

Compliance Insight, Inc.

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NUMBER OF EMPLOYEES
12

DATE FOUNDED
2000

OUTSOURCING and Consulting Services



Compliance Insight, Inc.

General Company Description

Compliance Insight, Inc. specializes in hands-on FDA Regulatory and Quality Assurance consulting and training for the pharmaceutical, dietary supplement, medical device, chemical, cosmetics, bio-technology and food industries worldwide. With over 150 years combined experience in FDA-regulated industries, our skilled and dedicated consulting team has the knowledge and expertise needed to support large and small companies in identifying and correcting compliance and regulatory issues. We are large enough to cover the full spectrum and small enough to assure that every client receives our personal attention.

Products/Services

Compliance Insight, Inc. specializes in GMP consulting, audits, training, due diligence and FDA response assistance. We also offer design and QA review services for viral clearance, cleaning validation, and product lot release testing.

Our QA/Regulatory consulting services provide valuable expertise and hands-on support for short term and long term projects. We are dedicated to helping you develop and maintain a quality-centered and GMP-compliant focus in your company.

Audit Services:

- PAI Preparation
- Laboratory
- Due Diligence
- Vendor
- GMP GAP Analysis
- Mock Audits
- Part 11 Compliance
- Contract Mfg

GMP Training

- In-house
- Annual
- New Employee

QA/Regulatory Consulting:

- GMP Consulting
- SOP development and writing
- Validation planning and review
- Risk assessment
- Part 11 compliance
- FDA response assistance
- 483 Resolution
- Consent decree resolution
- CAPA implementation
- Risk-Based Assessments
- Project Management
- Drug Master Files
- 510(k) Applications

Virology Consulting:

- QA Evaluation
- Viral clearance study design and review
- Cleaning Validation
- Product Lot Release Testing
- Risk Assessment

Markets Served

Compliance Insight, Inc. serves the pharmaceutical, dietary supplement, medical device, chemical, cosmetics, biotechnology, and food industries who market their products in the US. Support industries such as contract testing labs, raw material and component suppliers, and contract manufacturers are also served.

