

BioVigilant Submits Drug Master Files to U.S. FDA for Instantaneous Microbial Detections Systems

TUCSON, AZ – September 1, 2011 – **BioVigilant Systems, Inc.**, (www.biovigilant.com), inventors of [Instantaneous Microbial Detection](#)[™], announced today it has filed Type V Drug Master Files (DMFs) for its IMD-A[®] 300 series of rapid biologic detection systems for real-time environmental air monitoring in pharmaceutical manufacturing environments.

The DMF submissions contain information the Federal Drug Administration (FDA) can review to approve the use of BioVigilant's equipment in the manufacturing, processing, packaging or storage of drug products. Included in the filings are the test protocols and results of BioVigilant's extensive testing against the USP<1223> *Validation of Alternative Microbiological Methods* guideline; environmental, vibration and shock test results; a review of the IMD-A systems' technology, functionality, subsystems, and operation; and BioVigilant's IQ/OQ/PQ protocols.

BioVigilant's IMD-A 300 and IMD-A 350 systems can detect immediately the presence of bacteria in the drug manufacturing process, and in doing so, greatly accelerate the quality assurance processes for drug batch release. In addition, the systems may be used as constant monitors throughout the entire production period in contrast to other equipment which may be used for spot checks.

About BioVigilant

With headquarters in Tucson, Arizona, BioVigilant Systems invented instantaneous microbial detection technology to address environmental monitoring needs in the pharmaceutical, biotechnology, healthcare, and environmental applications. BioVigilant's IMD systems detect - instantaneously and in real-time - particle count, size, and biological status. Unlike other rapid microbial methods, BioVigilant's optically-based systems require no staining, no reagents, no waiting period, and little human intervention. The company holds 17 patents with an additional 35 applications pending. BioVigilant is an affiliate of Yamatake Corporation of the azbil Group. For more information, go to www.biovigilant.com.

Trademark Notice

IMD-A[®], BioVigilant[®], the BioVigilant logo, and the term Instantaneous Microbial Detection[™] are the trademarks or registered trademarks of BioVigilant Systems, Inc. in the United States and/or other countries. Other names or brands may be the property of others.

For More Information

Contact Mary Parsons, BioVigilant Systems, mparsons@biovigilant.com, 520-292-2342.