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US FDA clears GVK Bio's Ahmedabad facility

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Hyderabad: The Ahmedabad Clinical Pharmacology Unit of GVK Biosciences, Asia's leading contract research organization, has cleared the US FDA audit with zero 483s/observations from the agency. The USFDA visited the site in India and audited a first-to-file study for one of GVK BIO's customers.

The GVK BIO Ahmedabad facility, commissioned in 2010, has three clinics with 110 beds. The facility has been inspected and approved by Drugs Controller General of India (DCGI), ANVISA-Brazil and Ministry of Health (MoH)-Turkey. The Ahmedabad facility carries out Bioavailability and Bioequivalence (BA/BE) studies that are submitted to various regulatory agencies, including FDA, TGA (Australia), European Regulatory agencies, Health Canada, ANVISA-Brazil and MoH (Turkey).

Manni Kantipudi, chief executive officer, GVK BIO, said, "This is a clear testimony of the high standards of quality and processes followed at GVK BIO. The sponsor can now carry out BA/BE studies at either of our sites, Ahmedabad or Hyderabad, with a wider choice of population and capacities." The Ahmedabad clinical facility has the capability to execute

BA/BE studies in healthy human volunteers, in special populations and can conduct some patient based studies.

The Ahmedabad success comes on the heels of regulatory joint inspection by the FDA, ANSM (France), AGES (Austria) and WHO, of the GVK BIO Hyderabad facility. This inspection was the first joint inspection of a CRO by the four agencies. GVK BIO received zero 483s by FDA in this joint inspection.

The GVK BIO Hyderabad facility is a full service provider of BA/BE services with four clinics and 144 beds supported by a bioanalytical facility with 16 LC-MS/MS machines. The Hyderabad facility has been inspected and approved by various regulatory agencies such as the DCGI, ANVISA-Brazil, MoH (Turkey), FDA, AFSSAPS (France), WHO and MHRA.