



# Customized Solutions to Elevate and Streamline your Quality Management

**Pharmatech Associates develops a comprehensive understanding of your existing quality management system and identifies opportunities for enhancing efficiency to save you time and money. We are experts in:**

## **Process Standardization and Compliance**

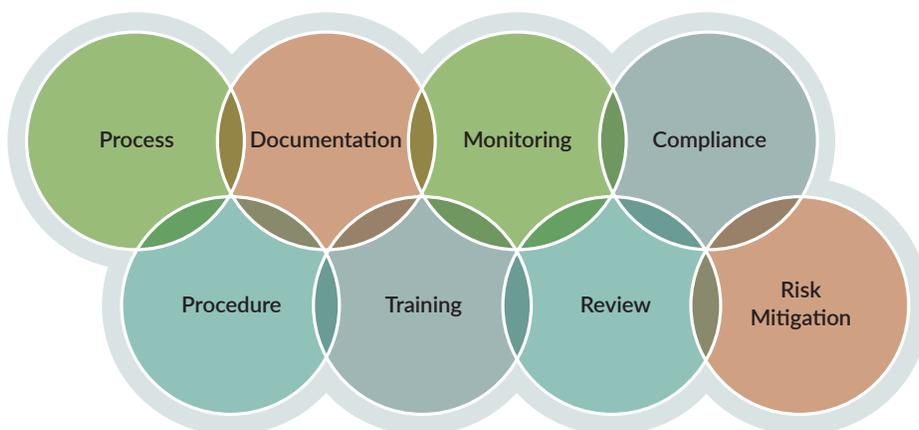
We recognize that addressing quality process challenges can involve various methods and immerse ourselves in understanding your specific requirements when crafting a phase-appropriate tailored roadmap to achieve your goals.

## **Quality Management Tools**

Our extensive experience with a wide range of QMS and LIMS software allows us to maximize the potential of these tools to enhance your organization's operations, mitigate risk, and ensure compliance.

## *Risk-Based Oversight of GxP Suppliers*

*A late-stage clinical drug sponsor needed to overhaul their supplier oversight program and establish a centralized, risk-based process. To encompass the various requirements for GLPs, GCPs, GMPs, and GVPs, we developed a centralized framework for supplier onboarding that included GxP-specific forms, checklists, and guidelines for supplier evaluations and audits. We also streamlined their supplier onboarding process and developed a plan to systematically transition existing suppliers to the new programs. Ultimately, the client achieved full visibility of their suppliers and the ability to tailor oversight requirements based on risk levels, which facilitated scalability as their drug products progressed through development.*



**The Integrated System of Quality Management where every element plays a vital role.**

[Contact us to speak with quality management experts that can assess your needs and support your goals.](#)

### Post-Acquisition QMS Harmonization

Following a series of recent acquisitions, each with its own QMS, one of our clients found itself entangled in a complex web of redundant and overlapping processes. To allow for easy diagnosis, we built a customized QMS roadmap that organized their processes into related topics. This clearly revealed the overlaps and redundancies, and even unearthed previously unidentified process gaps. Collaborating with our client, we developed a comprehensive remediation plan to consolidate and simplify their QMS, resulting in a more efficient and user-friendly system.

## The Core of your Quality is People. Pharmatech Associates is:

### Informed

In addition to our decades of combined experience, we also proactively stay updated on changes in the international regulatory landscape through webinars, conferences, and papers, enabling us to promptly adapt to emerging therapeutic areas and fuel our innovative problem-solving approach.

### Adaptable

Our experience with diverse therapeutic technologies, spanning small molecules, biologics, AMPs, C&GTs, personalized medicines, and innovative delivery systems, allows us to remain platform-agnostic.

### Proficient

We consider employee competency when developing our strategies to ensure that quality processes and tools will be effectively utilized in your organization through tailored training solutions.

### Mock-Inspections

To prepare a small biotech company for multiple pre-approval inspections within their in-house and outsourced manufacturing facilities, we created a comprehensive readiness framework. This included compliance summaries, pre-approval and surveillance inspection tools, an inspection risk register, a playbook, and role-based training for their staff. The initial pre-approval inspections yielded positive ratings and ultimately contributed to the client's successful BLA submission.

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 to schedule an initial consultation and explore how we can support you!



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

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