



Rose Tree Corporate Center II
1400 N. Providence Road, Suite 3005
Media, PA 19063
484.445.7200

3005 Carrington Mill Blvd., Suite 580
Morrisville, NC 27560
919.463.1990

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Contact: Marni Schribman, Compliance Implementation Services
marnischribman@cis-partners.com, 484-445-7200

Pharma Industry Veteran to Address Recent Changes to FDA/GCP Requirements at Quality System Event

PHILADELPHIA, PENNSYLVANIA, AUGUST 17, 2010 – Compliance Implementation Services (CIS), a pharmaceutical compliance consulting firm, announced today that Dr. Annette Horner, Ph.D., Senior Director of Clinical Compliance Services for CIS, will be speaking at the [“Effective R&D SOPs, Process Maps, and the Quality System”](#) event on September 14th at the Georgetown University Hotel and Conference Center, Washington, D.C.

Dr. Horner will address the business process impact of recent clinical/regulatory changes related to clinical registries and results disclosure; Risk Evaluation and Mitigation Strategies (REMS); and a proposed 21 CFR Part 312 requirement that sponsors report suspected falsification of data. Dr. Horner will recommend ways in which small, medium, and large pharmaceutical companies can address the related Standard Operating Procedure (SOP) development, revision and compliance issues that are involved with these proposed changes.

“SOPs play a crucial role in clinical quality assurance and it is critical that they align to the US FDA’s new Good Clinical Practice regulations,” said Dr. Horner when asked about the importance of this event and its subject matter. “If SOPs are not in place, or not followed correctly, clinical data may be compromised, leading to warning letters and delays in the trial process.”

Dr. Horner is an experienced and engaging speaker with more than 25 years of experience and international accomplishments in the pharmaceutical, biotechnology, and medical device industries. Her Clinical R&D expertise includes implementing global regulatory requirements across interdepartmental teams; providing guidance for controlled document development, implementation, and change control; training client staff on international procedures and systems; developing process improvement standards and metrics. She received her Ph.D. in Organizational Development & Design from Temple University in Philadelphia, Pennsylvania.

About CIS

Compliance Implementation Services (CIS) is a consulting firm specializing in compliance strategies for pharmaceutical companies, from Global Clinical Research and Development through U.S. Commercial Compliance and Government Programs. Founded in 2004, the firm’s deep understanding of industry laws and regulations, innovative and practical applications, and custom solutions help its clients establish a “Culture of Compliance” that is both meaningful and practical.

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CIS experts quickly identify exposure to compliance risks, help develop a strategic plan, and ensure its implementation and ongoing adherence to legal and regulatory requirements. For more information, visit www.cis-partners.com.

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