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IMARC Research Achieves ISO 9001:2008

CLEVELAND, *Ohio* — IMARC Research, a contract research organization based in Strongsville, Ohio, has announced that it has attained ISO 9001:2008 status.

Following the same process as manufacturing companies, IMARC spent more than a year and involved its entire staff of nearly 30 persons in pursuing the designation. "We invested significant dollars and hundreds of hours of staff time in the process," said Sandra Maddock, IMARC CEO and president.

"Quality is an essential focus of our business and we wanted someone from the outside – an independent third party – to confirm that we were doing it right," Maddock continued. "Being able to exhibit quality performance is such an integral part of today's healthcare industry," she added. "We've begun to see RFPs (requests for proposal) from companies and organizations that place a high value on ISO certification."

In issuing the ISO designation, the certifying group summarized the company's business saying, "IMARC assists clinical researchers pursuing regulatory approvals by providing cost-effective monitoring, auditing, training and research consulting services." In its entire 15-year history, sites monitored from the start by IMARC have never received an FDA warning letter.

To maintain its ISO status, IMARC will be subject to partial inspections annually as well as full quality inspections every three years.

From ISO.org:

ISO 9001:2008 specifies requirements for a quality management system where an organization:

- needs to demonstrate its ability to consistently provide product that meets customer and applicable statutory and regulatory requirements, and

– *more* –

- aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.

All requirements of ISO 9001:2008 are generic and are intended to be applicable to all organizations, regardless of type, size and product provided.

IMARC Research:

A privately-held, 15-year old company located in Strongsville, Ohio, IMARC assists the clinical research community in the pursuit of FDA and worldwide approvals. Our effectiveness is built on preparing, educating, complementing and guiding site teams from Day 1 — to control the complex management of trials via cost-effective monitoring, auditing and training services — which results in the support, proof and assurance they seek to overcome chaos caused by complexity while achieving compliance through consistency. Providing committed, competent and confident consultation is how IMARC sets the highest standards for site outcomes and study partnerships. Sites monitored from the start by IMARC have never received an FDA warning letter. More information is available at: www.imarcresearch.com