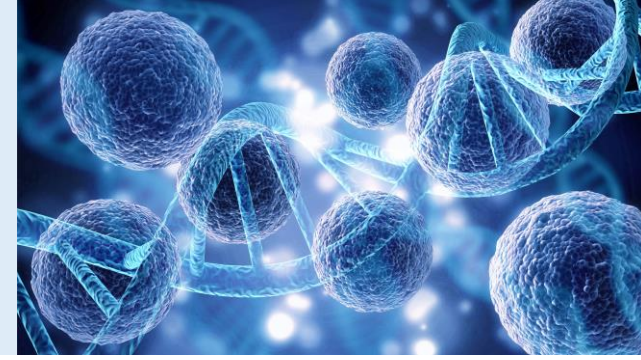




**Providing technical oversight and client representative support to of the Biotechnology, Gene Therapy, Cell Therapy, T-CELL, CAR T, Viral Vector, MRNA, Vaccine, and Medical Device Industries since 2010**

# Our Vision

## Focus on being the “Best” at providing Leading Edge Technical Solutions



- ✓ We leverage our extensive biopharma experience, the latest industry guidelines, and established regulations to provide quality solutions to our clients' complex problems
- ✓ PTSI professionals average over 15 years as 'the client.' We use this insider knowledge to anticipate our clients' needs and provide innovative solutions.
- ✓ Our commitment to excellence, work ethic, and drive support the achievement of our clients' objectives. Our high performance and results have consistently generated client confidence in the US and Internationally for nearly 14 years.

## Our Mission

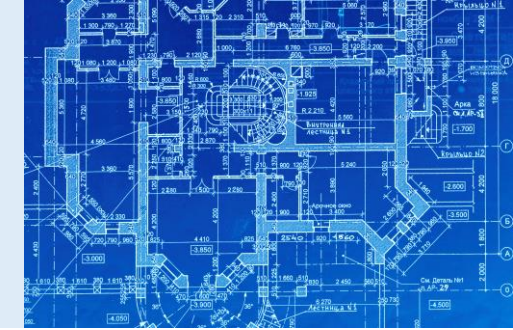
**Be the “Best” in providing High Quality, Compliant, and Proven Biopharmaceutical Solutions for our Clients**



The Biopharmaceutical industry is highly competitive, costly, and ever-changing. Companies rely heavily on consultants for expertise and hands-on execution in all aspects of the business. Inexperienced consultants can negatively impact our clients' business.

- ✓ PTSI has a vast array of in-depth knowledge and experience across all competencies in the biopharma space.
- ✓ We specialize in providing experienced engineering, manufacturing, RCM, process development, quality control, project management, quality assurance and regulatory, and subject matter experts to support our clients.

# Biopharma Design, Construction, & CQV Oversight Client Rep, Project Management, Project Controls, MFG Operations Readiness, & CQV Support



PTSI partners with our clients to provide efficient design solutions to meet MFG requirements and all international regulations and guidance while staying under budget.

- MFG Facility Conceptual Basis of Design, Rough Order of Magnitude, High Level Schedule
- Request for Proposals, Bidding Assessment, Schedule, Key Performance Indicators
- Client Representative through Detail Design and Construction
- Commissioning execution and Validation oversight
- EMPQ Readiness, Execution, and Report

Our biopharmaceutical operational experienced project managers offer flexible and dynamic solutions to drive each phase of the project. We employ strict project management principles to ensure on-time closure of deliverables.

# Quality Control Laboratories & QC Labs Operational Readiness



PTSI has over 30 years of experience in the quality control field in the Biopharmaceutical space. Our SMEs have experience in all aspects of analytical and microbiological quality control from early phase through commercialization.

