POLYMATH
REGULATORY CONSULTANTS LLC

CONSTANCE Y FEARS, JD, PHD

CEO & Principal Consultant
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SKILL SET

Regulations & Standards: 21 CFR 210, 211 and Part 11, FD & C Act, ICH, EudraLex Parts I and II and Annexes, Annex 1, PIC/S, ISO, Good Distribution Practices (GDP), Good Documentation Practices, Data Integrity Principles, world-wide GMPs

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

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

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

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

Certifications/Special Training: Former US FDA Certified Level I Drug Investigator, Microbiology inspector for US FDA, US and EU law and regulation

PROFESSIONAL EXPERIENCE

CEO & Principal Consultant **Jun. 2023 – present**
Polymath Regulatory Consultants, LLC *Cumming, GA*

- Provide expert knowledge of worldwide CGMPs, legislation, standards and guidance documents to drug, cosmetic and Medtech companies
- Research complex quality and CGMP compliance questions using artificial intelligence, legislation, regulations, industry benchmarking, peer-reviewed publications etc.
- Perform inspection readiness activities for single or complex/multi-Agency CGMP inspections; inspection support/management; drafting responses to Agency inspection reports; warning letter remediation

- Conduct site CGMP/ISO audits
- Author documents and conduct CGMP compliance review of Quality Management System (QMS)
- Develop and present CGMP training, including annual CGMP training
- Provide CGMP subject matter expertise for artificial intelligence and machine learning platforms

Adjunct Assistant Professor of Biotechnology **Summer 2024 - present**
Morehouse School of Medicine, Masters in Biotechnology Atlanta, GA

Relevant Courses Taught: Making Medical Devices, covering various stages of device manufacture, including CGMP

Director, Global CGMP Quality Compliance **June 2022 –June 2023**
Merck & Co., Inc. Remote

- Provided regulatory and inspectional intelligence using electronic platforms, e.g., Redica
- Served as a global subject matter expert for CGMPs for drug products, active pharmaceutical ingredients, vaccines, and medical devices
- Ensured new and developing global QMS standards and procedures impacting Merck manufacturing sites were fully compliant with international regulatory expectations
- Trended and analyzed inspectional observations received across the network for impact to various above-site teams and impact to the network as a whole
- Trended and analyzed inspectional observations and enforcement actions for impact and learning opportunities within the network
- Developed and oversaw program to share significant site-level inspectional observations between sites and above-site teams to prevent recurrence
- Supported pre-approval inspection readiness and post-inspection remediation activities
- Supported global audit program by identifying audit targets and develop protocols for targeted assessments
- Participated in industry organizations and pharmaceutical benchmarking groups
- Assessed draft and finalized regulations/laws for an impact to global quality and compliance

Director, Global Quality Systems & Compliance **Jan. 2021 – Jun. 2022**
Merck & Co., Inc. Remote

- Served as global business owner of Quality Management System (QMS), responsible for compliance with and implementation of CGMP/GDP regulations for Annual Product Reviews, Recalls/Market Actions, Product Discontinuation, Product Quality Complaints, Management of Returned Goods, and Health Authority Reporting, e.g., FARs, BPDRs
- Monitored QMS health and proactively identified, investigated and resolved trends and patterns before compliance and supply impact; defined and drove implementation of performance metrics, as appropriate, to measure effectiveness of the quality organization and management responsibilities activities across the network
- Authored and revised global QMS documents, e.g., quality standards and global procedures, for alignment with global regulatory requirements
- Monitored Health Authority regulations, issues, trends and changes to ensure relevant regulations were incorporated into QMS documents
- Reviewed pending and new global regulations for impact on QMS topics and amend documents as needed

- Provided subject matter expertise (SME) in CGMPs for worldwide and support audits and inspections
- Interfaced with Information Technology (IT) group to develop and implement IT tools to increase efficiency and CGMP compliance
- Initiated and led communities of practice (CoPs) or centers of excellence (CoEs) to drive best practice sharing and continuous improvements across the network
- Influenced and advocated positions on continued product assessment and reporting related Healthy Authority expectations through a strong partnership with internal connections
- Anticipated external trends through benchmarking and regulatory intelligence activities and prepare the company proactively for changes and continuous improvements
- Led the development and execution of significant innovation projects driving operational improvement
- Acted as a member of the QMS Leadership Team
- Supervised and managed QMS Team
- Drove continuous improvement initiatives within the QMS

Other Duties

- Divisional Quality Council (DQC) Coordinator- organized cross-departmental monthly meetings with senior management including determination of topics to be covered, presenting Global Quality KPIs, managing action items and drafting meeting minutes.

