



Regulatory Compliance Initiatives, Inc.

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Leading the Way

CURRICULUM VITAE

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11/02 to Present: Regulatory Compliance Initiatives, Inc.
Principal

Specializing in current Good Manufacturing Practice (cGMP) Regulations, Quality System requirements, and developing and directing regulatory corrective and preventative action (CAPA) initiatives; and GMP and DEA training seminars.

1/83 to Present: Medipharm International Consultants, Ltd.
President

Consultant to domestic and foreign pharmaceutical/chemical companies, including manufacturers of ethical and OTC pharmaceutical products, bulk active pharmaceutical ingredients (APIs) and intermediates, Controlled Substances, vitamins, herbal and dietary supplements, medical devices and cosmetics.

Preparation, submission and monitoring of Drug Master Files, IND's, Forms 6, NDA's and ANDA's, as well as development and implementation of Standard Operating Procedures which conform to FDA and International Good Manufacturing Practices; pre-approval inspections (PAIs) and facility audits to determine level of compliance required to conform to such regulations; contact with the Food and Drug Administration, Drug Enforcement Agency, Consumer Product Safety Commission, and Environmental Protection Agency, and International Regulatory Agencies,

Experienced in acquisition evaluation, strategic analysis and technology assessment, and have participated in market analysis and market research studies that involved special technical expertise.

6/90 - 6/04: Cox & Fay, Inc. & Technology Transfer, Inc.
Principal-Regulatory Compliance

3/84 - 6/86: Dell Laboratories/American Geriatric Drug Co. Teaneck, N.J.
Vice President Operations

3/80 - 2/84: Edward Mendell Company, Inc., Carmel, N.Y.
Vice President Operations

3/77 - 3/80: The Vitarine Company, Inc., Queens, N.Y.
Director of Regulatory Affairs and Quality Assurance

3/64 - 3/77: Manhattan Prescription Center, New York, N.Y.
Owner/pharmacist - ethical prescription pharmacy

Education: Columbia University College of Pharmacy
Bachelor of Science Degree in Pharmacy

Memberships: Parenteral Drug Association
International Society of Pharmaceutical Engineers
Regulatory Affairs Professional Society
Consumer Healthcare Products Association
Columbia University College of Pharmaceutical Sciences
Alumni Association

References furnished upon request