POLYMATH
REGULATORY CONSULTANTS LLC

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SKILL SET

Regulations: ICH**,** GLP, 21 CFR 600 – 800, Part 11, worldwide GMPs, ISO 14971:2019 Risk Management, ISO 13485:2016 Medical Device Quality Management System, ISO 22716:2007 Cosmetics Good Manufacturing Practices, ISO 15378:2017 Primary Packaging Material for Medicinal Products, ISO 9001:2015 Quality Management Systems, ISO 17025: 2017-General Requirements for the Competence of Testing and calibration laboratories, ISO 19011:2018 Guidelines For Auditing Management Systems, the ISO 9000 Set of International Standards on Quality, ISO 14155:2020 Clinical Investigation of Medical Devices For Human Subjects, MDR (Medical Device Regulation) 2021/(EU) 2017/745, MDD (Medical Directive) 93/42/EEC, MDSAP (Medical Device Single Audit Program), CMDCAS (Canadian Medical Devices Conformity Assessment Systems)

Quality Assurance: GMP Audits, Inspection Readiness Activities, Sterile Manufacturing, GMP and Auditor Training, QMS, GMP Compliance, Gap Assessments, Risk Evaluation, Health Authority Responses, Corrective and Preventive Actions (CAPA), Quality Metrics Assessment, Artificial Intelligence and Aseptic Processing

Quality Control: Data Integrity, Method Verification/Validation, Technical Method Transfer, Karl Fischer, HPLC, GC, FT-IR, UV Vis, Titrators, KjelFlex K360, Elemental Analysis, X-Ray Diffraction, Particle Size Analyzer, Surface Area Analyzer, Differential Equations, Organic/Inorganic Chemistry, Statistics, Discrete Mathematics, Instrumental Analysis, Dissolution, Densitometer, Muffle Furnaces, Viscometer, Osmometers and Differential Scanning Calorimeter (DSC)

Products/Services: Finished Drugs, Active Pharmaceutical Ingredients (API), Drug Substances, Biologics, Vaccines, Medical Devices, Combination Products, Raw Materials, Cosmetics & Cosmetic Ingredients, Cannabis, Foods, Dietary Supplements, Gas/Oil, Packaging and Labeling Components, Distribution and Storage

Applications: Microsoft® Office, LIMS, eQMS, SharePoint, SAP, TrackWise, EDMS (e.g., Veeva), Atlas-Compliance, Redica, Blue Mountain, LMS, QT9, Greenlight Guru, Master Control, Empower, Arena Solutions, ETQ, Qualio, Intellect, Ideagen, Dot Compliance, Propel, Windchill, Oracle Fusion Cloud, Empower (Millieum), Microsoft Project, Harvest, Salesforce and TraceLink

Certifications: TUV SUD North America ISO 13485: 2016 Medical Device-Quality Management System

Internal Audit-Issued January 27, 2022, BSI ISO 13485:2003 Medical Device-Quality Management System Lead Auditor Certification Pass Date September 15, 2015, TUV SUD North America Medical Device Regulation (MDR)-Issued November 18, 2021/(EU) 2017/745, TUV SUD North America Medical Device Single Audit Program (MDSAP)-Issued November 28, 2021, EXCiPACT (excipients used in pharmaceuticals) -Brussels, Germany, May 17, 2019, and Expired May 16, 2022, Rianne Tooten Clinical Research Professional ISO 14155:2020 Clinical Investigation of Medical Devices for Human Subjects-Good Clinical Practices-Issued March 30, 2022, Basics of Gamma Radiation Sterilization Process Requirements-Issued June 2022, Food Safety Preventative Controls for Human Food (FSMA-Food Safety Modernization Act) Certificate of Training Issued June 06, 2018. Global Food Safety Initiative (GFSI) Remote Auditor Training Issued on August 10, 2020, EFfCI (European Federation for Cosmetic Ingredients) GMP Auditor Certification December 17, 2018
Health Canada Certification (CMDCAS) -Certificate Issued October 28, 2019

- Canadian Medical Device Regulation (SOR/98-282)
- Canadian Medical Device Conformity Assessment System
- Relationship between ISO 13485:2003 and MDR

