pharmatech associates | a USP company

Compliance Through Science

What Challenges Are You Facing?

Speed to Patient

Ask any life science company what their core challenge is, and they'll tell you that it's delivering a safe and effective product to patients faster.

Synchronous Development

Developing a new drug or medical device is like building a plane while you're flying it. The challenge is to build a scalable ecosystem that helps you at every stage, while mitigating risk.

Compliance

Are you building compliance into your product and processes as early as feasible? Our priority is to minimize compliance risks for your entire product life cycle while establishing customized building blocks for scalability.

Time to Market

There is a business case for each innovation and meeting the expectations of key stakeholders is an important component of bringing your product to market. We help you achieve and communicate your progress throughout the development process to manage those key relationships and get to market faster.

Our Approach

Pharmatech Associates draws from decades of experience serving the complex needs of pharmaceutical manufacturers and regulated life science companies bringing quality products to market.

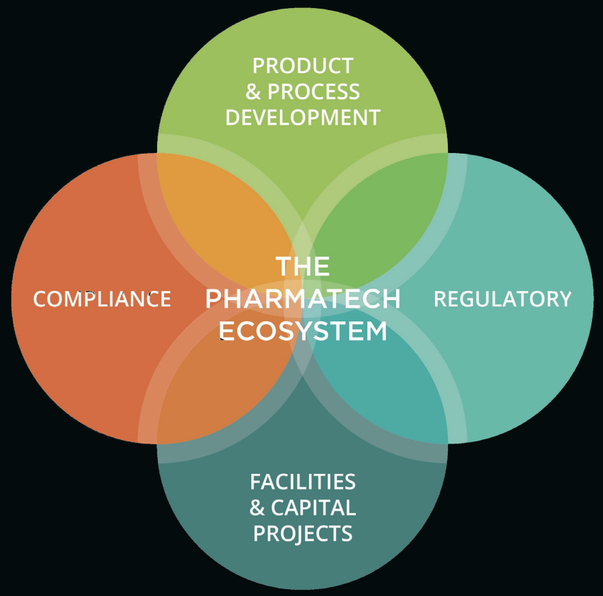
Our solutions are:

Patient-Centric **Nimble** **Holistic** **Scalable**

A Framework for Success

Drug and medical device development is often depicted as a linear process. While there are well-defined phases, those who have navigated this journey know its complexities. The actual development process is filled with starts, stops, delays, complex regulatory filings, copious documentation, investor demands, and rapidly changing resource needs.

All the while, there are real patients whose lives will be better if you succeed. The complex product development journey demands a framework that is up to the challenge. The Pharmatech ecosystem is a synchronous approach that transforms product development, from innovation to execution.



Bikash Chatterjee,
Chief Executive Officer

End-to-End Capabilities Built from Knowledge and Experience

Pharmatech and USP

Pharmatech and USP share a common vision of advancing access to quality medicines and medical devices worldwide.

"For more than 200 years, USP, globally recognized for our drug quality standards, 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 U.S. and international manufacturers and regulators. Now, Pharmatech, as a USP company, positions us to continue to strengthen the global supply chain and extend our collaborative relationships even more."

Ronald Piervincenzi,
Chief Executive Officer,
United States Pharmacopeia

Mission-Critical Solutions

Over-the-Horizon Capabilities

Tailored Outcomes

Success the First Time

Modern Quality Development

Over-the-Horizon Capabilities

Over-the-horizon capabilities offer a clear roadmap from innovation to execution. By starting with the end in mind, we can develop capabilities that fit into the larger picture and scale for future needs.

Throughout a product's development, the unknowns often outnumber the knowns. Uncertainty is high and success is imperative. Having an experienced advisor who can anticipate what challenges lie beyond the horizon and provide clear guidance on next steps is invaluable.

Wai Wong,
Vice President, Validation

How We Can Help

Regulatory

We develop a regulatory strategy to help you anticipate questions or challenges from regulatory bodies and negotiate on your behalf with alternative solutions to meet requirements. This facilitates more efficient regulatory interactions and shorter review timelines. We also consider and actively integrate the commercial impact of regulatory decisions into your strategy.

Compliance

Our priority for innovators is to maximize compliance and minimize regulatory risks that lie over the horizon. We will ensure that your Quality Management System is robust and defensible when evaluated by health authorities.

Facilities & Capital Projects

We will help you optimize your true cost of ownership from construction to operation with facilities and processes designed to meet business objectives. We offer expertise in small molecule and medical device projects, as well as biologics, combination products, and cell and gene therapy.

Product & Process Development

Effective product and process development lays the foundation for regulatory expectations in the future. By anticipating regulatory agency concerns, we are able to efficiently and effectively move a drug program through the development lifecycle with little to no rework.

Tailored Outcomes

Tailored outcomes are specific to your organization's success metrics, which could be key milestones, capabilities, or business initiatives.

You know your product, its intended therapeutic benefits, and stakeholder priorities better than anyone. Your focus is, understandably, on your own success metrics. The challenge is that you may not have the bandwidth to focus on specific, customized solutions that will ultimately improve time to market for your product.

