



## Specialized Life Science Consulting

PSC Biotech® focuses on providing quality consulting services to ensure our client's success. Our comprehensive selection of services enables our clients to perform at the highest standards and efficiently meet regulatory compliance requirements.

We provide cost-effective solutions, while maintaining exceptional technical capabilities and customer service to our clients for all projects ranging from supplier quality audits to greenfield projects. Contact us to learn more about how we can customize our services to fit your company's business needs today.

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## Professional Services Offered

### Computer Systems Validation (CSV)

- Enterprise System Validation
- Equipment and Instrument Validation
- Risk Assessment
- Data Integrity
- CSV Policies and Procedures

### Commissioning, Qualification, and Validation (CQV)

- Greenfield CQV Projects
- New Production Suite Commissioning
- Decommissioning
- Method Transfers and/or Validation

## Quality Assurance & Compliance

- Specialized Support
- QA Review (GLP, GMP, GCP)
- 483/Warning Letter Remediation
- Risk Assessments
- EM Program Analysis/Creation
- Microbiology Laboratory Consulting

## Regulatory Affairs

- Post-Approval Reports
- BLA Submissions
- Drug Master Files Submissions
- NDA/ANDA Submissions
- Regulatory Agency Interaction Consulting

## Engineering

- Staff Augmentation
- Conceptual
- Process Design and P&ID
- Facility Optimization
- Equipment Selection

## Technical Writing

- FDA Responses
- SOPs/Document/Forms
- Report Writing
- Technical Document Writing Expertise

## Calibration

- Equipment Validation Services
- Instrument Calibration Services
- Process and Quality Support
- Information Technology Compliance and Validation
- Safety, Quality and Environmental (SQE) Protection Support

## Project Management

- Scope Management
- Budget Management
- Schedule Management
- Risk Management
- Team Management
- Quality Management
- Stakeholder Management

## Audits

- Supplier
- Laboratory
- Facility
- PAI Preparation
- cGxP
- Gap Analysis

**Contact PSC Today**