Innovative SOLUTIONS

Pharma-Tech Process Services is a high-energy, schedule-driven, technical service provider. Our **innovative** consulting services cover Commissioning, Validation and Construction Period Services to the pharmaceutical, biotechnology, and medical device industries. We **specialize** in pharmaceutical and biotechnology renovations, expansions and greenfield facilities. In short, we are the **process doers** that facilitate your process from design to cGMP manufacturing.

Our goal is to provide **exceptional service** and **technical support** to our clients while maintaining their project's critical schedule and budget.

We offer world class expertise in the following areas:

- Pharmaceutical Construction and Project Management
- Startup, Commissioning and Validation for the following areas:
  - Fermentation & Cell Culture
  - Purification & Harvest
  - Formulation & Fill Finish
  - Media/Buffer Prep & Storage
  - Clean in Place (CIP) & Steam in Place (SIP)
  - Direct & Indirect Impact Utilities

Pharma-Tech
PROCESS SERVICES, LLC
Toll-Free: 866-797-0413
www.pharma-techs.com

Construction
PERIOD SERVICES

We provide world-class construction period services to a broad range of biopharmaceutical and semiconductor clients requiring clean construction. **We understand** the construction issues and pressures that arise when dealing with aggressive, fast paced, biopharma construction projects with tight budgets and tighter schedules. **We facilitate** communication between the architect, construction manager, subcontractors and the owner to quickly resolve issues to not only maintain the construction schedule but the design intent. **We protect** our clients from a subcontractor's or CM's poor interpretation of design documents and project specifications that could result in costly rework and schedule impacts.

We are committed to client satisfaction and we focus on building strategic partnerships and collaborative solutions that bring efficiencies to both your project's construction schedule and qualification life cycle.

Our Construction Period Services Include:

- Project and Construction Management
- Strategic Planning
- Construction Supervision and Trade Coordination
- Modular Construction
- Hygienic Piping
- Detailed Design Reviews
- Schedule and Budget Development and Tracking
- Project Scope and Bid Package Development
- Vendor Audits
- Factory and Site Acceptance Testing
- Punch Listing Against Design Documents
- As-Builts (Record Drawings)
- Turnover Package Development
- Passivation Coordination and Planning
- Procurement and Schedule Expediting

Pharma-Tech
PROCESS SERVICES, LLC
Toll-Free: 866-797-0413
www.pharma-techs.com

Commissioning

Pharma-Tech Process Services specializes in startup and commissioning of biopharmaceutical manufacturing and **medical device** production facilities. Unlike most commissioning agents out there today, we actually commission and **troubleshoot** hardware and software issues in the field. We work with the owner and engineer to initiate a **corrective action** or change control immediately. Our past experience in design and operations of sanitary process systems and equipment allows us to quickly resolve issues that will delay construction, commissioning or qualification activities.

Our goal is to start up your facility to operate as intended **by design** and to meet the final user's requirements. We will **work with you** to develop a commissioning plan that outlines the responsibilities of the design teams, construction contractors, commissioning agents and owners during the start-up and commissioning phase. We have an **extensive library** of startup and commissioning templates and checklists that allows us to quickly apply our procedures and test plans to your specific project. We also identify the required **inspections** and tests to be verified or leveraged into validation verification documents. This greatly minimizes document development time and allows for quicker document review, approval and execution.

Poorly executed commissioning efforts will result in **delayed** and **costly** validation and qualification activities.

