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QPS Taiwan Has Validated the Pristima™ Preclinical Data Collection and Management System

(Taipei, Taiwan; August 16, 2013) – Supported by the Xybion Corporation validation team, QPS Taiwan's Center for Toxicology and Preclinical Sciences (CTPS) has launched Xybion's Pristima™ —a fully integrated preclinical data collection and management system compliant with Title 21 CFR Part 11 Section 11.1 (a). This system captures, manages and reports the toxicology and pathology data for all studies conducted at CTPS. The management team anticipates a tremendous benefit for toxicology testing at CTPS as Pristima™ is specifically designed to reduce errors, enforce data integrity and save research time by eliminating much of the paperwork and data entry tasks toxicology studies entail.

Says Charlene Chen, Senior Director, CTPS: "By allowing staff to record data once, directly to a secure, enterprise-grade Oracle database, and having summarized reports immediately available to the study director, we expect leaps in staff efficiency and customer satisfaction."

The Pristima™ system benefits most departments at CTPS, from Study Management to QA/QC, Toxicology, Clinical Pathology and Pathology. According to the Pristima™ study protocol defined and approved prior to study initiation, Pristima™ applies a stratification algorithm to pre-test data to assign subjects to dose groups. The system then tracks recurring *in-vivo* assessments such as body weights, food and water consumption, clinical observations, dose administration, blood and urine collection and even the data review/approval process.

Additionally, clinical pathology equipment (for hematology, clinical chemistry, coagulation and urinalysis) is electronically interfaced with Pristima™ so that sample analysis data are transmitted directly from each instrument to the database. These results are subject to quality management rules enforced by Pristima™, itself; any questions that arise are immediately addressed by a designated staff member. Upon electronic approval of the data, summary reports are immediately available. These include embedded statistical analyses and associated footnotes identifying any significant differences among the dose groups. This quick turn-around on data capture-to-reporting enables the QPS Study Director to provide better and faster support to the Sponsor's Study Monitor.

Walter Bee, Vice President, Head of Global Safety Assessment and Regulatory Affairs, QPS LLC., noted: "Now, at the completion of validation and training, our staff is energized and anxious to perform all studies using Pristima™. In ongoing studies where the new system is in use, we are already receiving extremely positive feedback from our Sponsors, who remark upon how the quick data exchange enables rapid decision making."

About QPS

QPS is a GLP/GCP-compliant CRO that supports discovery and preclinical and clinical drug development. We provide quality services in Neuropharmacology, Drug Metabolism and Pharmacokinetics, Toxicology, Bioanalysis, Translational Medicine, and Early & Late Phase Clinical Research to clients worldwide. Our 30+ regional laboratories, clinical facilities and offices are located in North America, Europe, Asia, and India. For more information, visit http://www.qps.com.