

## ReComS bridges the gap between pharmaceuticals and regulatory agencies

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By B.G. DOYLE

With the mission of helping companies in the food, drug, cosmetic, and healthcare industries establish better working relationships with federal, local, and European regulatory agencies, Regulatory Compliance Services Corp. (ReComS) opened its doors in May 2003 and already has a long list of clients. "I saw the need for a group of individuals who could help companies work with a regulatory agency on a specific issue and build a bridge for better communication," said Eric Olivieri, vice president & treasurer of ReComS. "The only time many companies deal with these agencies is when there is an audit, which is usually an adversarial and intimidating event." With offices in San Juan, Isla Verde, and Caguas, the firm offers a unique mix of specializations.

Olivieri, who specializes in the regulatory aspects of food and drug laws, was formerly the director of compliance and industry liaison for Puerto Rico and Latin America at Pharmaceutical Sourcing Group Americas (a Johnson & Johnson company.) He was also heavily involved with the Pharmaceutical Industry Association of Puerto Rico. Miguel Lausell, who has concentrated his legal practice in the areas of tax, corporate, and banking law, has a great deal of experience in government affairs, having held various positions in the local government and in the private sector. Osvaldo Carlo, who specializes in corporate and individual liability issues, was formerly a law clerk for the U.S. district judge and the U.S. magistrate judge in Puerto Rico. He was also assistant U.S. attorney for the district of Puerto Rico and chief legal counsel at the U.S. Attorney's Office.

As a result of this combined wealth of experience, ReComS is fully qualified to help companies work with the FDA, the DEA, EMEA / MDA / MCA, ASSMCA, USDA, the EPA, OSHA, FEMA, Homeland Security, and other regulatory agencies that might affect a client's products and services. "There are a lot of companies out there focused on validation services and [service] to labs for testing and hiring personnel," said Olivieri. "While we can offer that, our expertise is mainly focused on the hard stuff related to the regulatory side." This includes compliance-related services such as internal audits, due diligences, facility and product registration, current Good Manufacturing Practices training, technical documentation preparation, and consent decrees, as well as controlled substances / security systems assessments, and corporate, product, and individual liability defense.

In addition to its three principal members, ReComS also relies on outside specialists from agencies such as the FBI, the Secret Service, and the Department of Justice. The firm also has ties to U.S. regulatory / legal firm King and Spalding in case a client requires representation in both Puerto Rico and the U.S.