



PDMA Compliance relies on the following factors:

- Knowledge of the regulations
- Documentation of those decisions
- Training
- Governance
- Decisions on how *your company* will interpret the regulations
- Programs and systems to address them
- Resources
- Organizational support

Summary

The TGaS® Advisors Commercial Compliance Benchmark helps pharmaceutical companies navigate in a demanding and evolving regulatory environment. **TGaS Advisors provides a comprehensive method for optimizing the Compliance requirements set forth in PDMA and the regulations set forth in 21 CFR Part 203.** The Benchmark will help you:

- Benchmark Resources (headcount & spending), Sourcing and Organization Structure
- Identify **PDMA issues** embedded in operational programs
- Construct a comparative evaluation against a peer set
- Identify how technology is currently being utilized to manage sample programs
- Provide industry standards for subjective regulatory requirements
- Understand the most current thinking with respect to the meeting regulatory requirements

Participating companies learn operational best practices in such areas as governance, organizational structure and resources. Aligned with current regulations, more than 250 elements are benchmarked.

Area of Focus

The PDMA Compliance Benchmark focuses on key Compliance functions and is designed to help Compliance Operations with its strategies, capabilities and efficiencies. These critical functions include:

- Reconciliation issues, timing, products, adjustments, reporting losses, costs and technology utilized
- Non-personal promotion programs, sample receipts, carrier electronic verification systems, follow-up with non-responders and managing patterns of non-response
- Federal and State reporting issues
- Audit & Security Programs and how they trigger reporting requirements
- Training platforms and documentation
- Disciplinary policies and corrective action programs
- Use of web-based and e-based sampling initiatives
- Self Monitoring and Compliance committees

Information provided in the peer set based benchmark is in the following areas:

- | | |
|--------------------------------|------------------------|
| * Organizational Structure | * Internal Policies |
| * Operational Data Management | * Technology |
| * Documentation & Reporting | * Training |
| * Monitoring & Self Assessment | * Resources & Sourcing |