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Pharmatech's Regulatory Compliance Group Offers Unique Scientific Approach

Ex-FDA Pros Join Pharmatech's Biopharma Industry Quality and Operational Experts

Foster City, Calif. – January. 17, 2007 – Pharmatech Associates, a leader in biopharma manufacturing process methodology, today announced that it has established a Regulatory Compliance Group staffed with former-FDA experts and offering a scientific methodology to ensure long-term compliance throughout the drug and device development cycle.

To implement sustainable FDA compliance, Pharmatech Associates' Regulatory Compliance Group consists of a team of top-tier former FDA specialists combined with industry quality systems experts. This combination offers a unique in-depth understanding of FDA regulations and data-driven scientific methodology, such as Six Sigma™, to ensure the effective remediation of FDA concerns for drug development and manufacturing problems.

“Because Pharmatech recognizes the challenges facing the FDA and industry to coordinate and review compliance activities, we have developed a project management structure to leverage the strengths of each piece of the compliance puzzle,” said Calvin Wong, CEO, Pharmatech Associates. “The combination of top-tier former agency personnel with industry-leading experts and operational staff is unique to Pharmatech's new Regulatory Compliance Group. This is part of our proven methodology of achieving problem-solving success for the regulated life sciences based on a deep understanding of the variables that affect overall product quality. Our group also will enable biopharma companies to successfully implement new FDA guidelines, such as Process Analytical Technology (PAT).”

Three top-tier FDA specialists, proven thought leaders and subject matter experts with significant regulatory compliance experience anchor the Regulatory Compliance Group. Mr. Tej Poonai has held senior positions with the FDA and in industry and specializes in process development and technical operations. Mr. Robert Sharpnack has held numerous positions in a career spanning three decades with the FDA, and specializes in inspecting active pharmaceutical ingredients (API), sterile and non-sterile finished dosage pharmaceuticals both domestically and internationally. Ms. Dusty Snoeberg, considered an industry expert in quality operations, has nine years within the FDA as a Field Investigator concentrating on pharmaceutical and medical devices.

New FDA guidance, as outlined in its Process Analytical Technology (PAT) approach, signals a shift in product assessment away from a product-centric approach based on inspection and final testing to one that is process-centric, built upon understanding the variables that affect overall product quality. This radical departure from historical methods of product development is the basis for a holistic approach to the drug development cycle that Pharmatech Associates terms “Compliance through Science”.

About Pharmatech Associates

Pharmatech Associates, Inc., based in the San Francisco Bay Area, is a full-service consultancy dedicated to serving the regulated life-sciences market, providing tailored project management, validation services and quality process optimization solutions that ensure optimal outcomes. Pharmatech Associates consulting services focus on cGMP readiness and Quality System development, and include product development guidance to negotiate the complexities of the product development life cycle on pharmaceutical, biotech and biopharma projects. Pharmatech is the national leader in applying Lean Manufacturing and Six Sigma processes to Biopharma manufacturing and production processes. For more information, please visit: www.pharmatechassociates.com

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