Six Critical Areas to Ensure Regulatory Compliance in Aseptic Manufacturing are Outlined in New Management Brief

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AGAWAM, Mass., July 31, 2012 /PRNewswire/ -- An unscheduled inspection of an aseptic manufacturing process can hit a pharmaceutical company with the fury of a New England nor'easter. But a new management brief explains how a best-practice control and monitoring system can minimize the danger of FDA noncompliance. The brief is available for download from http://www.microtestlabs.com/weathering-the-storm-brief [1].

In the aseptic manufacturing business, all processes must be best practice to ensure the process will comply with the regulations. If any are poorly designed, not utilized, or deviated from, then the entire aseptic manufacturing system is considered out of compliance. This means that the checks and balances of a quality system must ensure that the sterile environments and surrounding support SOPs truly are working and show no signs of trending towards failure.

The new management brief, "Weathering the Storm of Regulatory Compliance in Aseptic Manufacturing *[1]*," outlines six critical areas that should be addressed to avoid the possibility of product contamination:

- Training and professional development
- Environmental monitoring (EM) procedures
- Incorporation of single-use technology (e.g. needle/tubing sets)
- Facility design and maintenance
- Process simulation
- Raw material control, preparation, and sterilization

"The FDA has been very critical of aseptic fill/finish companies whose manufacturing environments are out of trend or outside of specifications," noted management brief author Alexander (Alex) Mello, M.S., SM (NRCM), the director of Project Management, Manufacturing at Microtest Laboratories, Inc., in Agawam, MA.

"Rigorous production system control and monitoring through data genera
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