Intrinsic Imaging Undergoes Third FDA Inspection with No 483 Observations

Intrinsic Imaging's third FDA inspection and its third inspection with no findings.

Boston, MA

Boston, MA — March 1, 2021 — Intrinsic Imaging, a full-service medical imaging core lab for clinical trials, announces today that it recently underwent an extensive Bioresearch Monitoring Program (BIMO) inspection by the U.S. Food and Drug Administration (FDA) Center for Drug Evaluation and Research (CDER). This inspection was related to a pivotal study of a novel drug to treat patients with metastatic cancer.

The FDA determined Intrinsic Imaging was in complete compliance with all federal regulations and the company received zero 483 observations.

This was Intrinsic Imaging's third FDA inspection and its third inspection with no findings.

During this successful inspection, the FDA audited Intrinsic Imaging's ISO certified quality management system, standard operating procedures, systems validation, clinical trial documentation, as well as case quality control and primary reviewer and adjudication assessments.

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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