POLYMATH
REGULATORY CONSULTANTS LLC

S. Morgan-Murray, MS

Senior Consultant
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SKILL SET

Regulations: 21 CFR 50, 54, 56, 58, 312, 812 and Part 11, FD & C Act, ICH, Good Documentation Practices, Data Integrity Principles, world-wide GCPs

Quality Assurance: GCP/GCLP/GLP Audits, Inspection Readiness Activities, GCP and Auditor Training, Quality Management Systems (QMS), GCP Compliance, Gap Assessments, Risk Evaluation, Health Authority Responses, Corrective and Preventive Actions (CAPA), Quality Metrics Assessment, Artificial Intelligence, SOP Gap Analysis and Protocol GAP

Quality Control: Data Collection, Analysis and Review

Products/Services: IRB/EC, Sponsors, Principal Investigators, Contract Research Organization Bioequivalence clinics & laboratories, IRBs/ECs following US GCP regulations, ICH guidelines

Applications: Microsoft® Office, Laboratory Information Management System (LIMS), eQMS, MyLearning, SharePoint, SAP, TrackWise, EDMS (e.g., Veeva), Atlas-Compliance, Redica, on-line learning platforms, Veeva Vaults, Medidata

Certifications: Former US FDA Certified Level I Drug Investigator

Other Skills: Histology, Histopathology, Immunohistochemistry

PROFESSIONAL EXPERIENCE

Polymath Regulatory Consultants, LLC
GMP and Quality Consulting
Independent Contractor

Sr. Quality Consultant
February 2025 - present
Atlanta Metro Area

Premier Regulatory Consulting, LLC
(GLP, GCP & GVP)

Quality Consultant
October 2023 - present
Atlanta Metro Area

- Independently conducting audits in various FDA regulatory areas, including Sponsors, CROs, Investigator Sites, Ethics Committees, and other Health Regulatory Authorities
- Conducted sponsor audits
- Conducted sponsored mock inspections
- Developed inspection preparedness plans
- Collaborated with independent auditing/consulting firms to conduct various GXP services

Idorsia Pharmaceuticals Ltd
Global Pharmaceutical Development
Quality Assurance

Sr Manager, Clinical Quality Assurance
June 2022- September 2023

- Planned, performed, and conducted audits in the USA and internationally (e.g. Europe, Asia, and South America for site, vendor, and process) using considerable latitude in determining best practices and approach
- Lead the preparation, facilitation, and follow-up of inspections by national and international regulatory authorities.
- Facilitated CAPA elaboration and follow-up
- Escalated serious/continuing non-compliance issues
- Ensured QS documentation was in accordance with US regulation and ICH-GCP requirements/regulations
- Contributed to process improvements and troubleshooting, e.g., CQA tools and processes
- Provided subject matter expertise on US regulation and ICH-GCP related activities/issues
- Collaborated with Company/CRO Clinical Trial Teams
- Supported Company/CRO staff in the implementation and maintenance of a robust and compliant clinical Quality Management System and clinical trial framework by providing training to CD staff, feedback to US regulation and ICH-GCP questions
- Represent CQA in internal and external meetings
- Performed CQA task that could assist with adherence to US regulation and ICH-GCP requirements
- Provided guidance and ensured all Company clinical trials research met the highest standards of quality and integrity and in accord with all human subjects and other ethical standards

Seagen, Inc.
Research & Development Quality

Sr Manager, Clinical Compliance
December 2021- May 2022

- Supported international clinical trials through quality oversight, program and team consultation, and auditing
- Developed and implemented cost-effective, risk-based, quality assurance, and compliance programs

- Performed gap analysis on internal systems, policies and procedures to ensure processes are in compliance with ICH GCP E6 guidelines and federal regulations
- Acted as lead auditor for GCP audits
- Led Directed audits
- Advised program teams independently for routine compliance inquiries
- Designed and managed compliance programs
- Reported on CAPA trends, conducted and managed common root cause investigations, impact assessments
- Served as lead investigator for CAPA effectiveness checks
- Managed regulatory agency inspections
- Conducted risk assessments

US Food & Drug Administration
Office of Regulatory Affairs

Consumer Safety Officer/Investigator
August 2015 – November 2021
Atlanta, GA

- Reviewed and evaluated evidence and findings indicating a possible lack of compliance with laws and regulations
- Independently planned and conducts domestic and international high priority/for-cause 21 CFR regulatory compliance audits and prepared establishment inspection reports (EIRs) for every audit which are available through Freedom of Information (FOI), and which involve applications that relate to:
    - New drug applications (NDAs)
    - Abbreviated new drug applications (ANDAs) and new animal drug applications (NADAs)
- Performed GCP audits of human subject protection/IRB/EC, Sponsors, Principal Investigators, Bioequivalence clinics & laboratories, IRBs/ECs following US GCP regulations and ICH guidelines.
- Analyzed study results, and determine whether an investigation is complete or what work may be required.
- Provided extensive advice to industry officials on rules and regulations and recommending changes that must be made for compliance
- Monitored and managed compliance initiatives and served as lead Agency representative on multiagency or multi-organizational investigations

National Institutes of Health (NIH)
National Cancer Institute (NCI)

Chemistry Instructor
March 2013 – August 2015
Bethesda, MD

- Collaborated with global scientists to optimize collection, preservation, and preparation of biological samples for histopathology processing.

- Managed and monitored the implementation of the compliance program in the clinical pathology department
- Conducted evaluations and clinical research studies to ensure compliance with accrediting organizations' regulatory requirements and the requirements of HHS, NIH and FDA
- Developed and performed novel molecular pathology assays including immunohistochemistry, RNAscope, multiplexing using automated platforms Ventana and Leica) and manual methods
- Provided expert advice on study protocol development, site readiness, and site preparedness for clinical research
- Served as GLP/GCLP expert
- Provided scientific leadership and expertise in the development and execution of research projects, and ensured scientific soundness and technical feasibility
- Collaborated with scientists to analyze and assess federal guidelines regarding the care and use of animal subjects in NIH-supported and sponsored research.
- Reviewed and evaluated clinical protocols for the NIH Laboratory of Pathology protocol review committee
- Collected biological and environmental samples to measure biomarkers exposure, susceptibility, or effects on human health and supported the researchers in epidemiology studies
- Extracted data from databases, highly-diverse medical diagnoses, procedures from autopsy reports and medical reports

EDUCATION

Arizona State University
Master of Science, Clinical Research Management (Regulatory Science) — Tempe, AZ (USA)

Clinton, IA (USA)

Ashford University
Bachelor of Arts, Health Care Administration

Hartford Community College — Hartford, MD (USA)
Histotechnology, Certificate