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National Organization Seeks Drug Safety Alliance's Expertise

Pharmaceutical Safety Company Shares Insight into European Quality Assurance Regulations

RESEARCH TRIANGLE PARK, NC, October 09, 2008 **/24-7PressRelease/** -- Drug Safety Alliance (DSA), a global leader in pharmaceutical safety and pharmacovigilance, was invited to share their extensive insight into quality assurance protocols in Europe with the Regulatory Affairs Professionals Society (RAPS) at their annual conference held recently in Boston.

Conference presenter Joseph Knight-McKenna (MBA, CQM/OE, CQA, CSQE, RAC), DSA's senior director, Quality and Regulatory Compliance, educated attendees on tools and strategies for selecting a qualified team responsible for pharmacovigilance (QPPV), analyzing existing pharmacovigilance systems, and incorporating regulations from the European Union into processes and procedures.

"There is a great deal of concern about meeting the guidelines of the European Union's 'Volume 9A'," Knight-McKenna explained following his detailed presentation which included an overview of pharmacovigilance system requirements as well as components of a regulatory compliance process map. "We understand the challenges of international pharmaceutical organizations and the myriad of reports that must be generated for compliance in the U.S. and abroad. We pride ourselves on the ability to make life easier for clients in that situation by pulling together their data and streamlining it for a more smooth reporting process."

"The feedback we're getting through our active engagement in the regulatory affairs industry tells us there is a need for access to the type of guidance that Joe presented at RAPS," said Cathy Stokes, president and CEO of Drug Safety Alliance. According to Stokes, her organization has plans to share similar insight through multiple seminars and presentations in the coming months and into 2009.

Knight-McKenna will also be presenting at the American Society for Quality's 17th Annual Audit Division Conference in Augusta, Georgia on October 16.

Knight-McKenna is responsible for Drug Safety Alliance's Quality Management System, Corrective and Preventive Action (CAPA) system, auditing programs and quality procedures. He has been Regulatory Affairs Certified (RAC) for the United States since 1999 and for the European Union (EU) since 2003.

About Drug Safety Alliance

Founded in 2000, Drug Safety Alliance (DSA) provides pharmacovigilance expertise to large and small pharmaceutical and biotechnology companies to help them develop safe drugs and improve patient safety. DSA's mission is to partner with clients to mitigate their drug safety risks and to maximize product longevity and value. Driven by the highest ethical standards, DSA is uniquely focused to provide high-quality pre- and post-market drug safety services including domestic and international regulatory compliance, safety database support and hosting options, risk management and adverse event case management. DSA is headquartered in the Research Triangle Park region of North Carolina with strategic partnerships worldwide. For more information please visit www.DrugSafetyAlliance.com.

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