



QUALITY SOLUTIONS

Quality Solutions is your one stop turn-key solution to assist your quality and compliance needs. Combining a range of services from Calibration to Validation and Project Management, Quality Solutions has built its reputation with firms across the regulated industries to become a preferred service provider.

Quality Solutions provides value added services to biopharmaceutical companies that exceed expectations and enhance cost efficiency by:

- showing the client a *Return on the Cost of Quality*
- reducing redundancies
- providing clients with up-front pricing with NO HIDDEN costs, agendas or shortcuts
- building long-term professional relationships with our qualified staff who evolve with the industry and its compliance guidelines
- providing your company with the necessary expertise to develop, implement and support your Quality Assurance Program

OUR PHILOSOPHY

Started in 2001, Quality Solutions has rapidly increased its portfolio of services to become a turn-key provider of services tailored to the bio-tech and pharma industries. Quality Solutions has conducted business across the United States, Canada, Japan, Central America, and Europe working with a full spectrum of companies of all sizes.

Quality Solutions' philosophy is built on three core areas:

- To provide our clients with professional services that yield a Return on the Cost of Quality
- To offer services that add value and anticipates change
- Up-front pricing with no hidden costs

Quality Solutions lives up to these core principles and puts the needs of the client first.



Quality Solutions

Phone: 410.852.5267

Fax: 410.601.0067

E-mail: info@qualsolve.net

www.qualsolve.net

Quality Solutions
A Turn-Key Solutions Provider

Our turn-key solution provides clients with a cost effective approach, without the inconvenience of using multiple vendors.

OUR QUALITY

How does Quality Solutions deliver quality? Put simply, it's about our people and their commitment to go beyond expectations. Quality Solutions' success lies in our relentless commitment to quality service delivered by personable and enthusiastic engineers and project managers. Our staff is trained and equipped with state of the art testing equipment and a dedication to work with you to ensure your quality objectives are reached. The company is built on the comprehensive experiences of its staff. This experience is comprised of a balance between practical experience working with leading bio-tech companies and a comprehensive understanding of current compliance guidelines. In addition to maintaining the highest technical experience, our employees provide smart, constant, and consistent communication throughout the project.

QUALITY SOLUTIONS' STAFF INCREASE YOUR CAPACITIES AND SHARE THEIR DIVERSE EXPERIENCE TO ACHIEVE COMMON GOALS.

OUR SERVICES

Validation

- Preparation of Validation Master Plans
- Validation Project Management
- Preparation and Execution of Validation Protocols
- Facility Qualification
- Utility Qualification
- Equipment Qualification
- Software Qualification
- Sterilization Cycle Development and Validation
- Process Validation
- FAT/SAT Testing

Calibration

- On-site Calibration
- Facility Calibration Program Management

Clean Room/HEPA/Laminar Flow Certification

- NSF Certified Services
- Program Management

Design

- Clean Room
- Laboratory
- Facility

Quality Assurance Services

- Evaluation of 21 CFR Part 11 (Electronic Records and Signatures) Compliance
- Vendor and Quality System Auditing
- SOP Development

USP 797 Compliance

- Quality System Development
- Pharmacy Testing

Support Services

- Project Management
- Troubleshooting, Repair, Maintenance

