



# Quality Audits

Quality audits are essential for compliance and maintaining a competitive edge.



**Audits ensure process integrity, patient safety, operational efficiency, and foster innovation and trust in your organization.**

## Enhance Compliance and Performance

Pharmatech's expert team engages to understand your compliance needs and develop a targeted audit plan that focuses on risk identification and mitigation strategies that enhance operational performance across all drug and medical device modalities.

## Independent Eye

Our thorough, rigorous, and customized auditing approach is an unbiased lens to identify even the minutest of oversights. This ensures the proactive detection of adverse risks and opportunities for improvement.

## Actionable Insights for Improvement

Identifying a problem is only the beginning. Comprehensive process and systems evaluations include strategic recommendations based on collective industry experience. We identify issues and provide a phase appropriate framework to bolster your quality systems.

## Outsourced Vendor and Internal Audits

*We are routinely engaged to augment capabilities of outsourced partners to complete their annual audit plans, which encompass both internal and external audits. Our services include scheduling and conducting audits, writing detailed audit reports, and reviewing proposed CAPA plans. Our breadth encompasses GMP, GDP, GLP, and GCP-focused evaluations of suppliers and service providers for multiple product modalities.*

STEPHANIE GAULDING, CQA, CPGP  
Managing Director

OVER 75 YEARS OF COLLECTIVE  
QUALITY EXPERIENCE

Contact us to speak with quality management experts that can assess your needs and support your goals.

**Our exceptional auditing services provide clients with the opportunity to be at the forefront of quality and compliance.**

**GxP Audits**

Ensure operational compliance against relevant guidelines and regulations and the quality of manufacturing, quality control, and quality assurance systems.

**Service Provider Audits**

Assess the reliability and compliance of vendors to safeguard your supply chain.

**Inspection Readiness Audits**

Evaluate your readiness for a regulatory inspection and identify opportunities for improvement.

**Internal Audits**

In-depth evaluations of your internal processes to ensure industry standards and best practices are met.

**Mock Inspections**

Regulatory inspection simulations to assess your organization's level of compliance and address potential issues.

**Data Integrity Audits**

Evaluate adherence to established data integrity principles to safeguard your GxP-regulated data, ensuring proper collection, retention, and protection.

**Unmatched Expertise in:**

- *Local & international regulation interpretation and application*
- *Evaluation against required standards and best practices*
- *Practical corrective and preventive action planning and oversight*
- *Risk identification, analysis, and mitigation strategy*
- *Measuring auditing programs against industry benchmarks*

**PHARMATECH IS BACKED BY US PHARMACOPEIA'S (USP'S) 200 YEARS OF INSIGHT AND EXPERIENCE PROVIDING QUALITY STANDARDS AND GUIDANCE TO THE INDUSTRY.**

**Call us at 1-877-787-0177 or email [contact@pai-qbd.com](mailto:contact@pai-qbd.com) to discover how Pharmatech's auditing services can support your commitment to excellence.**



Pharmatech Associates is a global consultancy for the life sciences and supports manufacturers in product and process development, quality, U.S. market entry, and advanced manufacturing for biologics, small molecules, C&GT, and novel drugs. With over 25 years of experience, the company works with clients ranging in size from start-ups to large multinationals. Beyond its foundational strength in core U.S. markets, Pharmatech has expanded service worldwide in lockstep with growing demand for life sciences regulatory expertise.

**pharmatechassociates.com**  
**1.877.787.0177**

