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Contact:

Cordell Koland

SIPR, LLC

650-799-1833

cordell@sipr.com

Kathy Luther

Pharmatech Associates

650-227-0179

kluther@pharmatechassociates.com

Pharmatech President to Instruct at PDA/FDA Joint Regulatory Conference

Focus on Six Sigma and Risk Management in Drug Development Lifecycle

FOSTER CITY, Calif. – Sept. 28, 2006 – Bikash Chatterjee, president of Pharmatech Associates, Inc., a provider of technical and business solutions for the regulated life sciences industry, will teach a course on Sept. 15th featuring his profound expertise with the application of innovative Six Sigma tools to critical drug development processes. The one-day intensive workshop is among many events scheduled during the PDA/FDA Joint Regulatory Conference (www.pda.org) from Sept. 11-16 at the Renaissance Hotel in Washington, D.C.

With this year's theme "The Foundation for Business Success: Continuous Improvement Throughout the Product Life Cycle," the conference's focus is on helping the pharmaceutical industry effectively meet government regulatory standards, and will bring together company executives and academics with FDA authorities for presentations, exhibitions and course offerings from Sept. 11-15.

Chatterjee, an internationally recognized authority within the regulated life sciences industry, will instruct on the application of Design for Six Sigma (DFSS) using an IAMV model (identification, analysis, mitigation, validation) in the development, compliance and approval processes associated with bringing pharmaceutical and biopharmaceutical products to market.

“The FDA’s new guidance document as well as the issuance of ICHQ9 offers our industry a really unique chance to take a new approach to designing and optimizing when, where and how to use our risk management tools to drive the drug development life cycle,” said Chatterjee, who will co-teach on Sept. 15th with Jeremy D. Green, a Lean Six Sigma Master Black Belt and quality assurance manager at ATS Systems Oregon.

After attending the day-long course, participants can expect to emerge with a new skill set that includes the ability to articulate the need for an iterative model for risk management throughout the drug development lifecycle; explain the IAMV DFSS model to coworkers and management teams; match a Design for Six Sigma tool to type of risk; and effectively use the IAMV DFSS model’s identification and analysis tools.

Chatterjee, a Six Sigma Master Black Belt, has been involved in the life sciences industry for more than 20 years. He also has ISO 9000 Lead Assessor certification, as well as more than 15 years of experience in the implementation of Lean Manufacturing programs in the regulated life sciences. He was recently elected president of ASQ Golden Gate Chapter and was selected by United States Pharmacopeia (USP) as an advisor to its program to assist drug companies in applying GMP requirements internationally. Mr. Chatterjee holds a B.A. in Biochemistry and a B.S. in Chemical Engineering from the University of California at San Diego.

The 2006 PDA/FDA Joint Regulatory Conference, Exhibition and Courses will take place from Sept. 11-16 at the Renaissance Hotel in Washington, D.C. Details are available at: www.pda.org.

For more information about Pharmatech Associates, visit www.pharmatechassociates.com

About Pharmatech Associates

Pharmatech is a full-service consultancy that bridges the gap between business problems and technical solutions for the regulated life-sciences industry . With an operational expertise that includes the exacting requirements of U.S. and European regulatory agencies, Pharmatech helps clients negotiate the complexities of the product life cycle with a methodology that encompasses proprietary practices as well as industry-standard processes such as Six Sigma and Lean Manufacturing principles. This methodology is a structured, analytical procedural map based upon a set of processes that transforms business problems - relating to risk factors, cost and speed to market - into quantifiable technology solutions.

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