NEWS RELEASE
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Alphora Research Inc. Adds GMP ICP/MS Heavy Metals Analysis to Support USP <232> & <233> Requirements

Alphora is pleased to announce that it has added GMP ICP/MS Heavy Metals Testing in-house, to align with the increased regulatory requirements of USP <232> & <233>, which became effective February 1, 2013. API Drug Substances, Drug Products and Excipients will now be tested for 15 single elements using more sophisticated and sensitive equipment, with ICP/MS being the accepted industry standard. Guidance on elemental impurity limits are now based on toxicity and environmental impact.

This change moves away from the USP <231> colorimetric heavy metals test, that has been described as qualitative/semi-quantitative. It was non-selective for individual elements and only captured a smaller subset of elements as a group. The ICP/MS procedure addresses these issues and also requires significantly less material to achieve the appropriate sensitivity. This can be advantageous at early stages of scale-up, especially for complex and highly potent compounds.

Having the expertise in-house for the new regulatory requirements has already proven to be successful, whereby Alphora can better understand the quality of their clients API and proactively react to address the synthetic process if needed.

This expansion represents a significant investment for Alphora that reinforces the company's capabilities in API Technology Development, ensuring its clients continue to receive "the right development at the right time".

Alphora Research provides API technology development services to the Pharmaceutical and Biotechnology industry that include process chemistry, analytical development and validation services, as well as GMP scale-up capabilities to the Pilot Plant scale. These services cover both early stage projects, where speed and quality are important, and later stage projects, where process economics and commercialization are important. Alphora also provides niche commercial manufacturing and has conducted validation efforts in advance of market launch.

Founded in 2003 by Dr. Jan Oudenes, Alphora Research is staffed by 90 employees, operates FDA inspected and approved operations that total 45,000 sq. ft. which include synthetic laboratories, analytical laboratories, GMP Kilo Laboratories, GMP Pilot Plant, GMP stability studies and supporting QC/QA.

For additional information on this news release or about Alphora, please contact:

Geoff Evans,
VP, Business Operations

or

Matt Frizzle
Manager, Business Development