POLYMATH
REGULATORY CONSULTANTS LLC

T. Harris, MS, CQA

Senior Consultant
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SKILL SET

Regulations: 21 CFR 210, 211, 11, 50, 56, 111, 117, 820; FD&C Act; ICH & ISO standards; EudraLex Parts I and II & Annexes; Annex 1 (Good Distribution Practice); PIC/S; Good X Practices (GCP, GMP, GLP, GVP, GDP, CGTP); International Council for Harmonization (ICH); International Organization for Standardization (ISO); relevant regional requirements (e.g., FDA, USP, cGMP, and Local MoH); Data Integrity Principles; worldwide GMPs.

Quality Assurance: GMP audits, Inspection Readiness Activities, Sterile Manufacturing, GMP and Auditor Training, Quality Management Systems (QMS), GMP Compliance, Gap Assessments, Risk Evaluation, Minister of Health Authority Responses, Investigations, Change Control, Process Validation, Consent Decree Remediation, Corrective and Preventive Actions (CAPA), Quality Metrics Assessment, Artificial Intelligence, Design Controls and 510K

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

Products/Services: Finished Drugs, Active Pharmaceutical Ingredients (API), Drug Substances, Biologics, Vaccines, Medical Devices, Combination Products, Raw Materials, Cosmetics & Cosmetic Ingredients, Packaging & Labeling and Distribution

Applications: Microsoft Office, Laboratory Information Management System (LIMS), Agilent, ChemStation, Empower, SharePoint, SAP, JD Edwards, TrackWise, and online learning platforms

Certifications: Former USFDA Certified Level I & II drug Investigator, ISO 9001:2015 Lead Auditor Certification, Punyam Academy; Certified Quality Auditor (CQA), ASQ; Quality Instructor Certification, Train the Trainer, Baxter Healthcare; Pharmacovigilance Auditing Certification, RQA; Sterilization & Sterility Assurance Certification, Baxter Healthcare; FDA-certified training in GMP compliance and regulatory standards.

Other Skills: Project Management, Computer System Validation, Regulatory Affairs and Physical & Analytical Chemistry, Solid, Liquid, Non-sterile, and Sterile formulations, Food Law, Pre-approval and Post-market Inspection Expertise, Regulatory Filings, Quality Systems, Data Integrity, Deviation Investigations, Change Controls, Microbiology, Regulatory Affairs, Regulatory Compliance, Exceptional Written and Verbal Communication, Problem-solving and Leadership Skills.

PROFESSIONAL EXPERIENCE

Polymath Regulatory Consultants, LLC
GMP and Quality Consulting
Independent Contractor

Sr. Quality Consultant
February 2025 - present
Atlanta Metro Area

Baxter Healthcare Corp.
Regulatory Quality Assurance
Corporate Compliance Division

Senior Global Quality Technical Consultant
May 2017 – September 2024
Deerfield, IL

- Led pharmaceutical and medical device manufacturing audits driving compliance to applicable procedures, regulations and standards
- Performed global GMP compliance audits to assess quality management systems
- Evaluated and approved CAPAs, risk assessments, root cause analysis and remediation plans
- Conducted inspection readiness activities and regulatory compliance training
- Assessed manufacturing processes, test methods, validation and qualification and data integrity
- Provided subject matter expertise on regulatory intelligence and compliance
- Independently conducted pharmacovigilance audits
- Developed audit procedures and compliance initiatives
- Reviewed and evaluated quality control and manufacturing data for ensure compliance with requirements.
- Collaborated with contract facilities, internal sites, and regulatory authorities to facilitate audits, achieving 70% decrease in number of regulatory actions
- Trained and qualified lead auditors and evaluated performance
- Collaborated with all levels of internal management across functions and business units to foster culture of compliance quality, facilitating collaboration and promoting transparency across organization

US Food & Drug Administration
Office of Regulatory Affairs

Consumer Safety Officer/Investigator
January 2009 – May 2017
Cincinnati, OH

- Executed complex inspections and investigations of drug manufacturing facilities, ensuring compliance with safety and quality standards.
- Led numerous pre-approval inspections for drug applications including NDAs, INDs, ANDAs, NADAs, ANADAs and OTCs.
- Independently conducted CGMP inspections for pharmaceuticals (e.g., API, oral solid, liquid, sterile and nonsterile) and dietary supplements
- Assessed manufacturing processes, sterility assurance, microbiological controls, analytical testing, OOS investigations and data integrity
- Provided regulatory assessments on pre-market and post-market activities
- Authored comprehensive inspection reports (EIRs) using the FD&C Act, Compliance Programs, Guidance Manuals, and applicable 21 CFR regulations.
- Acted as a subject matter expert and expert witness

Sinclair Community College — **Chemistry Instructor**
August 2001 – September 2008
Dayton, OH

Relevant Courses Taught: Introduction to General Chemistry, Intro to Organic Chemistry, Laboratory

EDUCATION

Wright State University — Dayton, OH
Master of Science in Organic Chemistry

Wilberforce University — Wilberforce, OH
Bachelor of Science in Chemistry