

# Quality Solutions

## USP 797 COMPLIANCE SOLUTIONS

Quality Solutions, LLC can assist your pharmacy with USP 797 compliance in a comprehensive and cost-effective manner. Drawing from its validation and technical services background in the regulated Biotech/Pharma industry we can:

- Accurately assess your facilities risk levels
- Perform a thorough gap analysis
- Audit your quality assurance program and 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.
- Provide consulting services to ensure clean room 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.
- 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

## **What is the benefit of using Quality Solutions as your USP compliance provider?**

If you can not afford to divert staff resources to manage or implement USP compliance, Quality Solutions, LLC is your ideal solution that can maximize your resources using one vendor.

## **Who is enforcing compliance?**

Last year the Maryland Board of Pharmacy developed regulations for Sterile Pharmaceutical Compounding. Refer to the Code of Maryland Regulations (COMAR) 10.34.19.01 - .16 that became effective September 10, 2007.

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.

USP 797 is FDA Enforceable.

## **FOR MORE INFORMATION CONTACT:**

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**Quality Solutions**  
*A Turn-Key Solutions Provider*