Innovative SOLUTIONS

Pharma-Tech Process and Facilities Services is an industry leader in providing innovative technical consulting and staff-augmentation services to the pharmaceutical, biotechnology and **advanced technology** industries. A majority of our work revolves around the engineering, construction, inspection, verification, validation, operation and maintenance of pharmaceutical and biotechnology manufacturing facilities, systems and equipment. Our learning management and on the job **training** programs allow us to provide our clients with qualified, trained cross-functional personnel equipped with the latest **industry best practices,** technology and experience to integrate seamlessly into client projects bringing immediate productivity with minimal learning curve.

Our goal is to provide exceptional service and **technical support** with a tailored approach to project execution that safely exceeds client project and business objectives.

"Our business is to bring operational excellence to yours."

We offer World Class Expertise in the following areas:

- Aseptic Processing
- Project Management
- Biopharmaceutical Operations
- Disposable Single-Use Technology
- Upstream and Downstream Processing
- Cleanroom Operations and Maintenance
- Process, Utility and Facility Support Systems
- Cleaning Engineering and Validation Services
- Sterilization Engineering and Validation Services

Pharma-Tech
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Construction
PERIOD SERVICES

Pharma-Tech Process and Facilities Services provides a broad range of construction and capital project services to the biopharmaceutical and advance technology industries. We understand the construction issues and pressures that arise when dealing with aggressive, **fast paced**, high tech/construction projects with tight budgets and tighter schedules. We facilitate cross-functional communication and coordination with the client and subcontracted trade services to ensure project requirements and **timelines** are met with a commitment to safety and quality. We assist our clients in establishing a transparent approach to project execution by documenting a clear definition of project objectives with roles and responsibilities that emphasize **accountability** with objective and measurable success criteria.

Our Construction and Capital Project capabilities include:

- Project and Construction Management
- Strategic Planning
- Construction Supervision
- Trade Coordination
- Modular Construction
- Hygienic Piping
- Detailed Design Review
- Project Execution Planning
- Criticality and Impact Assessment
- Risk assessment and Mitigation
- Annual Shutdown Planning and Management
- Pre-Construction and Construction Period Services
- Project Controls
- Vendor Audits
- Project Scope Development
- Cost Estimating and Scheduling
- Benchmarking
- Bid Packages
- Schedule Development and Tracking
- Budget Development and Tracking
- Factory and Site Acceptance Testing
- Punch Lists
- As-Builts (Record Drawings)
- Turnover Package Development
- Procurement
- Change Management

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Validation
AND COMPLIANCE

Pharma-Tech Process and Facilities Services provides a broad range of validation, verification and compliance services to the highly regulated pharmaceutical, biotechnology and medical device industries. We assist our clients to develop validation master and project plans that best **utilize** and **leverage** successful commissioning and verification activities. We have an extensive library of engineering, qualification and validation templates, **procedures** and protocols that allow us to quickly apply our verification test procedures to validation and compliance projects to greatly **minimize** document development, review and approval **time**.

Our Validation and Compliance Services include:

- Validation and Project Master Planning
- Criticality and Impact Assessment
- Risk Assessment and Mitigation
- Change Management
- Cleaning Validation
- Sterilization Validation
- Process Validation
- Computer Software Validation
- Technical Writing
- Strategic Planning
- Protocol Generation and Execution
  - Installation Verification and Qualification
  - Operational Verification and Qualification
  - Performance Verification and Qualification
- Traceability
- cGMP Documentation
- Standard Operating Procedures
- User Requirements
- Functional Specifications
- Detailed Design Specifications
- I/O Testing
- Control Loop Testing
- Alarms and Security Testing
- Riboflavin Coverage Testing
- Process Analytical Technology
- ASTM 2500
- Supplier Audit
- Factory and Site Acceptance Testing
- Quality Assurance
- GDP Review

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Start-Up

AND COMMISSIONING

Pharma-Tech Process and Facilities Services provides a broad range of start-up and commissioning services to the pharmaceutical, biotechnology and advanced technology industries. We assist our clients to develop effective commissioning project plans and strategies to best utilize and **leverage** successful commissioning and verification activities into subsequent validation activities. We have an extensive library of start-up and commissioning templates and checklists that allow us to quickly apply our verification test procedures to start-up and commissioning projects to greatly **minimize** document development, review and approval **time**.

Our start-up and commissioning capabilities include:

- Start-Up and Commissioning Master Planning
- Criticality and Impact Assessment
- Risk Assessment and Mitigation
- Change Management
- Drawing and Utility Verification
- Control System Testing and Troubleshooting
- Control Loop Tuning
- Cleaning Cycle Development
- Sterilization Cycle Development
- Engineering Runs
- Computer Software Commissioning
- Technical Writing
- Strategic Planning
- Protocol Generation and Execution
  - Installation Verification
  - Operational Verification
  - Performance Verification
- Traceability
- cGMP Documentation
- Standard Operating Procedures
- User Requirements
- Functional Specifications
- Detailed Design Specifications
- I/O Testing
- Control Loop Testing
- Alarms and Security Testing
- Riboflavin Coverage Testing
- Process Analytical Technology
- ASTM 2500
- Supplier Audit
- Factory and Site Acceptance Testing
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Single-Use

DISPOSABLE TECHNOLOGY

Pharma-Tech Process and Facilities Services provides a broad range of disposable single-use technology services to the pharmaceutical and biotechnology manufacturing operations. We assist our clients in navigating the evolution of aseptic processing from the traditional methods of stainless steel assets requiring cleaning and sterilization to the world of single-use disposable technology with new requirements of gamma irradiation and leachable/extractables. We provide leadership in developing turn-key, single-use implementation strategies that ensure a smooth technology transfer from one technology to another. We recognize the materials management impact this new technology brings with an increased volume of GMP raw materials and the need for nimble change management.

