

Quality Solutions

TURNKEY



Our Company

Introduction/Vision

Started in 2001 as a validation services provider, Quality Solutions is continually developing a portfolio of services to provide a high-quality, cost-effective solution to the Biotech/Pharma industry. This portfolio of service offerings can be tailored to any client project, regardless of size or scope. Our offices in Maryland and Utah have allowed us to execute projects both nationally and internationally.

Our Services

Quality Solutions is your turn-key solution to support your quality and compliance needs. Combining a range of services we have built our reputation with firms across the regulated industries to become a preferred service provider in the following core areas:

- *Validation*
- *Project Management*
- *Design Services, Construction Management, and Commissioning*
- *USP<797> Compliance*
- *Cleanroom/HEPA/Laminar Flow Certification/ISO 14644*
- *Calibration*
- *Technical Support Services*

Therefore, in selecting Quality Solutions, you will work with a single trustworthy service firm, which is committed to long-term relationships, quality, and cost-effectiveness.

In providing this array of service offerings, you can expect to receive consistent performance that exceeds expectations and improves cost efficiency by:

- Providing your company with the necessary expertise to develop, implement, and support your Validation Program.
- Providing timely execution of projects so that your employees can focus on other priorities.
- Building long-term professional relationships with qualified staff who evolve with the industry and changing guidelines.
- Reducing redundancies.

“Ensuring a return on the cost of quality.”



Our Philosophy and Commitment to Quality

Our company is built on three core principles:

- To provide our clients with consistent professional services which yield a return on the Cost of Quality.
- To offer services that complement and add value to the client organization.
- To provide a direct project scope with defined pricing and no hidden costs.

Dedication to Quality

How does Quality Solutions deliver quality?

Put simply, it's about our people and their commitment to go beyond expectations. Our staff is trained and equipped with state of the art testing equipment and a dedication to work with you to help reach project objectives. To keep abreast of industry standards and trends, professional development opportunities are a regular part of employment with Quality Solutions. Finally, our employees possess the communication skills necessary to provide critical feedback, analysis, and guidance during the project.

EU
GMP
GLP
GTP
ICH
ISO

Quality System

To ensure that we meet the same quality objectives of each client, our management team developed a clear and concise Quality Manual. This document is continually monitored and outlines our internal document control system, vendor/supplier requirements, continual improvement process, training, and corrective/preventative action procedures.

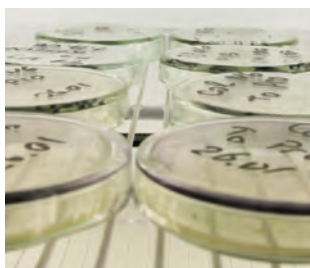
SOPs

As part of our Quality Manual, we have developed SOPs relating to equipment usage, validation procedures, and protocol execution. In the event that the client does not have any procedures in place, our staff uses our approved SOPs to perform test functions described in the protocols.



USP<797> Compliance Solutions

As of June 1, 2008, a second revision of USP<797> became official. Sterile Compounding Pharmacies around the country, in conjunction with State Boards of Pharmacy, started integrating the new USP<797> into their overall requirements to help protect patients from microbiological contamination of sterile compounded drugs.



USP<797> is a valuable tool and benchmark that will impact pharmacy design, engineering controls, and procedures.

The revised USP<797> provides new challenges and opportunities to sterile compounding pharmacies. As pharmacies move toward compliance, opportunities exist to design an overarching Quality System that can maintain compliance while streamlining operations and procedures.

Quality Solutions can assist your pharmacy with USP<797> compliance in a comprehensive and cost-effective manner. Drawing from its validation, certification, cleanroom, and technical services expertise, we can:

- Accurately assess your facilities engineering controls.
- Provide consulting services to ensure Cleanroom design parameters deliver a controlled air environment.
- Provide Project Management assistance in working with contractors and hospital staff for design and renovation of a pharmacy to recommended design criteria.
- Perform a thorough gap analysis.
- Audit your Quality Assurance and training program.
- Create an action plan to strengthen procedures and policies.
- Implement or revise the necessary procedures to your Quality Assurance program to provide continued support of USP<797>.
- Execute all testing requirements on an on-going basis.



Testing Services

Once an action plan is in place, or if your pharmacy needs assistance with your current testing, Quality Solutions can conduct all required testing and environmental monitoring including, but not limited to:

- NSF Certification of Laminar Flow Hoods and Biological Safety Cabinets
- Challenging of HEPA Filters and repair as necessary
- Determination of Air Changes and Room Differential Pressure
- Room Temperature and Humidity Testing
- Cleanroom Viable and Non-Viable Particulate Testing
- Trending of Viable and Non-Viable Particulate Testing
- Gloved Fingertip Sampling
- Media Fill Training Testing

What is the benefit of using Quality Solutions as your USP<797> compliance provider?

Quality Solutions will provide all the required testing equipment and experienced staff to execute all implementation and testing activities. This approach reduces capital costs and full-time staffing requirements.

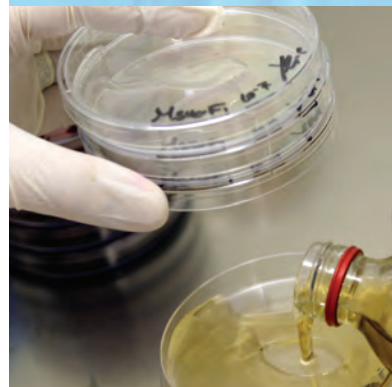
Who is enforcing compliance?

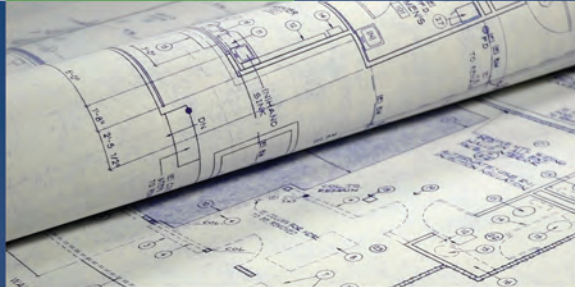
In 2003 the Maryland Board of Pharmacy along with other states developed regulations for Sterile Pharmaceutical Compounding that are harmonized with USP <797>. In many cases, this harmonization has brought USP <797> guidance into the State Code of Regulations. Refer to the Code of Maryland Regulations (COMAR) 10.34.19.01 - .16.

In addition, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) is in the process of requiring compliance with USP<797> in order to maintain accreditation.



“Quality Solutions can help your pharmacy comply with USP<797> and ensure a return on the Cost of Quality”





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