



What Our Clients Say About Us

Clients welcome our hands-on approach and have this to say about us:

- One of the finest consultants who I have ever had the pleasure of working with.
- Works extremely hard to provide constant value to his customer and always provides a common sense approach to issues.
- Unique ability to provide training and mentoring, as well as, communicate effectively with all levels of an organization.

— JH

- A great asset to QA team.
- Demonstrated the effective management characteristics, behaviors and/or best practices.
- Clarifies goals and objectives for everyone involved.
- Facilitates work through team building, training, coaching, and support.
- Provides feedback honestly and constructively.
- Keeps things moving by relying on schedule, deadline, and helpful reminders.

— RRV

Welcome!

In 2000, **Cynthia A. Ipach**, President, established Compliance Insight in order to bring her many years of pharmaceutical industry experience and expertise to FDA-regulated industries in the US and abroad. Shortly thereafter, **Troy Fugate**, Vice President, joined the company and together they set out to build a consulting firm that would not only provide expert advice, but that would provide the hands-on support many companies need when facing regulatory and compliance issues. Since then, the company has grown to include a number of experienced compliance specialists with expertise in a wide range of QA/Regulatory disciplines.

With over 150 years combined experience in FDA-regulated industries, our dedicated consulting team has the knowledge 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.



**COMPLIANCE
INSIGHT Inc.**

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Your Hands-On Quality And Regulatory Specialists



Compliance Insight, Inc. specializes in Regulatory and Quality Assurance consulting and training for the pharmaceutical, dietary supplement, medical device, chemical, bio-technology and food industries. Biosafety and viral testing consultation services are also available. We travel nationally and internationally to support companies in their endeavor to bring safe and reliable products to the US.

Our Insights Will Keep You In Compliance

When You Work With Compliance Insight

Compliance Insight, Inc. is a group of skilled Quality Assurance and Regulatory Affairs professionals with proven track records in a variety of FDA-regulated industries. We offer U.S. FDA Regulatory and Quality Assurance consulting to companies worldwide.

We specialize in **GMP consulting, audits, training and FDA response assistance.** We also offer design and QA review services for viral clearance, cleaning validation, product lot release testing, and product risk assessments for viral contamination.



Feel confident and **ready to respond** to the FDA during your next inspection.

At **Compliance Insight**, it is our belief that a **proactive** solution works best. Our thorough evaluation identifies regulatory and compliance issues and our experienced team offers **hands-on** support to ensure the corrections are performed quickly and effectively. We are dedicated to helping you develop and maintain a quality-centered and GMP-compliant focus in your company.

Our proactive services include:

- Auditing
- Inspections
- GAP analysis
- Training
- SOP development
- Viral clearance study design
- Validation planning and review
- Risk assessment
- Part 11 compliance



Well trained employees and clearly written SOPs reduce costly GMP errors.

However, when a **reactive** solution is needed, **Compliance Insight** can help too. With FDA inspections a routine occurrence, companies large and small must resolve issues with 483's and warning letters. Our professionals have firsthand experience in dealing with the demands of everyday work life in the FDA-regulated industries. **Our reactive services include:**

- FDA response assistance
- Consent decree resolution
- CAPA implementation



Properly-designed **viral clearance studies** will bring your biologic to market faster.

Services

AUDIT SERVICES

Our **Audit Services** enable you to be proactive with regard to your quality assurance and regulatory compliance status.

- PAI Preparation Audits
- Laboratory Audits
- Due Diligence
- Contract Manufacturer Audits
- Vendor Audits
- GMP Gap Analysis
- Mock Audits
- Part 11 Compliance

GMP TRAINING

Our **Training Programs** provide a hands-on solution to your training needs.

- In-house Training
- New Employee Orientation
- Annual Training
- QA Accreditation

QA/REGULATORY CONSULTING

Our **QA/Regulatory Consulting Services** provide valuable expertise and hands-on support for short term and long term projects.

- GMP Consulting
- Risk Based Assessments
- FDA Mock Inspection
- Warning Letter Response
- Annual Product Reviews
- Project Management
- Investigations/CAPA
- 483 Resolution
- 510k preparation
- Biosimilars Consulting
- New Construction Compliance Assistance
- Custom Standard Operating Procedures
- Cleaning Validation Consultation
- Validation Planning and Review
- Consent Decree Resolution
- ANDA/Supplements/Annual Reports
- Establishment Registration

VIROLOGY CONSULTING

Our **Virology Consulting Services** provide you with the expertise needed to perform QA evaluation, design protocols and prepare reports for viral product challenges and viral clearance studies.

- Viral Clearance Study Design and Review
- Cleaning Validation
- Product Lot Release Testing
- Product Risk Assessments