Intrinsic Imaging Obtains ISO 13485 Medical Device Certification

ISO 13485 certification demonstrates ability to provide imaging core lab services meeting customer and regulatory requirements for medical devices.

Bolton, MA / San Antonio, TX

Bolton, MA, San Antonio, TX, September 24, 2013 — Intrinsic Imaging, LLC, a medical imaging core lab specializing in providing imaging core lab services for clinical trials, announces today that the company has obtained quality certification for the International Organization for Standardization (ISO) standard for medical devices, ISO 13485.

Intrinsic Imaging's ISO 13485 certification, FM 587032, demonstrates the company's ability to provide imaging core lab services that consistently meet customer and regulatory requirements applicable specifically to medical devices.

Intrinsic Imaging was certified by the British Standards Institution (BSI), one of the world's largest certification bodies. From its origins as the world's first national standards body, BSI is among the most respected and reputable quality management systems certification bodies in the world and is the largest certifier for both the United Kingdom and North America.

This successful ISO 13485 certification is the latest quality achievement for Intrinsic Imaging. In November 2011, Intrinsic Imaging obtained ISO 9001:2008 certification, and in March 2012, the company successfully implemented ISPE GAMP5®. Most recently, in August 2012, Intrinsic Imaging underwent an extensive routine audit from the Food and Drug Administration (FDA) and was found to be in complete compliance with all federal regulations and received zero 483 observations from the agency.

Intrinsic Imaging's ISO 9001 and ISO 13485 quality certifications are applicable across the entire organization for all imaging core lab services for clinical trials, and are applicable to all therapeutic areas including, but not limited to, Cardiovascular, Central Nervous System, GI & Genitourinary, Medical Device, Musculoskeletal, Respiratory and Oncology.

"Intrinsic Imaging is an FDA audited, ISO 9001 and ISO 13485 certified and GAMP 5® medical imaging core lab specializing in providing imaging core lab services for clinical trials. With our team of more than sixty board-certified diagnostic radiologists, our robust and scalable clinical imaging technologies and our ISO certified and registered quality management systems, Intrinsic Imaging is ideally positioned to provide unprecedented imaging core lab services around the world." said Todd A. Joron, BSc, MBA, President & COO at Intrinsic Imaging.

About Intrinsic Imaging, LLC

Intrinsic Imaging is a full-service medical 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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