

## **BioVigilant Introduces Next-Generation Rapid Biologic Detection System to Safeguard Pharmaceutical Manufacturing Areas**

TUCSON, AZ – June 2, 2011 – **BioVigilant Systems, Inc.**, ([www.biovigilant.com](http://www.biovigilant.com)), inventors of [Instantaneous Microbial Detection](#)<sup>™</sup>, today announced the introduction of its next-generation [IMD-A](#)<sup>®</sup> family of rapid biologic detection systems for real-time environmental air monitoring in pharmaceutical manufacturing environments.

BioVigilant's IMD-A 300 and IMD-A 350 systems can detect immediately the presence of bacteria in the drug manufacturing process, in contrast to traditional growth methods, which can take as long as one week while cultures are being grown. As a result, IMD-A systems can greatly accelerate the quality assurance processes for drug batch release.

Based on the principles of Mie Scattering and the intrinsic fluorescence of microorganisms, the IMD-A 300/350 systems utilize laser light to simultaneously distinguish inert from biologic particles, on a single particle basis. This single particle analysis capability offers greater sensitivity in the detection of bacteria, in contrast to the limited operational ranges displayed by common types of traditional equipment, making them less sensitive in detecting low levels of bacteria. In addition, IMD-A systems can be used to continuously monitor the environment as opposed to traditional methods that are used periodically for spot checks.

The IMD-A 300 samples 1.15 liters of air per minute while IMD-A 350 samples 28.3 liters per minute. Inert and biologic particles are grouped into one of six bins from 0.5 microns to greater than 10 microns as displayed in PharmaMaster<sup>®</sup>, the systems' 21CFR Part-11 compliant software. The software offers different levels of functionality based on user need and authority, and allows for a library of profiles to be created, each with discrete alert and action levels to address a range of applications and manufacturing process environments. Both visual and audible prompts warn the operator when an alert or action limit has been reached, with a video feed from an optional Webcam available to assist with root-cause analysis when needed.

BioVigilant CEO Aric Meares said, "The US FDA continues to be very supportive of industry's move to adopt modern technology and reap its benefits. BioVigilant's IMD-A systems offer a ready tool for the advancement of Quality by Design principles and Process Analytical Technology inside pharmaceutical manufacturing."

He added, "BioVigilant and the IMD Consortium, a group of renowned pharmaceutical drug companies from around the globe, share a common purpose: to advance the course of healthcare everywhere. For BioVigilant's part, our aim is to deliver real-time information about the microbial risks present in an environment, empowering our customers to act. We are fortunate to have cultivated strong relationships with these industry leaders over the past several years and have tailored our products to meet their needs."

### **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](http://www.biovigilant.com).

**Trademark Notice**

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**For More Information**

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