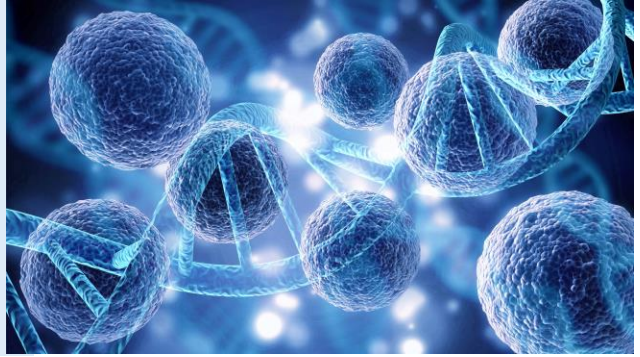
PTSI

PHARMACEUTICAL TECHNICAL SOLUTIONS, INC.

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 supports 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.

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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.

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Our Experienced Biopharma Professionals

Steve Sandoval: CEO/ Operations Head
Over 30 years of experience in Biopharma including role of Chief Manufacturing Officer and licensure of commercial drug substance.

Jeff Hogan: VP of Process Development
Over 30 years of experience in biopharma with focus on process development, tech transfer, and IND/ BLA/ CMC filing.

Deisy Corredor, PhD: Sr. Director CMC Process Development
Over 20 years of experience in biopharma with focus on CMC process development, tech transfer, and process science.

Mike McCalister: Director External Manufacturing
Over 20 years of experience in biopharma/ manufacturing with focus on external manufacturing and tech transfer.

Mike May: VP of Manufacturing & Quality
Over 25 years of experience in clinical and commercial manufacturing including upstream, downstream, and process transfers.

Sara Pind: Plant Manager, CDMO
Over 10 years of experience in biopharma/ Cell Culture, and medical device with focus on all aspects of operations and manufacturing.

Raphi Hanessian: VP of Engineering
Seasoned professional with almost 30 years of experience in Biopharma (Amgen/ J&J). Managed Drug Product Facility CMO.

Michael Paeltz: Director of QC
Over 10 years of experience in biopharma with focus on QC Micro, QC Analytical, tech transfer and process development.

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Our Experienced Biopharma Professionals

Erika Reid: Sr PM/ Design Lead
Design lead in the biopharma industry with experience in creative conceptual design for large greenfield projects to redesign of brownfield projects.

Patrick Peralta: VP of Process Development
Over 20 years of experience in biopharma engineering with experience in design, start-up, utility, Commissioning, and Validation.

Russ McKnight, Quality Control/CQV
Biopharma professional with focus on commissioning, qualification, validation, and quality control.

Paul Malone, Director CQV
30 years experience in biopharma specializing in CQV, Facilities, construction, project management, mechanical, electrical, and design.

Dan Garcia, VP Strategy/ Business Development
Over 25 years of experience in biopharma business development with focus in strategic program management and CDMO services.

Eduardo Becerra, Director of Automation
Automation and controls SME with over 20 years of experience specializing in automation and metrology, systems, CQV, and CMMS.

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.

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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

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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
- 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

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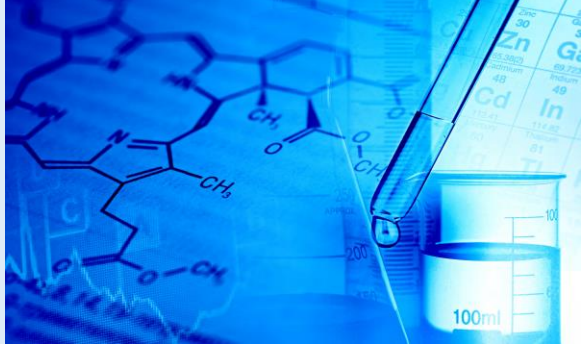
Tech Transfer & Process Development



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

- 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

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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

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Manufacturing Operational Readiness

PTSI doesn't stop at design and troubleshooting. 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

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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

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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

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