



Pharmaceutical & Biotechnology Sectors

Paciv applies risk-based approach for 2006

BY JONATHAN MAY

To satisfy a new trend in the pharmaceutical industry, Paciv is adapting a risk-based approach to its services. "The latest trend in the market is the 'risk-based approach,' which promotes the 'right-sized validation' and leveraging of commis-

sions," said Jorge Rodríguez, president & CEO of Paciv Inc. "This method also uses qualification/validation activities to accelerate speed to market and meet all compliance and regulatory requirements while at the same time minimizing cost and efforts," he added.

A risk-based approach is a method



Paciv's management team from left to right: Rick Straw, vice president of operations for region III; Samuel Estrada, vice president of operations; Jorge Rodríguez, president and CEO; Luis Meléndez, director of validation; José Calderón, vice president of operations; Adrienne Muñiz, comptroller and director, and Shawn Perkins, director of engineering services

employed by pharmaceutical companies and their validation firms to assess the probability of things going wrong with a new product or service. "Experts have developed matrices to accurately predict the probability of risks associated with a new product, production method, etc.," said Rodríguez. The matrix is then studied to determine the impact of the potential risks. "Once those steps are completed, a company like Paciv will develop ways to mediate these risks," he said. "The ultimate goal is to raise our clients' confidence in the proposed product or service by reducing the risks before anything is started."

Rodríguez is convinced his company is ready to handle this development in the industry. "With our knowledge we are capable of providing both the commissioning of automation systems and the validation of them without causing rework or development or execution errors. This reduces our business partners'

costs and time to market while maintaining sound regulatory and validation standards," he said.

Paciv, a leading provider of validation, design, qualification, fabrication, installation and consulting services, is expecting to continue its sizeable growth in sales for 2006. "In 2004, we had sales of \$12 million, in 2005 sales of \$14 million and we are looking for the same \$2 million in growth for this year," said Rodríguez. "Our intention for 2006 is to reach new clients within Puerto Rico that are in need of our expertise, provide our services to other regions within the mainland U.S., and grow our Ireland-based clientele," he added.

Working in such a highly regulated industry means Paciv has to juggle multiple client demands. "Our clients need a partner like Paciv that can reduce the time, effort and cost of production for them while at the same time ensuring compliance with their policies and procedures," Rodríguez said. ■



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