Our Disposable Single-Use Technology capabilities include:

- Project Management
- Prototype Development and Testing
- Fit for use Assessment and Evaluation
- Subject Matter Expertise
- Vendor Coordination
- Feasibility Studies
- Comparability Studies
- Engineering Test Plans
- Change Management
- Conceptual and Detail Design
- Commissioning
- Validation
- Procurement
- Material Specifications
- Leachable/Extractables
- Single-Use Technology Transfer
- Process Flow Diagrams (PFD, P&ID)
- Bill of Materials
- User Requirements
- Materials Management and Supply Chain Coordination
- Mixing Studies
- Temperature Mapping
- Destructive Testing
- Process Optimization
- Return on Investment Analysis
- Media Challenge
- Vendor Audit and Inspections
- Vendor Documentation

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Clean in Place
AND CYCLE DEVELOPMENT

Pharma-Tech Services is an industry leader in Clean in Place systems, cycle development and **cleaning validation.** We offer a wide array of services and **expertise** required to validate your manufacturing cleaning procedures for both manual and automated cleaning processes. Our CIP cycle development and cleaning validation programs provide **documented evidence** that ensure your cleaning and equipment procedures are **capable** of removing residual process soils, effectively, **repeatedly** and efficiently. We summarize all relevant cleaning qualification data, parameters and test summaries in our exclusive CIPTOPs. Let us compile yours today!

Clean in Place Services:

- CIP Troubleshooting and Consultation
  - Surveys and Assessments
  - Control Loop Tuning
  - Spray Device Modification and Specification
  - FAT, SAT, RV, IV, PV, IQ, OQ, PQ
  - Cleaning Impact/Risk Assessment
- CIP Cycle Development and Optimization
  - Protocol Development and Execution
  - Parameter Development and Justification
    - Manual and Automated Operations
    - DeltaV, Rockwell, Parts Washers
    - Parts Washer Load Configuration
    - Rinse Out Curves
    - Riboflavin Coverage Testing
    - Visual Inspection
    - Design of Experiments
    - Confined Space Entry
  - Cycle Optimization
    - Reduce time, water and detergent usage
  - Custom Passivation and De-rouging Procedures
  - Standard Operating Procedure Development
- CIP Cleaning Validation
  - Master Planning
  - Protocol Development and Execution
  - Acceptance Criteria Development
  - Test Method Development
  - Swab and Rinse Recovery Studies
  - CIP Sample and Data Management
  - Continuous Monitoring Strategies
- Exclusive Pharma-Tech CIPTOP Turnover Packages

Portable TOC Analysis

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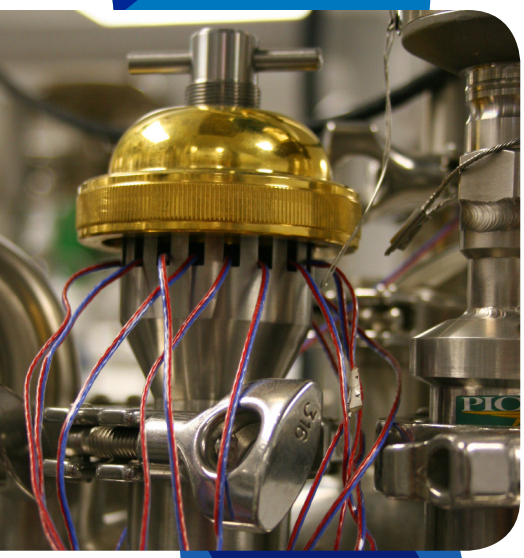
Steam in Place
AND THERMAL VALIDATION

Pharma-Tech Services is an industry leader in Steam in Place systems, cycle development and **sterilization validation**. We offer a wide array of services and **expertise** required to validate your sterilization and aseptic processing procedures. Our SIP cycle development and sterilization validation programs provide **documented evidence** that ensure your sterilization procedures are capable of providing adequate kill, lethality and sterilization, effectively, **repeatedly** and efficiently. We summarize all relevant SIP and sterilization qualification data, parameters and test summaries in our exclusive SIPTOPs. Let us compile yours today!



Steam in Place Services:

- Steam in Place Troubleshooting and Consultation
  - Clean Steam and Sterility Surveys and Assessments
  - Control Loop Tuning
  - FAT, SAT, RV, IV, PV, IQ, OQ, PQ
  - Sterilization Impact/Risk Assessment
- SIP Cycle Development and Optimization
  - Protocol Development and Execution
  - Parameter Development and Justification
    - DeltaV, Rockwell, Autoclaves
    - Autoclave Load Configuration
    - Thermal Mapping
    - Biological Indicator Lethality Verification
    - Design of Experiments
    - Confined Space Entry
    - Kaye Validator 2000 Operation and Training
  - Cycle Optimization
    - Sterilization—Empty and Full Vessel
    - Decontamination—Empty and Full Vessel
    - Autoclaves—Dry and Liquid Loads
  - Standard Operating Procedure Development
- SIP Sterilization Validation
  - Acceptance Criteria Definition
  - Media Simulation and Challenge
  - Contamination Investigation
- Thermal Validation
  - Temperature and Humidity Room and Equipment Qualification
  - Shipping Validation
  - Cold Rooms and Refrigerators
  - Ovens and Incubators
- Clean Steam Consultation
  - Clean Steam Generator Start-Up and FAT
  - Clean Steam System Design and Operation
  - Clean Steam Quality Testing
  - Clean Steam System Start-Up and Tuning
- Exclusive Pharma-Tech SIPTOP Turnover Packages

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