



**COMPLIANCE**  
INSIGHT, INC

## ***Compliance Insight Overview***

Compliance Insight, Inc.  
Corporate office Cincinnati, OH Area

Phone: 513.860.3512  
[www.compliance-insight.com](http://www.compliance-insight.com)  
[info@compliance-insight.com](mailto:info@compliance-insight.com)



# COMPLIANCE INSIGHT

At Compliance Insight, we support top Medical Device and Pharmaceutical manufacturing and Clinical sites by providing effective GxP training as well as mission critical quality assurance and regulatory affairs support. Founded by our President, Ms. Cynthia Ipach, in 2000, and joined later by our Vice-President, Mr. Troy Fugate, we have assembled a team of highly qualified, subject matter experts with hands-on experience, knowledge and skills to infuse GxPs into your organization's DNA. We are former FDA inspectors and industry professionals with a common mission, **to move beyond regulations to compliance that makes sense.**

## ULTIMATELY, OUR GOAL IS TO PUT CONSULTANTS OUT-OF-BUSINESS!

What do we mean by that? We mean that we want to change the industry standard. The cycle of annual GMP training, followed by FDA audits that lead to 483s, and then eventually mitigation by outside consultants, is a cycle that can be broken. Research tells us that organizations are historically committing the same offenses, year after year. We call them the "Three Sins of GMP." We want to introduce you to an approach that is effective and sustainable, one that will lead to an end to mitigation work, and the need for outside consultants altogether.

Our purpose is to safeguard the health and wellness of all stakeholders. This includes everyone from the suppliers of raw materials and components, the final product manufacturer, the FDA and, most importantly, to the patient. We do this by building a team of subject matter experts and knowledgeable colleagues who all share this same passion.

Many customers are starting to understand that annual GMP training is simply a "compliance event" with little improvement in quality or productivity. Our GMP Infusion workshop will move you to get enthused and infused! Please contact us to learn more about the "Three Sins of GMP". This is the first step in understanding how to build a culture of quality, and the first step to breaking the cycle.

Here at Compliance Insight we do business by strict core values. The following attributes have become the core values of the company upon which everyone is evaluated. They are as follows:

### OUR CORE VALUES:

- Always do the right thing
- Provide comprehensive and systemic actions
- Be flexible and options oriented
- Make it happen
- Positive attitude
- Be empathetic



"THREE SINS OF GMP."



"GMP INFUSION"



# THE CHALLENGE QUESTIONS

## GMP TRAINING

What was the topic of the last GMP Training?  
What changed as a result?  
What improvements were made?  
What is the level of retention for the participants who attended?

## SUPPLIERS

How do you learn about supplier issues?  
How would you assess your alignment with key customers?  
What level of cooperation exists between key suppliers?  
What level of dialogue is occurring?

## PREPARATION FOR THE FDA VISIT

What resources are available?  
How do you know if you are prepared?  
What is your organization's commitment to GMP?  
Will FDA agree and see your commitment?  
What is your level of experience in working with the FDA?  
When is the worst timing for an audit to occur?

## MITIGATION SUPPORT (483s/WL)

How will you manage the timeline?  
How will the response be written?  
What is the review process?  
What if the FDA does not accept the response?  
How do you evaluate potential issues?  
How will this affect the production schedule?  
What resources will be needed?

## INFLUX OF NEW WORKERS

What are the training needs?  
What is the onboarding process?  
What resources will be allocated?  
What process is in place to manage large number of new workers?  
What are the language barriers to consider?  
What are the time constraints?  
How do you make on boarding process dynamic, significant?

## CLINICAL

Are adverse events reported timely?  
Is the protocol followed?  
Is the TMF complete?

### GMP

#### Quality Assurance

- FDA Remediation of 483/Warning Letter/Consent Decree
- FDA Audit Support/Mock Audit
- CAPA/Deviation Investigation
- Risk Based Assessments
- SOP writing and review
- Equipment/Facility/Computer Validations
- Contract Manufacturer/Vendor Audits
- GxP GAP Analysis Audit
- Laboratory Audit
- Due Diligence
- Good Supplier Practices (GSP)

#### Regulatory Affairs

- Investigative New Drug (IND)
- New Drug Application {NOA}
- Abbreviated New Drug Application (ANDA)
- Investigational Device Exemption (IDE)
- Premarket Approval {PMA}
- SOI(k) Submissions
- Establishment Registration
- Annual Reports/Supplements

### GCP/GLP

- How to Handle an FDA Inspection Training
- Note to File Training
- Regulatory Binder Training
- Ethics (Nuremberg/Helsinki/Belmont)
- IRB and Investigator Responsibilities
- FDA Remediation of 483/Warning Letter
- SOP Writing and Review
- Medical/Protocol writing and review

### GCP Audits

- IRB Audits
- Clinical Site Audits
- Sponsor Audits
- CRO Audit
- Phase I-IV Audits
- FDA Audit Support/Mock Audit
- Vendor Audits

# OUR CODE OF COMMITMENT TO YOU

All of the members of Compliance Insight appreciate your commitment to use our services to meet your compliance goals. We, therefore, commit the following actions to you – our partner:

## ETHICAL EXECUTION OF WORK

- Trustworthy – We will:
  - Not deceive, cheat or “milk” a client for time or services performed
  - Be honest and reliable
  - Be loyal, reliable and maintain integrity
- Respectful – We will:
  - Abide by the Golden Rule — do unto others as you would have them do unto you
  - Be respectful of the clients’ money – be a good steward

## EXPERTISE AND SKILLS

- Colleagues assigned to the project will have the skillsets to perform the task
- Being accountable. Ethical people show responsibility by being accountable and pursuing excellence by being diligent and persevering
- Have the ability to respond to expectations
- Own the task assigned

## CUSTOMIZATION OF EXECUTION

- Fitting project actions into the client’s unique circumstances and operations
- Learn the specific processes at the site to understand how best to effectively and efficiently implement compliance

## TIMELINESS

- Rapid response to effectively execute the tasks assigned
- Have skilled colleagues on site and/or actively working to resolve issues quickly

## ACCESSIBILITY

- Easy availability to discuss the project execution with key decision makers

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### Our mission:

Go beyond the regulations to compliance that makes sense

### Our vision:

Your first and best choice for decisive insight into GxP compliance!

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## 2018 Pharma Tech Outlook: Company of the Year

*Compliance Insight has been selected for Company of the Year they have demonstrated a commitment to excellence and gained strong industry credibility,” Said Stacy Smith, Managing Editor, Pharma Tech Outlook. “I congratulate Compliance Insight and look forward to its continued success.”*