Director, Global Quality Compliance (Inspection Readiness) **Sept. 2018 – Jan 2021**
Merck & Co., Inc. Remote

- Monitored and reviewed new CGMP legislation, regulations, and guidance documents and reported to internal and external sites via quality councils and external communications
- Directly interacted with Health Authorities, e.g., during inspections by answering inquiries and acting as the liaison between the site and global level
- Served as global SME for CGMPs related to active pharmaceutical ingredients (APIs) and finished drugs for contact manufacturing organizations (CMOs)
- Reviewed global QMS documents to ensure compliance with regulatory requirements
- Assessed regulatory intelligence and partnered with External Quality Assurance (EQA) and CMO management to prepare for Health Authority inspections, e.g., mock inspections, inspection readiness, training etc.
- Assessed regulatory trends and reported to internal and external sites via quality councils and external communications
- Provided on-site guidance during CMO Health Authority regulatory inspections
- Partnered with EQA and CMO management to identify appropriate corrective action and preventive action (CAPA) Plans to address global audit and Health Authority inspection observations
- Monitored CAPA status and ensured timely CAPA implementation and effectiveness
- Monitored and analyzed outcomes of Health Authority inspections to identify, investigate, and resolve trends and reported results to Quality Councils
- Reviewed and approved quality agreements

Special Projects:

- Lead for site implementation of Merck Global Nitrosamine Impurity Project (2020)
- Compliance review of global QMS documents for Material Management, ensuring compliance with regulations (2020)
- Compliance lead for supplier management of subcontractors (2020)
- Assisted with development of global inspection portal for remote inspections (2020)

Associate Director, Quality Assurance (Auditing & Compliance) **Oct. 2017 – Sept. 2018**
Merck & Co., Inc. Wilson, NC

- Site Lead Auditor & Compliance Lead:
    - Led all site internal audits, including drafting and issuing audit agendas and final audit reports
    - Led all CGMP-related regulatory inspections, including preparation, execution, response writing, CAPA tracking and closeout
    - Managed auditing personnel
    - Mentored and supported new and existing site auditors to ensure performance of auditors contributed to the effectiveness of the internal audit program
    - Led change and process improvement initiatives related to auditing, inspections, CAPA etc.
    - Presented site auditing metrics and emerging regulatory trends at site quality council
    - Reviewed and ensured audit and inspection responses and CAPAs were robust and performed CAPA effectiveness checks
    - Led continuous improvement projects related to auditing and inspection readiness
    - Led permanent inspection readiness activities– organizing SMEs, formulating the tour routes, and facilitating audit/inspection logistics
    - Drafted and reviewed Health Authority responses
    - Provided compliance advice to site related to development and commercial product teams

Special Projects:

- Developed and implemented site-wide Data Integrity Improvement Plan
- Developed and implemented an integrated approach to site auditing by combining permanent inspection readiness with the internal audit program.
- Developed global audit curriculum for use Merck-wide for the training of site internal auditors

Consumer Safety Officer **Nov. 2014 – Sept. 2017**
U.S. Food and Drug Administration Silver Spring, MD
Office of Regulatory Affairs (ORA)
Center for Drug Evaluation and Research (CDER)

- Performed independent CGMP inspections of pharmaceutical manufacturers world-wide
- Acted as inspectional SME for development of artificial intelligence and machine learning platform
- Assessed public comments on FDA draft guidance documents and provided legal and technical advisory opinions to senior management
- Performed data analytics on post-marketing events, e.g. FARs, complaints, and reported trends to senior management
- Served on working committees to improve Agency relationships with industry

- Authored inspectional dossiers for foreign and domestic drug inspections, advising inspectors of high-risk coverage topics and areas
- Drafted technical guidance documents, e.g., SOPs and work aids for Agency stakeholders
- Authored comprehensive establishment inspection reports (EIRs) using the FD&C Act, Compliance Programs and Guidance Manuals, and 21 CFR 210, 211, and ICH Q7
- Authored post-inspectional memoranda to drug firms addressing the adequacy of proposed CAPAs
- Collaborated directly with the Office of Compliance to obtain regulatory actions against non-compliant firms
- Partnered with state agencies (e.g. Georgia Department of Agriculture) and other Federal Agencies (e.g. Veteran's Affairs)

Awards:

- 56th Annual FDA Awards Ceremony, August 8, 2016. Recognition for contributions to:
  - *Wallcur Simulated Saline Incident Task Force*- For sustained efforts in both containing the public health threat associated with simulated 0.9% sodium chloride bags and efforts to prevent future patient exposures.
  - *Drug Shortages Mobile Application Development Team*- For developing an innovative tool that will offer easier and faster access to important drug shortage information.
- Performance-based time and monetary awards and positive reviews from senior investigators, trainers, and trainees

Assistant Professor of Biology (Tenure Track) **August 2012 – Dec. 2014**
Middle Georgia State University Cochran, GA

Relevant Courses Taught
Cell Biology, Molecular Biology, General Biology I and II, and Ethics in Bioscience

EDUCATION

University of Texas at Austin, School of Law Austin, TX (USA)
Juris Doctorate (JD)

Université Jean Moulin III, School of Law Lyon (FRANCE)
Diploma in International and French Law

University of Alabama at Birmingham, School of Medicine Birmingham, AL (USA)
Doctor of Philosophy (PhD), Cell & Molecular Biology/Cancer Biology

Florida State University Tallahassee, FL (USA)
Bachelor of Science in Biological Sciences