Intrinsic Imaging Undergoes Extensive FDA Audit – Receives Zero 483 Observations

Extensive FDA pre-approval audit concludes with complete compliance and zero 483 observations.

Bolton, MA / San Antonio, TX

Bolton, MA, San Antonio, TX (PRWEB) August 7, 2012 — Intrinsic Imaging, an FDA audited, ISO 9001:2008 certified and GAMP® 5 contract research organization providing medical imaging core lab services for clinical trials, announces today that it recently underwent an extensive United States Food and Drug Administration (FDA) audit and received zero 483 observations from the agency.

This routine FDA pre-approval audit was conducted from July 30 to August 3, 2012 and was in relation to Intrinsic Imaging's participation in a large Phase III clinical trial for breast cancer. During this trial, Intrinsic Imaging provided imaging core lab services, clinical trial expertise and 12 board-certified subspecialized radiologists to evaluate the trials primary endpoints. During this trial, Intrinsic Imaging processed over 4300 images, radiologic evaluations and associated case report forms.

During this 5 day audit, the FDA thoroughly inspected Intrinsic Imaging's entire quality management system (QMS) and all clinical trial data to ensure compliance with all federal regulations. The audit included, but was not limited to, a review of all clinical trial documentation as well as Intrinsic Imaging's standard operating procedures, training records, facilities, resource and subcontractor management records, corrective and preventative action documentation, computer software qualifications, internal audit documentation, quality control procedures, equipment maintenance logs, back up and disaster recovery plans, image and data transfer procedures and the company's compliance with 21CFR11 electronic records and electronic signatures regulations.

At the conclusion of the audit, Intrinsic Imaging was found to be in complete compliance with all federal regulations and received zero 483 observations from the FDA.

"From the inception of Intrinsic Imaging, we have dedicated ourselves to the implementation of an effective quality management system that would meet or surpass the requirements of the FDA and other regulatory bodies. Our goal was to implement a scalable QMS which would enable successful execution of smaller trials as well as have the robustness to handle large Phase II and Phase III drug and device clinical trials. Intrinsic Imaging's successful FDA audit is a further testament of our capability to effectively provide quality imaging core lab services for sponsors of clinical trials." said Todd A. Joron, BSc, MBA, President & COO at Intrinsic Imaging.

This successful FDA audit is the latest quality achievement for Intrinsic Imaging. In November 2011, Intrinsic Imaging's quality management system successfully attained ISO 9001:2008 certification and in March 2012, the company successfully implemented ISPE Good Automated Manufacturing Practice GAMP® 5 : A Risk-Based Approach to Compliant GxP Computerized Systems.

Intrinsic Imaging's recent FDA audit was the second time in 2012 that the company received positive feedback from the FDA. Earlier this year, one of Intrinsic Imaging's clients received FDA clearance of one of its neurointerventional medical devices for the treatment of acute ischemic stroke. During the Phase III clinical trial used as basis for the Food and Drug Administration's clearance of that device, Intrinsic Imaging provided imaging core lab services and conducted the complex interpretation and radiological assessment of the revascularization device's primary endpoints.

"Intrinsic Imaging's FDA audited, ISO 9001:2008 certified and GAMP® 5 quality management system has been implemented across the entire organization for all phases of clinical trials." said Jatinder Kaur, BS, MS, MCPM, Vice President, Medical Imaging Operations at Intrinsic Imaging. "Our robust and scalable QMS allows us to provide quality imaging core lab services for all therapeutic areas including, but not limited to, Cardiovascular, Central Nervous System, Gastrointestinal & Genitourinary, Medical Device, Musculoskeletal and Oncology."

This recent FDA audit of Intrinsic Imaging and the data associated with the Phase III clinical trial for breast cancer was one of the final steps in the FDA approval process. With this successful audit of Intrinsic Imaging, the sponsor now anticipates imminent FDA approval of their application.

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 650 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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