

# TSI Completes Drug Master File for the BioTrak® Real-Time Viable Particle Counter

SHOREVIEW, MN, USA, May 2, 2014 /EINPresswire.com/ -- TSI Incorporated is pleased to announce the submission of a Type V Drug Master File (DMF), with the United States Food & Drug Administration (FDA), for the BioTrak® Real-Time Viable Particle Counter.

TSI Incorporated, the premier provider of [particle counting solutions](#) for life science applications, is pleased to announce the submission of a Type V Drug Master File (DMF), with the United States Food & Drug Administration (FDA), for the BioTrak® Real-Time Viable Particle Counter. The [BioTrak Particle Counter](#) instantly detects microbial contamination, a vast improvement over century-old culture-based methods.

The DMF submission contains information including technology description, scientific references, test methodologies and results, evaluation guidance, operating information, and validation information (IQ/OQ/PQ). Specialized aerosol microbial testing was conducted and performance validated in accordance with USP Validation of Alternative Microbial Methods. The DMF contains information supporting the use of the BioTrak detector which is reviewed by the FDA when referenced in manufacturer's regulatory submittals.

Darrick Niccum, TSI's Vice President of Marketing stated, "Excellent discussions were held between TSI and the FDA throughout the DMF submittal process. The submission is another step forward for this innovative technology that provides real-time microbial information and helps customers identify root cause of microbial excursions. Ultimately, this enables safer products, helping our customers save money through process improvements."

Released in 2012, the Biotrak Real-Time Viable Particle Counter is a leading technology in the exciting new field of [airborne viable particle detection](#). Based on 25 years of biological detection experience, the BioTrak Particle Counter utilizes TSI's field-proven, patented Laser Induced Fluorescence (LIF) technology to determine particle viability. Leveraging multiple channels of



fluorescence, the BioTrak Particle Counter provides the best viable discrimination available. It also measures total particles and comes with a collection filter for speciation.

#### About TSI Incorporated

As a global industry leader in the design and production of precision instruments, TSI partners with research institutions and customers around the world to set the standard for measurements relating to aerosol science, air flow, health and safety, indoor air quality, fluid dynamics and biohazard detection.

For more information on TSI Incorporated, visit our website: [www.tsi.com](http://www.tsi.com), check out our page on Facebook: [www.facebook.com/TSIIncorporated](https://www.facebook.com/TSIIncorporated), or follow us on Twitter: [www.twitter.com/TSIIncorporated](https://www.twitter.com/TSIIncorporated).

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