



Cynthia A. Ipach
President

OVERVIEW

As President of Compliance Insight, Inc., Cindy has worked with companies regionally and worldwide in the Pharmaceutical, Medical Device, Dietary Supplement and Biotechnology industries in the fields of Regulatory Affairs and Quality Assurance. Her consulting realm includes FDA, USDA, BATF, EU, etc. regulation compliance. Cindy's primary strengths are Regulatory Affairs and Quality Assurance.

PHARMACEUTICAL EXPERIENCE

- ◆ Nine years as President of a consulting firm for FDA regulated industries.
- ◆ Seven years as Director of Scientific Affairs (including Regulatory Affairs, QA, QC Chemistry, QC Microbiology, and Validation) in a global pharmaceutical company following continuous advancement through management
- ◆ Participated in Management Committees for API and Medical Device Divisions
- ◆ Coordinated multi-departmental efforts to achieve business goals
- ◆ Project Manager for Regulatory Affairs, Quality Assurance, Quality Control, Microbiology and Validation activities required to establish a new API plant in Asia
- ◆ Participated in global QA/QC meeting to set standards for the corporation
- ◆ Leader for inspections by Regulatory agencies
- ◆ Maintained compliance with US and foreign regulations
- ◆ Provided various levels of training on numerous subjects
- ◆ Assembled and updated US and foreign government Pharmaceutical and Medical Device applications
- ◆ Wrote, reviewed and approved SOPs and Specifications
- ◆ Reviewed and approved Batch Records and Safety Policies
- ◆ Reviewed and approved process, equipment, test method, cleaning and viral validation protocols and reports
- ◆ Audited raw material suppliers
- ◆ Assisted multiple companies with corrective action planning for 483's or warning letters to avoid further Regulatory action
- ◆ Coordinated efforts on recalls and provided progress reports to the FDA
- ◆ Coordinated and monitored R&D-Formulation, R&D-Analytical, and Regulatory Affairs Department activities
- ◆ Conducted departmental meetings to facilitate transfer of newly developed products into mass production
- ◆ Prepared annual reports, adverse drug reaction reports, supplemental applications, import/export permits and deficiency responses

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FORMAL EDUCATION

- 1986 Bachelor of Science - Natural Science with concentration in Biology and Chemistry (dual major); College of Mount Saint Joseph
1984 Medical Technician Internship; Providence Hospital, Cincinnati

CORPORATE HISTORY

- 2000-Present Compliance Insight, Inc., Fairfield, Ohio, President
1991-2000 Pharmacia Hepar Inc., Franklin, Ohio, Director of Scientific Affairs
1985-1991 Duramed Pharmaceuticals, Cincinnati, Ohio, Manager of ANDA Filings

PROFESSIONAL AFFILIATIONS

- ◆ Regulatory Affairs Professional Society (RAPS)
- ◆ Parenteral Drug Association (PDA)
- ◆ Advisor to the Gerson Lehrman Group on Drug Discovery