



The GVK BIO Clinical Pharmacology Unit granted major accreditations

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The Clinical Pharmacology Unit (CPU) of GVK Biosciences (GVK BIO) received approvals from all major regulatory bodies globally including USFDA, AFSAAPS, WHO and ANVISA. The approvals open global markets to GVK BIO's clients in the US, Europe and Latin American countries in addition to the domestic sector.

Manni Kantipudi, President of GVK BIO stated, "The approvals validate GVK BIO's high quality systems and practices".

As a first step, GVK BIO has expanded and built a new state-of-the-art Bioanalytical facility in addition to the existing one to cater to the growing business demands. GVK BIO is also setting up its own Clinical Laboratory and aims for an early accreditation.

"GVK BIO aims to be a full service Clinical Research Organization offering services from BA/BE to Phase I through Phase IV Clinical Trials", said Mr. G.V.Sanjay Reddy, Managing Director, GVK BIO.

Set up in 2001, GVK BIO is a leading CRO in India. GVK BIO started offering Bioavailability/Bioequivalence(BA/BE) services in 2004 and in a very short time received major accreditations from international regulatory authorities such as ANVISA (Brazil) and AFSAAPS (French) and the US FDA. The US FDA has inspected the facilities twice and approved several BA/BE studies conducted by GVK BIO. The BA/BE facility was also inspected and cleared by WHO after a recent audit of one of the studies. GVK BIO's BA/BE Centre was requalified by ANVISA (Brazilian Regulatory Body) for the third consecutive year.

About Clinical Pharmacology Unit (CPU)

The Clinical Pharmacology Unit (CPU) located at Hyderabad, is one of the largest units in India for Bioavailability and Bioequivalence studies with state-of-the-art infrastructure to cater to global regulatory requirements. The SBU with 144 beds and a comprehensive volunteer database has the capability of undertaking studies for special population and dosage forms like injectables in addition to the conventional studies, which sets it apart from the competition. As of now, CPU has conducted around 300 studies of which more than 50 studies are for USFDA submission.

About GVK BIO

GVK Biosciences (www.gvkbio.com), India's premier Contract Research Organization, delivers integrated research services to big Pharma and Biotech companies globally. The company accelerates the Drug Discovery and Development process of its customers through science and innovation. Currently the company has more than 1,300 employees spread across facilities in Hyderabad, Chennai and Gurgaon.

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