



## FACILITIES & CAPITAL PROJECTS SERVICES

FACILITY DESIGN

ENGINEERING

PROCUREMENT

CONSTRUCTION MANAGEMENT

QUALIFICATION

**Pharmatech Associates** provides expertise in all areas of facility design, engineering, procurement, construction management, and qualification / validation to the life science industry. Our solutions are designed to meet the complex business performance requirements of today's state of the art facilities. To achieve a facility designed with the highest standards, we consider process flexibility, scalability, product requirements, short-term and long-term company objectives and total cost of ownership (TCO) including facility lifecycle management and decommissioning.

Services Include:

- Conduct feasibility studies
- Develop project charters and execution plans
- Perform conceptual and basic design
- Support selection of architects, general contractors, OEMs, and trades
- Contract negotiation and procurement
- Project cost controls
- Oversight of detailed design
- Client representation
- Commissioning, startup, and training
- Regulatory support

Our Facility and Capital Projects team employs an innovative delivery design model to bridge the gap between owner and architect. Our subject matter experts have fully integrated development experience across all knowledge areas of Product & Process Development, Compliance, and Regulatory Affairs. This breadth of knowledge allows for strategic decisions during critical phases of the facility design process. **Compliance Through Science<sup>®</sup>** is your assurance that Pharmatech's method, expertise and performance provide your organization with expert guidance to meet the continually evolving compliance demands of our global marketplace.

**Compliance Through Science<sup>®</sup>**

## Service Offerings Include:

### Facility Design Services

Our planning and execution methodology incorporates key elements of product lifecycle management which is at the core of designing GMP facilities. We transform your product, process and future scalability requirements into facility attributes that maximize business performance while integrating all operational, regulatory, and quality requirements of your program.

- Feasibility Studies
- Develop Facility Requirements based on Product & Process Specifications
- Conceptual & Basic Design
- Detailed Design Review
- Design Qualification
- Pre-Operational Reviews with Regulatory Agencies

### Procurement Services

We construct GMP compliance procurement systems based on key long-term objectives, operating, and supply chain models. We perform a thorough assessment of suppliers to ensure compliance, financial viability and longevity to minimize risk and support your supply chain. Our experienced team can also manage procurement services and support building the supply chain organization.

- Establish GMP Procurement Systems: Virtual/Vertical Integrated
- Manage Procurement Systems
- Contract Negotiations- Development, Supply and Quality Agreements
- Contract Oversight

### Construction Management Services

We support both start ups and big pharma and provide representation, expertise and guidance in planning and constructing GMP facilities. These facilities include laboratories, manufacturing and warehouses /distribution for both clinical and commercial scales for small molecule, large molecule (API, drug substance, drug product) to complex large molecule modalities such as cell and gene therapy.

- Construction Budget Development
- Project Controls
- Owners Representative
- Identification and Selection of GCs and MEPs
- RFQ and Proposal Reviews
- Construction Oversight and Scope Management

### Qualification Services

Pharmatech's approach to C&Q is based on User and Functional Requirement Specifications, Vendor Documentation, Basis of Design (BOD) and Supplier provided documentation to develop commissioning and qualification programs. We incorporate a structured risk-based framework or best-in-class principles such as ATSM E-2500 in developing C&Q programs to reduce time and cost.

- Commissioning & Start Up
- Operational & Maintenance Programs
- Asset Induction Management
- Qualification & Validation
- Computerized System Validation
- Training

**Pharmatech Associates, Inc.**

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