



Established in 1996, PSC® has supported over 1000 clients in +35 countries worldwide with our professional services.

PSC® has offices across North America, Europe, Asia, and the Middle East. Our Professional Services division represents one of the world's largest specialty biotechnology life sciences consultancy firms.

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Trusted leaders in CSV, CQV, and more.



"I am very happy with the services that PSC® has provided. They have helped me here in San Diego and at our Madison site for many years now. They have provided highly-skilled validation specialists that have complemented our full time work force."

*Chris Brady
Manager, Facilities Engineering*

illumina

**Contact us for tailored professional
services consulting!**

✉ **sales@biotech.com**

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BIOTECH.COM

Life Science Consulting Services

Compliance Solutions

Specializing in validation and quality, PSC Biotech® consultants help you triumph over challenges and maximize performance

**EXCLUSIVE SNEAK PEEK FOR BIO
MEMBERS - CHECK IT OUT!**



Customized Services for Experienced Professionals

Commission, Qualification & Validation

- CQV Plans and Documentation
- Final Summary Reports
- Greenfield CQV Projects
- Manufacturing Execution Systems (MES)
- Clean Room IQ/OQ/EMPQ

Computer Systems Validation

- Enterprise Resource Planning (ERP)
- Electronic Quality Management Systems (eQMS)
- Laboratory Information Management Systems (LIMS)
- Automation Systems
- Calibration Management Software Implementation & Validation

Audits

- Supplier Qualification Program
- Regulatory Gap Assessment
- Internal Audit Support
- Risk Management
- Auditor Selection and Training

Quality Assurance & Compliance

- Root Cause Analysis/Investigation
- Corrective and Preventive Actions (CAPA)
- Risk Management
- Regulatory Inspection Preparation/Remediation
- Establishing Quality Management System (QMS)

Regulatory Affairs

- Regulatory Strategy Development
- Global Submission Management
- eCTD Submission Support
- Risk Benefit Analysis
- Post-Approval Product Compliance

Technical Writing

- Documentation Gap Assessment
- Developing SOPs
- Harmonization, Simplification and Consolidation
- Compliance with Industry Standards
- Writing Submissions for Regulatory Bodies

Project Management

- Risk Management
- Scope Management
- Budget Management
- Stakeholder Management
- Lifecycle Management

Metrology

- In-field and In-lab Calibration in NIST-Traceable Standards
- Chamber Mapping Services
- Specialized Equipment Rental and Sales
- Computerized maintenance management system (CMMS) Support
- Calibration Program Development and Maintenance



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We have supported critical projects and operational readiness for over 1000 clients in 35 countries since 1996.

Are you a BIO Member?

You can get a discount on our professional services through the BIO Member Discount

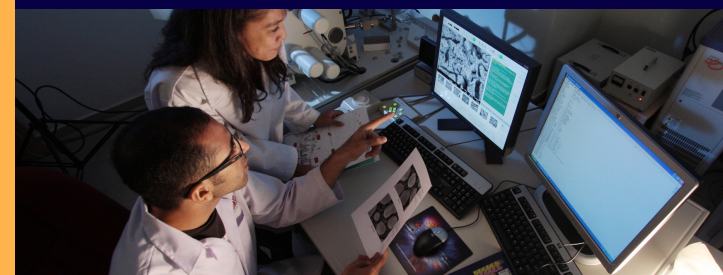
"The professionalism, attitude, and expertise of the PSC® staff enabled a cooperative and efficient work environment that performed at a very high level."

Victor Graham
QA Program Engineer III, Surgical

Johnson & Johnson **VISION**

Expert Consultants

PSC Biotech® consultants act as a seamless extension of your company to assist you in producing the highest quality products. Together with PSC Software, we help you smoothly implement robust quality and validation procedures.



ACHIEVE PEAK PERFORMANCE WITH OUR PROFESSIONAL SUPPORT