POLYMATH
REGULATORY CONSULTANTS LLC

P. Purwaha, Ph.D., CQA (ASQ)

Senior Consultant
2300 Bethelview Road, Suite 110-189, Cumming, GA 30040
P: (470) 423-0185
info@polymathregconsultants.com
www.polymathregconsultants.com

SKILL SET

Regulations: 21 CFR Part 820, 21 CFR Part 11, 42 CFR Part 493, 21 CFR 58, FD & C Act, ICH, GMP, GLP, GCP, CLIA, CAP, Joint Commission, ISO 9001, ISO 13485, FDA IVDR, EU IVDR, GDPR, ALCOA, HIPAA, OSHA

Quality Assurance: GxP Audits, Regulatory Licensures, Inspection Readiness, Gap Assessments, Quality Risk Management, Data Integrity, Audit & Inspection Responses, Root cause analysis and CAPA, Product Complaints, Quality and Performance Metrics Assessment, Training, QMS/eQMS set up and administration, SOP writing and review, Vendor/Supplier Qualification and Audit, Support supply chain management, Project Management

Quality Control: Data Collection, Analysis, and Review, Microbiological Testing, Mass Spectrometry, Immunoassays and any other technical instrumentation QC, Validation of Instruments and Processes, Stability Testing

Products/Services: Biologics, Medical Devices, IVD, Laboratory Developed Tests (LDTs), Biopharmaceuticals

Applications: Microsoft Office, Laboratory Information Management System (LIMS), eQMS, Salesforce, Box, SharePoint, DocuSign, Chromatography and Mass Spectrometry Data Analysis (Agilent, Waters, AB Sciex)

Certifications: Certified Quality Auditor from ASQ, Toxicological Chemist from National Registry of Certified Chemists

PROFESSIONAL EXPERIENCE

Polymath Regulatory Consultants, LLC — **Sr. Quality Consultant**
June 2025 – present
Houston, TX

Sanguine Biosciences **Associate Director, QA**
Aug 2024 – Feb 2025
Houston, TX

- Oversee QC/QA activities of three Sanguine sites including environmental and safety compliance with OSHA, FDA GxP guidelines and state specific guidelines
- Vendor/Supplier Management including risk assessment per products/services used, vendor qualification, ongoing communication, evaluation and documentation
- Compliance with GMP for production of aseptic manufacturing of leukopaks and other blood products; review raw material QC, daily batch production records, instrument records and CofAs
- Compliance with GCP and ICH for Biorepository and donor medical records management; review ICFs and other clinical documentation, submission to IRBs, review of CRFs
- Validation of new laboratory protocols for testing of raw materials and final products per CLIA/CAP/CLSI guidelines
- Supply chain QA management to ensure uninterrupted supplies to avoid production downtimes
- Manage QMS (Zen eQMS) for document control, inspection readiness, personnel training and ongoing management
- Lead internal and site inspections (ISO 9001:2015, FDA, CLIA, Sponsor Audits)
- Employee Quality Training, Onboarding/Off boarding
- Deviation, Complaint and CAPA management for compliance with GxP and ISO
- Case Review on Salesforce
- SOP writing, and review, Clinical Protocol writing/review
- Compliance with CLIA, ISO9001, ISO27001, ISO27701, GCP, GMP and GLP, GDP, HIPPA, FDA guidelines

Lighthouse Laboratory Sciences **Senior Quality Manager & High Complexity Laboratory Director**
Dec 2018 – Aug 2024
Houston, TX

- Manage QC and QA for labs performing testing (high, moderate complexity and waived)
- ISO 9001 and 13485 accreditation and Audit, for Manufacturing, Procurement, shipping, Instrument repair and refurbishment of medical devices.
- Quality Management (QMS), SOP writing and periodic review, administration of document control on Media lab.
- GCLP, GLP and GMP process controls for Standards, labelling, manufacturing, packaging, sampling, stability studies, certificate of analysis etc. Perform on-site Laboratory Audits to ensure Quality and Compliance, monitor, review, and approve Quality Assurance and Quality Control metrics, Lead CMS/CLIA, CAP, The Joint Commission (JC), COLA, inspections.
- Review of new LDT, IVD Validations, and stability studies.

- Complete Root cause analysis and CAPAs.
- Proficiency testing (PT), Accreditation, regulatory filings for FDA, CLIA, COLA, CAP, Joint Commission.
- Personnel training and Competency and all other areas of Quality.
- Acquire and maintain regulatory, accrediting, and state certificates/licensure.
- Ensure Laboratories follow all safety guidelines per OSHA/CAP/CLIA.
- Laboratory Director/ Clinical Consultant/ Technical Supervisor of CLIA/CAP/COLA/JC accredited laboratories performing high complexity testing.

Baylor College of Medicine **Staff Scientist**
Oct 2015 – Dec 2017
Houston, TX

- LC/MS method development, validation, maintenance and troubleshooting for quantitation of metabolites (all classes), small molecules, drug metabolites and environmental toxicological/ xenobiotic compounds using LC-MS (Agilent and AB Sciex triple quadrupole, Q-TOF, Triple TOF), unbiased metabolomics using Q-TOF.
- GC/MS method development, validation, maintenance and troubleshooting for quantitation of oncometabolite 2-hydroxy glutarate (2-HG) in clinical samples.
- Optimization of sample preparation protocols for clinical samples and bio-fluids such as blood, plasma, serum, cell lines, urine etc.

EDUCATION

North Dakota State University Fargo, ND (USA)
Ph.D. (Pharmaceutical Sciences)

MD Anderson Cancer Center Houston, TX (USA)
Post-Doctoral Fellowship in Onco-metabolomics