

Press Release – April 28, 2014 i-Solutions' proactive approach to compliance issues

i-Solutions

RALEIGH, NC – More attention is being focused on Regulatory Compliance within the Life Science industry. Why? To ensure the integrity of products entering the marketplace is of the highest quality for the patients who rely on these products.

At i-Solutions, we have a revolutionary new way to solve these regulatory compliance demands and expectations. We are pleased to report the launch of **COMPAS** (**C**ompliance **P**roactive **A**dvocacy **S**upport). i-Solutions' staff and industry experts have invested years designing and vetting our COMPAS services to assist our clients through the compliance and regulatory processes. COMPAS creates a direct path using a proactive approach to the challenging regulatory compliance aspect of pharmaceutical manufacturing. This new service works in conjunction with our LAMPS and CATS technologies.

The Life Science industry gives an enormous amount of attention to the quality of its products, but is always looking for new ways to ensure compliance proactively. Proactive Compliance is about ensuring that quality compliance measures are in place and are being appropriately followed. This includes remediation of any observations that have been cited by internal, agency, client, or vendor audits. It also includes insurance that the solutions are documented. Integrating quality with the manufacturing process is why i-Solutions is a leader in manufacturing processes.

Regulatory Compliance is one of the Life Science industry's greatest challenges. The receipt of a Warning Letter or a Consent Decree can throw a company into an unbelievable series of events that wreak havoc with normal supply chain activities, resources, budgets, stock values and the company's public image. No matter how prepared an entity is for such an event, the fact that it is unplanned creates tremendous stress.

This approach, utilizing the Consent Decree model with proven tools and without onerous terms and conditions, allows a company to plan for remediation of any aspects of operations that need attention. It allows a company to budget for the remediation effort as opposed to providing an open check book during the aforementioned events. It minimizes the interruption of normal supply chain activities and ensures continued product delivery to patients. It allows a company to effectively communicate the proactive efforts it is taking to maintain the highest level of quality achievable to the FDA.

Additional information about COMPAS and our compliance and regulatory services can be found by visiting our website at www.i-solutionsco.com - tab brochures.

To find out more about i-Solutions:

www.i-Solutionsco.com

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Our Mantra

Enhanced value, proven expertise and commitment to customers' needs, deliver success!

i-Solutions, where technology meets service