- EMPQ Readiness, Scheduling, Execution, Report, Supporting SOP Developing, and Project Management
- Analytical Method Development and Testing
- Analytical Method Transfer, Qualification, and Validation
- Product Characterization
- Development of Analytical Control Strategies
- LIMS Implementation

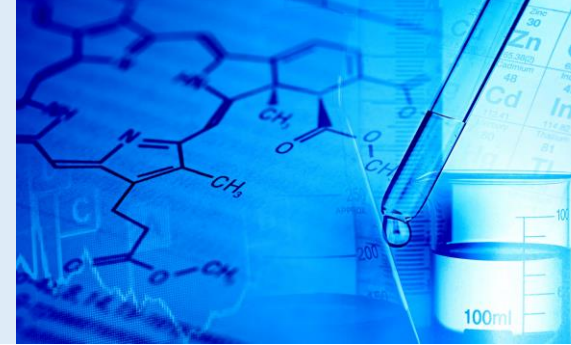
# Quality Assurance



Our QA experts have experience in the field and as the client. These SMEs provide sound guidance based on best practices and all applicable regulations/ guidance.

- Development of Quality Manual and Quality Systems
- Risk Management
- Experienced technical writers and PTSI library of SOPs, Protocols, and Reports
- FDA/ Regulatory PAI, Biennial, QP Certification, and Inspection Readiness/ Remediation execution
- QA CMO PIP review/ approval of manufacturing batch records, deviations, OOS, excursions, CAPA, change control, and protocols

# Tech Transfer & Process Development



PTSI understands our clients' needs, goals, and strategy, and aligns those needs with our fully vetted CDMO partners to make a comprehensive recommendation

- Outsourcing business management
- Proposals and term sheets (non-binding)
- Master supply and development agreements (MSA/ DSA)
- Quality Agreements
- Evaluation of client processes, needs, restrictions, limitations, budget, and timeline
- Audit, assessment, and approval of CDMO partners
  - Scalability, phase, QC support and assay development, raw material sourcing, capacity limitations, quality strategy, supply chain, vendor qualification
- Process Definition and Technology Transfer Support
- Process troubleshooting and training
- Person-In-Plant to oversee transfer and ongoing manufacturing process

# Regulatory & Compliance Support



Our Regulatory Compliance experts have experience in the field, as the client, and as ex-FDA investigators. These SMEs provide sound guidance based on best practices and all applicable regulations/ guidance.

- Support for regulatory submissions including BLAs, CTAs, and INDs
- Expertise in strategic lifecycle CMC development and world-wide regulatory interactions
- FDA/ Regulatory PAI, Biennial, QP Certification, and Inspection Readiness/ Remediation execution
- Extensive track record in product approvals, comparability, changes to process, and change management for scalability from pre-clinical through commercial



# Manufacturing Operational Readiness



PTSI doesn't stop at design and trouble-shooting. We ensure our clients' facilities, infrastructure, documentation, and staff are ready for MFG operations.

- Author/ Review all documentation: SOPs, Work Instructions, Batch Records, Sampling Plans, Test Methods, BOMS, Protocols, Reports, Equipment Lists, Training, Safety Plans, & Policies
- Process Flows, Visual Management Tools, Continuous Improvement Tools
- Resource Management Plans: Hiring, Staff Allocation, Training/ Qualification
- Manufacturing Personnel and Gowning Qualification
- Site Safety, Security, Access Control, Pest Control, & Fire Systems
- Building Management Systems & Environmental Management Systems

# Reliability Centered Maintenance Program CMMS



Implement RCM Program (Preventative Maintenance/ Repair, Calibration, and HEPA Certification Programs) that is compliant with the regulatory cGMP requirements that utilizes a CMMS (BM-RAM or Maximo) electronic system for our clients

## Reliability Centered Maintenance Process Flows:

- RCM Program (Preventative Maintenance/ Repair) Process Flow
- Calibration Process Flow
- Cleanroom/ Equipment HEPA Filter Certification Program Process Flow
- Implementation experience with Blue Mountain and Maximo

# Supply Chain Strategy



- Establish Biopharma Clinical/ Commercial Supply Chain Strategy Development and Oversight
- Lead in the establishment of the client's tech transfer to their own Biopharma products to their own MFG Facility or a Contract MFG Operations Site

# Strategic Planning and Leadership



- Workforce Planning & Organizational Design Tools and Templates
- Primary or Secondary Supplier Readiness
- Financial Forecasting (Cost and Revenue)
- Business Case (Funding & Capital) Enablement
- Flex Capacity Modeling (Auto/ Allo)
- Talent Acquisition (Hiring & Training)



# PTSI PARTNERS



Bristol-Myers Squibb



CAPSIDA  
BIOTHERAPEUTICS



ABZENA

