



EDITH LEWIS-ROGERS

Associate

QUALIFICATIONS SUMMARY

Edith has over 30 years of FDA field experience, Quality Assurance/Quality Control Head at a top 10 Pharma company, corporate compliance management with a top 10 pharmaceutical/healthcare company, corporate compliance with a mid-size healthcare company, regulatory consultant with a private consulting firm and world wide compliance management at a Phase III biotech company.

EXPERIENCE

Initiated Corporate Regulatory Compliance program for biopharmaceutical development company of Phase III drug/device. Initiated Corporate Integrity and Corrective Action/Preventative Action program. Recognized by COO as positive change agent. COO commitment included letter to all employees regarding improving GCP compliance and corporate integrity.

Provided GMP, GCP and GLP compliance communications with FDA and EMEA for international and domestic biotech and pharmaceutical clients at consulting firm. Responsible for compliance positioning for e-mail diary manufacturer for FDA requested meeting.

Provided consultant and auditing services to all divisions of a top 10 healthcare company in the biologic, prescription, bulk pharmaceutical, medical device and in vitro diagnostic specialties. Audit reports were written to the Chairman of the Board to assure company compliance at the highest levels of division management. Significant organizational changes occurred in the bulk pharmaceutical and the in vitro diagnostic divisions as a result of my audits. Successful pre-approval inspections for biologics and prescription products

Built quality and GLP, GCP and GMP compliance into development products as the Director, QA/Compliance at a top 10 international Pharma company.

Provided timely launches and NDA approvals for top 10 Pharma company. Launched over 70 new products from 1997 until 2003 including three major Rx to OTC switches, and three device products.

Provided global expertise for a Pharmaceutical division in GMPs and GLPs. Played a critical role in the development of a globalized GCP program through the development of SOPs and audit program, supporting global submissions.

Provided pivotal role in CMC coordination as well as the identification and correction of issues before submission. Prepared active ingredient suppliers as well as internal and external manufacturing, laboratory and packaging sites for successful pre-approval inspections by FDA. Major role in removing Warning Letter constraints at an API supplier.

Performed over 35 drug GMP and pre-approval inspections and over 40 medical device/in vitro diagnostic GMP inspections as an FDA field investigator. Trained in GCP clinical investigations and GLP inspections. Involvement in one FDA prosecution, and multiple Warning Letters and voluntary corrective actions.

EDUCATION

MBA, Finance, June 1986
Pace University, Lubin Graduate School of Business
New York, NY
Outstanding Scholarship Award, Finance Department

BS, Environmental Science, June 1976
Rutgers University, Cook College
Outstanding Service and Leadership Award

AWARDS

2001 "CEO's Top 10 Employee Award" Novartis Consumer Health, NA "Externally Focused, Internally Aligned and Right-on-Target"

PUBLICATIONS, PRESENTATIONS, AND MEMBERSHIPS

"New Drug Approval Process - Accelerating Global Registrations", Fourth Edition, Marcel Dekker Press, 2004

"HIPAA: A New Requirement to the Clinical Study Process"

"Clinical Supplies, A Quality Assurance Perspective", Contract Pharma, May 2003

Minimizing Risk: FDA Environmental Monitoring Expectations, IVT, Environmental Monitoring August 2006

Principals of Environmental Monitoring for Isolators, IVT, Environmental Monitoring August 2006

Are disposables meeting the requirements of your environmental monitoring program, IVT, Environmental Monitoring, August 2006

Measuring the Effectiveness of Your Risk Management Program, IVT, Risk Assessment and Management, June 2006

FDA Expectations: GMP IQPC Contract Manufacturing 2006, IQPC, May 2006

Maintaining Control to Uphold Quality, IQPC Contract Manufacturing 2006 May 2006

Drug Safety: Impact on FDA Approval Time, Project Management, IVT, June 2005

Improving Time to Market, Project Management, IVT June 2005

ACRP, Controls and Documentation to Comply with HIPAA, June 2003

DIA Annual Meeting, GCP Due Diligence Audits, June 1998

FDA/NDMA GLP Seminar, Laboratory GMPs, July 1995

American Association of Pharmaceutical Scientists

Parenteral Drug Association

Drug Information Association

International Society of Pharmaceutical Engineers

American Society for Quality