IATA (International Air Transport Association) Audit Quality and Risk Management for Temperature Controlled Cargo (classroom five days) March 20-March 24, 2017, SGS ISO 22716:2007 Cosmetics Good Manufacturing Practices Auditor Training According to ISO 19011-Issued September 25, 2019, SGS ISO 9001:2015 Quality Management Systems -Issued June 22, 2019, COVID-19 Remote Auditing Training-Issued March 18, 2020, Lean Six Sigma Yellow Belt Certification-2012, FMSA (Food Safety Modernization Act), Allergen Management, and Food Defense SGS Certification July 31, 2024, Medical Device Software Process Black Belt November 10, 2023, MDSAP (Medical Device Single Audit Program, Canada) Auditor Training Certification by RQM+ October 16, 2024, 21 CFR (Code Federal Regulations) 820 QMSR (Quality Management System Regulation) RQM+ October 14, 2024

Other: Teaching/Training of GMPs and ISO standards, knowledge of FSMA, GFSI, EffCI IATA audit Quality and Risk Management for Temperature Controlled Cargo, EXCiPACT, Basics of Gamma Radiation Sterilization Process, Medical Device Software Process Black Belt and Lean Six Sigma

PROFESSIONAL EXPERIENCE

Polymath Regulatory Consultants, LLC
GMP and Quality Consulting
Independent Contractor

Sr. Quality Consultant
January 2025 - present
Atlanta Metro Area

All Call Staffing Firm, LLC

Manager, Quality Lead Auditor
November 2021 – present
Conyers, GA

- Manage and conduct audits to ensure compliance and continuous improvement
- Control logistics and planning of audits for medical devices, pharmaceuticals, and clinical organizations
- As a lead auditor, train junior auditors in various international organizational standards
- Manage audit proposals, negotiated pricing, and determined customer audit timeframe
- Conduct gap assessments, audit readiness, and internal and supplier-customer audits

SGS North America

Quality Lead Auditor
January 2015 – present
Conyers, GA

- Make informed decisions regarding the audit process and communicate with SGS to address issues outside the audit process.
- Assess organizational processes, e.g., turtle diagram
- Gather and analyze data to recommend certification, maintaining authority over the control and performance of auditing activities
- Lead team of auditors to conduct pharmaceutical and supplier audits per SGS Global/Local procedures
- Determine whether manufacturers are following all relevant standards/regulations and whether registration should be recommended or allowed to continue
- Present SGS standard training courses, develop training material including case studies, assessments
- Consult with start-up/existing companies to deliver process improvements
- Author standard operating procedures in alignment with applicable standards and regulations
- Collect data including measurable objectives, complaint trends, and CAPAs
- Formulate reports using risk analysis tools, e.g., FEMA, SWOT, decision tree, root cause analysis, etc.
- Conduct audits against Canadian Good Manufacturing Practices Guide for Drug Products (GUI-0001-Government of Canada)

British Standards Institute

Assessor
April 2015 – October 2018
Remote

- Maintained and developed assessment skills to technical management system standards
- Led and coached colleagues and established effective partnerships
- Recommended the issue, reissue, or with-drawl of certificates and recommended opportunities for improvement, plan, schedule, budget and prompt information to support services
- Prepared assessment reports and approved CAPA plans
- Monitored managers and suppliers to ensure processes were operating efficiently and objectives were met
- Supervised and conducted over sixty-eight (68) audits, worldwide using the following: ISO 9001:2015/ISO 13485: 2016/ Certified in CMDCAS, IATA, TAPA (C-TPAT), ISO 14001: 2015, ISO 22716:2007, FSMA, and Medical Device Regulatory, skilled in IEC 62304:2006 Amd 1: 2015 and IEC 60601.

Alcon

Chemist
March 2014 – April 2015
Johns Creek, GA

- Peer-reviewed and prepped for laboratory audit readiness
- Conducted quality control and in-process tests
- Conducted process improvement activities for analytical method validation

Johnson & Johnson (Noramco) **Chemist**
April 2012 – March 2014

- Authored standard operating procedures
- Approved and reviewed stability testing for control substance schedules I, II, and III
- Investigated and authored investigations, determined root cause(s) and implemented CAPAs
- Approved testing results using a variety of chemistry-specific software programs, e.g., Empower 3, LIMs
- Coordinated, designed, and implemented a hazardous waste system

EDUCATION

Florida Institute of Technology Melbourne, FL (USA)
Master of Project Management

Oakwood University Huntsville, AL (USA)
Bachelor of Science in Chemistry