Webinar Calms Medical Gas Companies Confused by FDA's New Electronic Registration and Listing Rule

Reg-E-Stration's seminar attracts over 75 companies/200 practitioners

Bethlehem, Pennsylvania – September 21, 2009 – If the number of companies that participated in the recently completed webinar conducted by Reg-E-Stration is any measure, there are a lot of medical gas suppliers who are still confused by the new on-line registration requirements of the FDA that went into effect earlier this year.

As of June 1, 2009 all drug establishment registrations, product listings (including labeling) and renewals must be submitted to FDA in a new electronic format that requires sophisticated computer technology knowledge to navigate through the system. It requires a new computer language, Data Universal Numbering System (DUNS) numbers, Global Unique Identifier (GUID) numbers, HTML forms, SSL Certificates, and Secure Electronic Gateways.

Last week more than 75 companies and a total of over 200 medical gas practitioners participated in a seminar conducted by Reg-E-Stration. Among the attendees were people responsible for handling annual submissions to the FDA, as well as company managers and computer systems personnel. They represented a cross-section of the medical gases industry – gas suppliers, industrial gas producers, home care companies, including respiratory service providers and durable medical equipment suppliers.

Among the topics discussed during the webinar were some of the basic requirements of the new reporting system, including an overview of expectations, what is needed to prepare and submit SPL files, roadblocks and pitfalls, as well as successfully managing the process of change. "It is monumentally evident from the webinar that the FDA's new registration program has caused a lot of confusion and uncertainty in the medical marketplace," said Bob Yeoman, a Reg-E-Stration partner.

The electronic seminar lasted over an hour, consisting of a half hour presentation by Reg-E-Stration and the rest of the time dedicated to a Q&A session. "Most attendees stayed to the very end, which indicates to me that there is a serious need for assistance in the medical gas community to comply with the new FDA reporting requirements," said Yeoman. "Many of the post-seminar comments indicated that the attendees recognize that it would be much quicker and more cost-effective to work with Reg-E-Stration than to try to muddle through the FDA electronic process themselves," he said.

“We believe there are many more companies that are confused and intimidated by the new FDA regulations. That’s why we’re planning several more webinars in the near future,” he concluded.

Reg-E-Stration is a joint venture between B&R Compliance Associates, a firm that has been working with gas producers for the past seven years helping them with all of their FDA compliance needs, and Quality Partners, a company dedicated to providing sustainable solutions to the challenges faced by the medical gases, medical device, and pharmaceutical industries in complying with FDA regulatory requirements.

For more information, contact Bob Yeoman at 610-390-7483 or visit the Reg-E-Stration website at www.Reg-E-Stration.com.