VEEDA CLINICAL RESEARCH REAFFIRMS QUALITY CREDENTIALS BY SUCCESSFULLY CLEARING USFDA INSPECTIONS AT THE SHIVALIK, VEDANT AND INSIGNIA FACILITIES

Ahmedabad, Veeda Clinical Research Pvt. Ltd. is pleased to share the successful completion of the USFDA Inspections at its Shivalik and Vedant clinical facilities as well as a simultaneous USFDA inspection at its Insignia bioanalytical facility in August 2019 without any 483 issuances. While the inspections at the clinical facilities were routine inspections under USFDA's BioResearch Monitoring Program (BIMO), the inspection at the bioanalytical facility by the USFDA Office of Study Integrity and Surveillance, CDER was unannounced.

The inspection covered a comprehensive evaluation of the Clinical and Bioanalytical systems along with the respective study data. The methodology included a comprehensive review of Protocol and SOP compliance as well as the entire workflow of the clinical and bioanalytical study plans. In the clinical facilities, the inspection covered activities starting from recruitment to study conduction and

data generation whereas in the bioanalytical facility, the inspection covered bioanalytical method validation, sample management and project sample analysis related activities including batch acceptance, repeat analysis and incurred sample reanalysis. The inspection also included electronic data review of chromatographic system and audit trails.

The inspection outcomes reaffirmed Veeda's commitment to the highest Quality standards and compliance with the defined SOPs and regulatory guidelines. The outcomes also validated Veeda's successful progression towards 'anytime audit readiness

With an enhanced focus on 'Right First Time' and sustaining a strong Quality Culture that underscores its Quality Policy and robust Quality Management System, Veeda continues to steadfastly pursue its mission – "To Strive for Excellence in Quality and endeavor to become the partner of choice for our Sponsors and our Stakeholders".

About Veeda CR

Veeda is the leading independent CRO in India. Veeda offers a diverse range of clinical studies including bioequivalence as well as PK, PD and Clinical End point studies for Generics, NCE and Biopharmaceuticals. Veeda is a partner of choice for many global pharmaceutical companies and is reputed for its best-in-class scientific knowledge, quality and ethics. Veeda has an exemplary regulatory track record of successfully completing 33 USFDA, 7 ANVISA, 5 WHO, 3 MHRA, 1 AGES, 1 ANSM, 1 MCC, 13 DCGI and 4 NPRA audits till date.

For more information kindly visit us at www.veedacr.com

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