Our Startup & Commissioning Services Include:

- Protocol Generation and Execution
  - Installation and Operational Commissioning
  - Standard Operating Procedures
  - Factory and Site Acceptance Testing
  - Maintenance Manuals
  - Summary Reports
- Plan, Coordinate and Direct All Startup and Commissioning Activities with Required Vendors, Contractors, Owners and Construction Managers to Best Meet the Project Schedule
- System Walk Down and Punch Listing Against Design Documents
- Drawing and Utility Verification
- Control System Testing & Troubleshooting
- Functional Specification Review
- cGMP Documentation
- Turnover Package Review and Development
- Riboflavin Coverage Testing
- Change Control Management
- Equipment Operation Training
- ASTM E2500
- Cleaning and Sterilization Development

Pharma-Tech
PROCESS SERVICES, LLC
Toll-Free: 866-797-0413
www.pharma-techs.com

Validation

Pharma-Tech's validation team provides a broad range of services from system and component level impact assessments to validation master planning and staff augmentation. We can work with you to develop **validation** master plans to best utilize and leverage successful commissioning activities into your validation strategy. We work closely with each client to provide the desired level of **detail** and content to be written within their validation documents. We have an extensive library of Validation and **Qualification** templates and procedures that allows us to quickly apply our test procedures to your project. This greatly minimizes document development time and allows for **quicker** document review and approval.

Our success stems from our ability to help our clients define appropriate functional and **performance** specifications for which the equipment is tested. Errors during the functional specification review phase will have a tremendous **impact** on the cost and delivery of your validation project. It is imperative to catch errors on paper early in the design phase rather than during the construction or qualification phases.

Our Validation & Qualification Services Include:

- Validation Project and Master Planning
- Criticality & Impact Assessments
- Protocol Generation and Execution
  - Installation Qualification
  - Operational Qualification
  - Performance Qualification
  - Factory and Site Acceptance Testing
  - Summary Reports
- GMP Documentation
- Quality Assurance Planning
- Change Control
- FAT & SAT Testing
- Process Validation
- Cleaning and Sterilization Validation
- Temperature Mapping – Kaye Validator 2000/Biological Indicators
- DeltaV Computer Software Validation
- Material Verification
- I/O Testing
- Alarms and Security Testing
- Control Loop Testing
- Riboflavin Coverage Testing
- Validation Procedures Training
- 21 CFR Part 11 Compliance
- GAMP Compliance
- Detailed Design Specifications
- Functional Specifications
- User Requirements Specifications
- C&Q Leverage Strategies
- Process Development
- Process Analytical Technology
- ASTM E2500 Compliance

Pharma-Tech
PROCESS SERVICES, LLC
Toll-Free: 866-797-0413
www.pharma-techs.com

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:

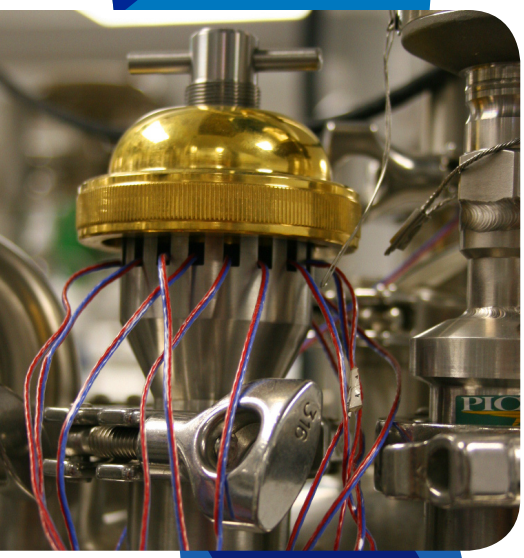
- CIP Troubleshooting and Consultation
  - Surveys and Assessments
  - Control Loop Tuning
  - Spray Device Modification and Specification
  - FAT, SAT, RV, IV, PV, IQ, OQ, PQ
  - Cleaning Impact/Risk Assessment
- CIP Cycle Development and Optimization
  - Protocol Development and Execution
  - Parameter 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

Pharma-Tech
PROCESS SERVICES, LLC
Toll-Free: 866-797-0413
www.pharma-techs.com

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

Pharma-Tech
PROCESS SERVICES, LLC
Toll-Free: 866-797-0413
www.pharma-techs.com