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LAB HIGHLIGHTS GLP / cGMP ANALYTICAL SERVICES AT INFORMEX 2005

[Las Vegas, NV] -- Manufacturers of pharmaceuticals, specialty chemicals and personal care products will have access to extensive problem-solving abilities from a GLP / cGMP registered facility to be showcased at INFORMEX 2005, held January 17-20th in Las Vegas, NV. Impact Analytical (Midland, MI) will highlight resources for characterizing reference standards and raw materials, analyzing metabolites, identifying and quantifying impurities, measuring stability and detecting leachables, along with a host of other materials research capabilities.

“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,” commented Sarah Diener, Quality Manager for Impact Analytical.

“Good Manufacturing Practices define a quality system to ensure that products developed and produced according to these standards are safe, pure and properly identified,” Diener explained.

“The requirements are established by the U.S. FDA, and they aid manufacturers in safeguarding the quality, consistency and potency of their products,” she said.

To attain the registration, Impact Analytical’s facilities underwent a 3-day, on-site review by FDA representatives, who toured the entire location and conducted an extensive laboratory inspection. The firm has completed several GLP / cGMP projects since its successful registration in August of this year and plans an expanded effort to serve customers with a need for such documentation and control.

GMP regulations cover methods, equipment, facilities and controls for manufacturing pharmaceuticals, medical devices, processed food and biologically-derived products. The U.S. pharmaceutical product regulations are labeled “current” GMPs (cGMPs) to emphasize that the expectations are dynamic, evolving over time as technology continues to advance. All product studies submitted to the FDA or the Environmental Protection Agency must follow GLPs and GMPs, as compliance is required to meet the regulatory standards for the release of new products.

INFORMEX is sponsored by the Washington, DC-based Synthetic Organic Chemical Manufacturers Association (SOCMA). As the leading trade association for the specialty-batch and custom chemical industry, its members manufacture some 50,000 products valued at more than \$60 billion annually.

Held at the Venetian Hotel in 2005, INFORMEX is now in its 21st year. The annual conference is on track to host about 700 booths in 2005, representing 480 exhibiting companies. Over 4,000 industry professionals are expected as attendees, nearly a third of them from outside the United States.

Quality and Compliance

For any manufacturers whose products are regulated by the EPA or FDA, Impact Analytical's successful evaluation by certified GLP and GMP auditors means they have a resource for outsourced testing that fully complies with regulatory agency requirements. "The audit confirmed that all required standard operating procedures, documentation, quality guidelines and archives have been established, and that a continuous training program is in place," Diener said. She added that GLP compliance extends the customer confidence earned by the laboratory's accreditation under ISO 9001:2000 quality management standards. ISO 9001:2000 is one of the most widely-recognized international standards 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.

Impact Analytical has more than 500 years of combined experience on staff, and is among the few domestic facilities with the expertise to not only generate test data, but also offer complex analysis, draw detailed conclusions and make recommendations for problem-solving. The company's experienced technical personnel also help customers implement quality control programs, certify suppliers and characterize unknown materials. With considerable resources in specialty chemicals, Impact Analytical maintains resident expertise in product formulation, process engineering, packaging and physical properties testing.

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