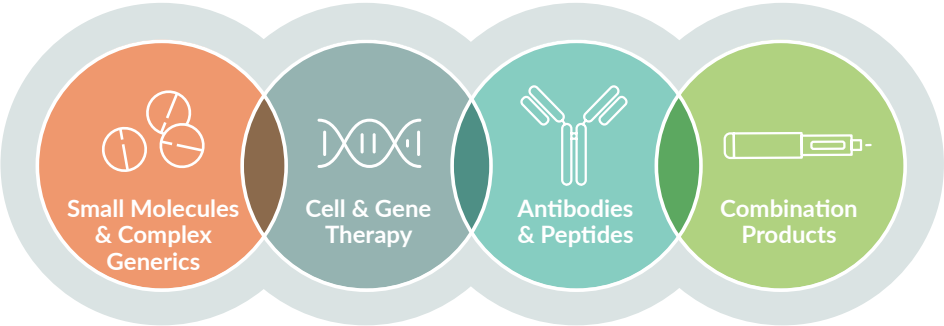
pharmatech™ associates | a USP company

Your Partner in Bringing Quality Medicines to the World

Confidently navigate complex, global regulations and emerging technologies across therapies and devices with expert guidance from Pharmatech Associates.

Offering end-to-end expertise, Pharmatech Associates is a full-service global consultancy for the regulated life science industry, supporting manufacturers for more than 25 years in product and process development, regulatory affairs, quality, US market entry, and advanced manufacturing. Whether you are developing a small or large molecule, complex or novel modality, or combination product, our unique-to-you solutions get you to market faster, accelerating the delivery of quality medicines to major markets worldwide.



BACKED BY US PHARMACOPEIA

US Pharmacopeia (USP) and Pharmatech Associates share a vision of helping manufacturers bring safe, quality medicines to patients.

> *For more than 200 years, USP has worked to expand the supply of quality medicines. For our work to be successful, we know we must help strengthen quality systems by working with both US and international manufacturers and regulators. Now Pharmatech Associates, as a USP company, positions us to continue to strengthen the global supply chain and extend our collaborative relationships even more.*

RONALD PIERVINCENZI, CEO, USP

Accelerate Time to Market

PHARMATECH ASSOCIATES BRINGS DOMAIN EXPERTISE TO CLIENTS FOR A RANGE OF THERAPEUTIC MODALITIES

We help you lower your program risk, extend your financial runway, and get products to market fast. By integrating our experts with your team, we deliver customized solutions in:

Product and Process Development

Whether you are developing a cell or gene therapy, mAbs, or other drug or device, Pharmatech can partner with you to develop your CMC strategy and content for all drug modalities. From product and process design and analytical method development through commercial scale-up and technology transfer, our customized support enables you to manage your total development program and realize your business strategy.

Seamless Process Transfers

We helped a CGT CDMO transfer the manufacturing process and analytical methods for eight products to a new facility, each with unique process parameters and control strategies. We performed risk assessments for each and created protocols, batch records, and SOPs to support successful, seamless relocation.

Regulatory

As industry specialists and former FDA reviewers in all drug modalities, we foresee and mitigate delays and identify critical gaps before they become a problem. We offer customized strategies for organizations of all sizes and stages of clinical development and commercialization so you can confidently navigate IND, BLA and other regulatory submissions.

Quality

A phase-appropriate Quality Management System that matures as your organization grows can save time and money. We deliver the quality solutions your specific program needs, offering expert help in process standardization, compliance, and Quality Management tools so you can fully reap the benefits of your eQMS or LIMS.

We are a one-of-a-kind consulting partner

US Market Entry

Bringing a drug product into the US market calls for deep knowledge of regulatory, quality, and product and process requirements. Pharmatech Associates' onshoring experts integrate with your team to define success metrics, develop your commercial strategy, create a roadmap for manufacturing and distributing your product, and work with regulatory agencies to help you painlessly gain approval.

Simplifying US Regulatory Filings for Foreign Products

We helped a cell therapy client in Asia identify critical gaps and deficiencies that otherwise would have precluded them from filing an IND in the US. We also laid the scientific groundwork for post-approval commitments and saved the client's overall program a significant amount of time and money.

Advanced Manufacturing/PCM

We help you evaluate the benefits of moving to a continuous manufacturing platform and offer strategic support with business case analysis, development, equipment, and regulatory requirements. Our experts are familiar with all of the latest equipment and technology, simplifying your transition to pharmaceutical continuous manufacturing.

The customized solutions we offer across these focus areas are in addition to Pharmatech's long-established expertise in helping clients optimize the true cost of ownership, from construction to full operation. Our services are designed to evolve as regulatory, scientific, or business conditions change, meaning we're always ready to make your route-to-market more resilient.

As the global consulting arm of USP, we're committed to helping you take advantage of every opportunity that accelerates your path to market.

We Do:

- Leverage our diverse, multidisciplinary team of technical experts covering all domains from project management to regulatory compliance, from APIs to cell and gene therapies
- Definitively solve complex problems so you can be successful the first time
- Operate with a hands-on approach, visiting your facility or taking other steps to develop fully customized solutions that work for your unique situation

We Don't:

- Provide cookie cutter solutions
- Provide general advice
- Waste your time and money

Achieve Essential Goals — No Matter How Complex Your Project

The Devil is in the Details: 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, including compliance summaries, pre-approval and surveillance inspection tools, an inspection risk register, a playbook, and role-based training for their staff, which contributed to positive ratings on initial pre-approval inspections and a successful BLA submission.

Our end-to-end capabilities, technical knowledge, regulatory insight, project management, and business acuity help our clients achieve four essential goals:

Faster to Market We ensure rapid fulfillment of your goals so you can more quickly bring quality medicines to the global market.

Risk Reduction We proactively address regulatory challenges so that you can achieve more efficient regulatory interactions and shorter review timelines.

Compliance We architect agile quality management systems responsive to evolving compliance requirements, minimizing compliance risks for your entire product life cycle.

Synchronous Development We tackle your problem from multiple perspectives simultaneously, bringing you from idea to execution rapidly and cost-effectively.

Accelerated Time-to-Market with Customized Roadmaps

We recognized the potential for a new chemical entity (NCE) to obtain breakthrough drug status and amended the CMC strategy at Phase 1 to support commercial-scale quantities. They achieved breakthrough drug status and the drug sponsor simplified the CMC comparability argument in its filing using the same clinical lots used in Phase 1. As a result, the regulatory review was much simpler and the client launched 3-6 months sooner.

Call us at 1.877.787.0177 or email contact@pai-qbd.com to schedule an initial consultation and explore how we can support you!

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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.

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