Intrinsic Imaging Implements ISPE GAMP 5: A Risk-Based Approach to Compliant GxP Computerized Systems

Implementation of ISPE GAMP 5 establishes a risk-based framework for compliant computerized systems supporting clinical image management and radiological review.

Bolton, MA / San Antonio, TX

Bolton, MA / San Antonio, TX — March 6, 2012 — Intrinsic Imaging, LLC, announces today that in addition to its ISO 9001 certification, it has now implemented, and is consistent with, the International Society for Pharmaceutical Engineering (ISPE) Good Automated Manufacturing Practice GAMP 5 : A Risk-Based Approach to Compliant GxP Computerized Systems.

Developed by some of the world's largest international pharmaceutical and biotechnology companies from the Americas, Europe and Japan, the ISPE GAMP 5 is a pragmatic and practical industry guide to achieve regulatory compliant GxP computerized systems in an efficient and effective manner.

Contributing regulatory authorities of GAMP 5 include the United States Food and Drug Administration (FDA), United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA), Health Products Safety Agency of France (AFSSaPS) and Regierungspräsidium Darmstadt of Germany.

In providing clinical image management and radiological review services for Phase I-IV clinical trials, Intrinsic Imaging designs, develops or implements advanced computerized imaging management systems. Intrinsic Imaging's implementation of GAMP 5 demonstrates that it currently maintains an effective, scalable and robust framework that safeguards patient safety, product quality, and data integrity and ensures all computerized systems are fit for intended use and compliant with applicable local and international regulations.

Intrinsic Imaging's GAMP 5 systems development life cycle has been implemented across the entire organization and is applicable to all therapeutic areas including, but not limited to, Cardiovascular, Central Nervous System, Gastrointestinal & Genitourinary, Medical Device, Musculoskeletal and Oncology.

"Intrinsic Imaging's ISO 9001:2008 quality management system certification and GAMP 5 system implementation are testaments of our ongoing commitment to providing quality imaging core lab services to pharmaceutical, biotechnology, medical device and clinical research organizations around the world." said Todd A. Joron, BSc, MBA, President & COO at Intrinsic Imaging.

About Intrinsic Imaging, LLC

Intrinsic Imaging is an ISO certified medical imaging CRO and imaging core lab providing comprehensive services in support of Phase I-IV clinical trials and Class I, II, III medical device trials. Intrinsic Imaging is also a world leader in conducting Artificial Intelligence studies. With its team of more than 750 board-certified and fellowship-trained physicians, Intrinsic Imaging's team has sub-specialization in all therapeutic areas, including Cardiovascular, Central Nervous System,Gastroenterology, Musculoskeletal, Oncology and Ophthalmology. Certified by the British Standards Institution (BSI), Intrinsic Imaging is the only company in the world to hold five ISO certifications specifically for providing imaging core lab services on clinical trials. For more information, please visit www.IntrinsicImaging.com.

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