Stephanie Gaulding, *CQA, CPGP*
Managing Director

How We Can Help

Regulatory

We develop a tailored regulatory strategy that defines CMC and non-clinical and clinical requirements based on your intended claims and markets.

Compliance

As you approach late-stage clinical and regulatory submission, we proactively develop a tailored Quality Management System which will evolve with your organization and business strategy.

Facilities & Capital Projects

We design lean facilities and processes that align with your current budget, resources, and goals, providing outsource management when needed. We also ensure that all facilities and processes are scalable to meet your business objectives.

Product & Process Development

We support your tailored product and process development efforts, from developing your strategy for CMC characterization through commercialization. We provide turnkey solutions and guidance as your trusted advisor.

Success the First Time

Drug development is a complex undertaking, and success the first time ensures more efficient development from innovation to execution.

Sadly, we've come to expect delays in the drug and medical device development process, but it doesn't have to be that way. An experienced team of development specialists will anticipate regulatory requirements in advance and foresee issues before they arise, infusing your entire process with an end-to-end strategy that is proactive.

Allison Cacciatore,
Executive Director, Facilities Design & Engineering

How We Can Help

Regulatory

To ensure success the first time, we offer stakeholder management that aligns all stakeholder goals early in the development process. We also facilitate successful interactions with health authorities and regulatory bodies to ensure productive outcomes.

Compliance

We build tailored Quality Management Systems that align with development activities to minimize compliance and regulatory risks, including compliance audits and gap analysis against the regulatory bodies. As your program moves toward commercial manufacturing, we consider data management and data integrity.

Facilities & Capital Projects

When designing the facilities structure and function, we integrate business performance requirements, development, and marketing strategies to ensure your facility can operate at nameplate capacity on turnover.

Product & Process Development

Pharmatech's proven methodologies ensure that your process is robust, consistent, and reliable the first time. We provide the scientific and technical guidance to develop a robust and defensible CMC program for your product.

Modern Quality Systems Development

A modern Quality Management System (QMS) requires an integrated approach, in which the quality framework and philosophy is infused in the development science as a foundation for building compliant systems.

As an innovative, small-to-midsize drug development company, you are developing a product, your company, and supply chain simultaneously. Developing a modern Quality Management System, including processes and procedures, data management, roles and responsibilities, and training at the same time is challenging, but the benefits are significant. Having a dedicated team of experts to help you with this integrated development is invaluable.

Adam Lambert,
Vice President, Product & Process Development

How We Can Help

Regulatory

We offer strategic guidance to help you build a Quality Management System focused on efficient processes that support regulatory activities and filings.

Compliance

We create unique Quality Management Systems that ensure the safety and efficacy of your product as it moves through characterization and commercial readiness activities.

Facilities & Capital Projects

Using risk-based tools, we condense timelines and work within your budget while minimizing compliance risks. We offer agile validation services based on a documented procedural map designed to evolve as your regulatory, scientific, or business conditions change.

Product & Process Development

We develop your product and process development strategy from inception through the regulatory process using proven methodologies that support the complex needs of a modern QMS.

The Pharmatech Story

After decades of experience in the nutrition and pharmaceutical industries, Calvin Wong was working in business development and validation for an architectural design firm in San Francisco. While meeting over lunch, a long-term client suggested that there was an unmet need for validation consulting services in the Bay Area's growing pharmaceutical industry. Calvin left the meeting with no intentions of starting his own firm, but it was too late—the seed had been planted. In 1995, Calvin founded Pharmatech, a small validation firm that qualified facilities and equipment in the Bay Area.

Over the years, the pharmaceutical and biotech industries evolved and more consulting needs emerged. With the addition of Warren Baker and Bikash Chatterjee to the Pharmatech leadership team, our services grew to support clients throughout the U.S. and Asia across the entire product life cycle. We recognized the need for an integrated approach and the Pharmatech Ecosystem naturally emerged: Compliance, Regulatory, Product & Process Development, and Facilities & Capital Projects.

Calvin Wong, *Founder*

Your Trusted Advisor

Our enduring mission is to help bring novel therapies to the patients who need them and to serve as trusted advisors to the scientists and engineers behind the innovations. With Pharmatech, you have access to subject matter experts who can guide you through the complexities of product development, from innovation to execution.

A Culture of Scientific Thinking

Pharmatech has grown to more than 50 employees and in 2021 was acquired by USP, bringing a 200-year legacy of building trust in medicine through standards for drug quality and safety and programs that create greater access to medicines for patients around the world.

Science is the core of our business, and it's also the root of our company culture. Our team members are excited by new challenges and stand ready to help.

We would love to connect with you!

Contact any member of our business development team at contact@pai-qbd.com or 877-787-0177 Toll Free.

Visit pharmatechassociates.com and follow us on LinkedIn.

Steve Schiltz,
Business Development Manager

Janette Buechler,
Director, Sales & Marketing Communication

Gregory Downs,
Director, Business Development