POLYMATH
REGULATORY CONSULTANTS LLC

J. Eckenfels, MS, CQA

Senior Consultant
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SKILL SET

Regulations: 21 CFR 820, 210, 211, 11, EU MDR 2017/745, ISO 13485:2016, ISO 14971:2019, MDSAP, GCP, QMSR, FDA QSR, cGMP

Quality Assurance: Internal and Supplier Audits, FDA Inspection Readiness, Gap Assessments, CAPA Management, Regulatory Strategy, Risk Management, Technical Documentation, Quality Planning, Design Controls, Complaint Handling

Compliance: Internal Auditor Training, FDA Mock Inspections, Regulatory Training Programs, SOP/WI Development

Products/Services: Respiratory Devices, Electromechanical Devices, SaMD, Pharmaceuticals (Oral Solid, Sterile), Clinical Trial Devices

Applications: Microsoft Office, SharePoint, Greenlight Guru, TrackWise, MasterControl, Dot Compliance, Veeva, Arena

Certifications: ISO 13485:2016 Lead Auditor, ISO 9001:2015 Lead Auditor, EU MDR Auditor, GCP Auditor, Lean Six Sigma Yellow Belt

Other Skills: Project Management, Quality Metrics Development, Audit Hosting (Front Room), Regulatory Intelligence, FDA 483 & Warning Letter Remediation

PROFESSIONAL EXPERIENCE

Polymath Regulatory Consultants, LLC
GMP and Quality Consulting
Independent Contractor

Sr. Quality Consultant
February 2025 – present
Atlanta Metro Area

Medical Device Consulting Firm
GMP and Quality Assurance

Principal Consultant
June 2018 – present
Remote

- Lead global internal audits and FDA mock inspections for Class II/III device manufacturers including respiratory device companies
- Develop and delivered internal auditor training aligned with ISO 13485:2016 and FDA QSR/QMSR
- Support FDA inspection readiness including simulation of inspection protocols and front/back room coaching
- Develop and implement QMS documentation (SOPs, WIs, Forms) tailored to client-specific workflows
- Serve as Management Representative and PRRC for start-ups seeking ISO 13485 certification and FDA market entry
- Execute gap assessments and regulatory roadmaps for clients in preparation for MDSAP, EU MDR, and FDA inspections
- Provide expert support during remediation activities for 483s, Warning Letters, and Notified Body nonconformities

Oriel STAT A MATRIX

Affiliate Instructor
August 2023 – present
Remote

- Conduct instructor-led training on ISO 13485, Design Controls, Risk Management, and Internal Auditing
- Developed course content for auditor qualification programs and FDA readiness

TecTraum, Inc.

Head of Quality and Compliance
August 2022 – May 2023
Remote

- Designed and implemented internal audit and supplier audit programs for Class II medical devices
- Conducted pre-inspection FDA readiness reviews and quality plan development
- Authored SOPs and training programs to support ISO 13485 certification

XaTrek, Inc.

Head of Regulatory Affairs and Quality Assurance
August 2022 – May 2023
Remote

- Led FDA, ISO, and Notified Body inspection readiness projects
- Implemented internal audit program and trained cross-functional staff
- Supported clinical trial compliance and regulatory documentation development Designed and implemented internal audit and supplier audit programs for Class II medical devices

EDUCATION

Arizona State University
Master of Science in Regulatory Science

Tempe, AZ (USA)

Arizona State University Tempe, AZ (USA)
Bachelor of Science in Organizational Leadership