

New company takes pain out of complying with FDA's new electronic registration system
B&R Compliance, Quality Partners joint venture has expertise to ease the pain

Bethlehem, Pennsylvania – August 24, 2009 – For those medical gas producers who have been pulling their hair out trying to figure out how to comply with FDA's new requirements for electronic drug establishment registration and drug listing ...expert help is now available. Reg-E-Stration, LLC, is a new firm dedicated to working with medical gas producers and suppliers to help them wend their way through the very complicated FDA registration maze.

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.

Reg-E-Stration was formed for one purpose: to work with gas producers to prepare their registrations, drug listings, and labeling electronically, and allay their worries and fears – and confusion – created by the complicated new FDA electronic submission system.

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 process. 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.

“This is a very complicated system,” said Bob Yeoman, president of both B&R Compliance and Reg-E-Stration. “Even the FDA itself estimates that it will take nine to 10 man hours over a three week period just to set up the web portal. So, if you're part of the US population that thinks sending and receiving emails and surfing the web is high tech stuff, these new issues will require some significant increased education in computer technologies.”

For example, the xHTML forms that are used to generate the SPL files alone could boggle the mind, Yeoman points out. “Once you've downloaded the structured product listing forms, in order to read them, your web browser needs to be configured or modified with an add-on utility to read the xHTML format. In fact, you may have to dedicate a computer exclusively for this FDA registration system.”

This mind-boggling complexity is exactly why B&R principals formed this company with Harold Jones, president of Quality Partners. Jones, formerly an FDA employee, has spent the past six months working on this electronic reporting project for a number of US gas companies. “The combination of Harold's intimate knowledge of all aspects of this complicated reporting system and B&R's track record working with the gases industry and FDA adds up to a truly unique service,” Yeoman said. “For a minimal fee, gas producers can rest assured that they are

registered properly ... product-by-product, location-by-location, label-by-label. It's a pretty inexpensive insurance policy," he said.

The associates at B&R Compliance, collectively, have over 100 years of experience in the medical and industrial gases business spanning the production floor to executive management. The company specializes in delivering cost-effective regulatory solutions which are customized to suit a broad cross section of business and compliance needs.

Quality Partners provides sustainable solutions to the challenges faced by the medical gases, medical device, and pharmaceutical industries in complying with FDA regulatory requirements by partnering its consultants, with their unique combination of FDA and industry experiences, with company quality and regulatory professionals. Quality Partners staff and its Associates have many years of experience both with FDA and in the medical devices, pharmaceuticals and medical gas industries. Harold Jones, alone, has 23 years of experience with FDA, and has served as a PMA reviewer in the FDA Office of Compliance, and as a testing engineer at FDA's Winchester Engineering and Analytical Center.

For more information contact Bob Yeoman at 610-868-7183 or visit the Reg-E-Stration website at <http://www.reg-e-stration.com/>.