



**Aseptic Solutions, Inc.<sup>SM</sup>** is a consulting firm offering specialized solutions to pharmaceutical manufacturers relative to sterility assurance, aseptic processing and environmental control issues. By reviewing and evaluating our clients' processes, we are able to work with them to define corrective actions, where warranted, and to assist them in preparing for regulatory inspections and/or responding to regulatory actions. We offer "hands-on" testing and training in Cleanrooms, including airflow studies, velocity measurements and environmental sampling rationales. Our skilled personnel help companies attain compliance with US, European and Canadian regulations.

### Putting it all in place...

When you just can't seem to make it fit, Aseptic Solutions, partnering with your in-house experts, will work to find the most effective strategy to help your company meet their regulatory requirements. Our experts possess over 25 years of combined industry experience specializing in FDA, GLP, cGMP and Quality Systems regulations. Areas of expertise include: coordinating and conducting aseptic processing training courses, cleaning validation, GMP and technical training documentation, equipment and process change management, drawing control, validation master plans, safety incident monitoring, equipment engineering standards, NDA reviews, and trending process data, to name a few.

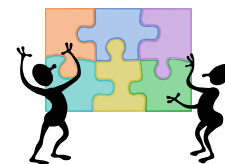


Microbiology	Testing	Training	Procedures
General Microbiology, including Sterility Assurance/Bio-burden Evaluations	Airflow/Velocity Evaluations	Aseptic Processing	Environmental Monitoring/Control Programs – Routine and Validation Sample Plan Rationale
Total Aseptic Processing and Control	Disinfectant Testing/Sanitization Effectiveness Evaluation	Micro Lab Techniques	Change Control System Evaluation and Development
Microbial Identification System Evaluation/Validation	Particulate Characterizations and Identifications	Regulator Inspection Preparation	Facility/Utility System Control
			Aseptic Filling Simulation Evaluation
			Endotoxin Testing/Validation

In addition, Aseptic Solutions can bring to you something no other consulting firm offers - a state-of-the-art training tool that will visually walk you through a cleanroom to help identify potentially troubled areas. To learn more about this tool, please contact us for more information.

### How do I complete the puzzle?

Make your first step towards regulatory compliance—contact us today.



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