laboratory test kits and resolving queries.
- Coordinated information and communication of global projects as well as the site level, which included the identification and escalation of patient or clinical trial-related discrepancies.
- Ensured work was conducted according to SOPs, policies and GCP/GLP standards.
- Performed technical reviews and provided feedback to senior management.
- Participated in external and internal audits.
- Maintained effective systems for project documentation.
- Developed and presented lessons learned, audit findings, department training, best practices and Investigator meeting presentations
- Managed budgets and communicated budget changes to clients.
- Acted as a liaison between the study sponsor and third-party laboratories.
- Led sponsor and client meetings and discussions for clinical studies.
- Managed internal project databases, e.g., STARLIMS, QLIMS, QLIMS2000, Infosario Analytics, eTMF and Lotus Notes.

Centers for Disease Control & Prevention **Chemist**
Clinical Chemistry Branch - Lipid Reference Laboratory August 2008 – March 2011
National Center for Environmental Health Atlanta, GA
Division of Laboratory Sciences

- Executed analytical schemes for method improvement and evaluation
- Provided traceability to CDC's reference measurement procedures
- Prepared and characterized quality control (QC) pools and reviewed QC data to ensure that reference methods remained in a state of control
- Provided technical support in the standardization and characterization of samples
- Operated and maintained instrumentation, e.g., UV/VIS, spectrophotometers, gas chromatography systems, mass selective detectors
- Assisted with the method development and validation
- Performed method comparison studies
- Compiled and analyzed data to determine equipment efficiency and issues with a method.
- Managed sample database
- Developed standard operation procedures and work instructions
- Reviewed and edited scientific papers and abstracts

EDUCATION

Morehouse School of Medicine Atlanta, GA (USA)
Master of Public Health

Spelman College Atlanta, GA (USA)
Bachelor of Science in Biology