

For Immediate Release

LAB OFFERS GLP-COMPLIANT ANALYSIS

[Midland, MI] -- Manufacturers of pharmaceuticals, agricultural products and other chemicals have a new resource for GLP (Good Laboratory Practices)-compliant analysis, as Impact Analytical announces the successful results of its evaluation by a certified GLP auditor. The announcement brings customers the confidence that outsourced testing will be completed in accordance with FDA (Food and Drug Administration) and EPA (Environmental Protection Agency) requirements, and that their larger studies will be GLP compliant, helping to reduce development costs and time to market.

Business Manager Andrew Wood sees the recent audit results as a logical progression of the firm's ongoing work. "This fills in another piece of the analytical outsourcing function," he commented. "We've been providing GLP services on long-term assignment at customer facilities for some time, but now we can offer GLP validation and compliance as a direct service in our own laboratories," he added. The audit confirmed that all required standard operating procedures, documentation, quality guidelines and archives are in place, and that an ongoing GLP training program is in place.

Wood said that GLP compliance extends the customer confidence earned by the laboratory's recent UL accreditation under ISO 9001:2000 quality management standards. ISO 9001:2000 is one of the latest international standard for quality management and quality assurance systems, covering a wide

range of issues, including: records control, formal quality policy, customer feedback, addressing complaints and quality system audits.

With these standards in place, suppliers of food and beverage additives, drugs and agricultural products can be assured that test data from Impact Analytical are both valid and supportable, as they prepare for submission to the FDA or EPA.

“Having GLP compliance means we can participate in discovery stage chemistry before documentation is prepared for the FDA or EPA,” Wood continued. “We can now apply our extremely broad technical base to serve those customers who manufacture food and beverage products, pharmaceuticals, medical devices and agricultural products,” he said, “which are required to have regulatory approval to ensure safety and efficacy.”

The backbone of GLPs is documentation of protocol, reports, data collection techniques and archival capabilities. The process requires complete traceability from sample submission, through the Impact Analytical laboratories, to the time the data are ultimately archived.

The Good Laboratory Practice Act (GLP) pertains to non-clinical laboratory studies done in support of applications for research or marketing permits for products regulated by the FDA or EPA. All product studies submitted to either organization must follow GLPs, and compliance is mandatory in order to meet the regulatory requirements for new products.

Since 1971, Impact Analytical has delivered extensive problem-solving capabilities, detailed analysis and method development to customers in manufacturing and processing. The company’s experienced technical staff provides characterization of unknown materials, permeability testing, competitive

product analysis, impurity identification, investigation of product failures and supplier certification.

The laboratory is registered under ISO 9001:2000.

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