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Piramal Enterprises receives GLP Compliance Certificate from NGCMA

28 March 2014 | News | By BioSpectrum Bureau

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Piramal Enterprises Limited (PEL), announces that its Good Laboratory Practices (GLP) Department at Research & Development (R&D) facility in Goregaon, Mumbai has received the GLP Compliance Certification from the National Good Laboratory Practice Compliance Monitoring Authority (NGCMA), Government of India.

GLP is a quality system concerned with the organizational process and conditions under which non-clinical health and environmental safety studies are performed. The R&D facility in Goregaon, Mumbai is engaged in drug discovery and development of New Chemical Entities (NCE) in the area of Oncology and Metabolic Disorders.

Dr. Owe Owar, president, NCE Research, Piramal Enterprises Limited said, "The GLP certification is a testament to high quality research through thorough SOP-driven Good Laboratory Practices, competent well-trained personnel and systematic documentation at Piramal's NCE R&D facility in Mumbai. Piramal's NCE R&D unit is committed to realize its mission towards serving patients globally with medicines that matter."

The certification states that specified studies in the areas of toxicity, mutagenicity, analytical and clinical chemistry testing, and others like hERG, bioanalysis and toxicokinetic evaluation conducted at Piramal Enterprises Ltd are compliant with GLP under OECD principles.

Dr. Swati Piramal, vice-chairperson, Piramal Enterprises said, "I am very happy that our GLP lab has received this certificate. This is a leap forward in the field of quality compliance and best practices. The GLP laboratories are designed as per OECD guidelines. GLP helps assure the integrity and quality of the laboratory data used to support a regulatory submission."

The 3,450-odd sq. ft. GLP facility is a part of 200,000 sq. ft. fully integrated NCE R&D unit which houses more than 400 scientists. Since its inauguration in June 2012 PEL has made significant investments in creating this in-house facility with state-of-the-art infrastructure. The GLP certification will enable PEL to do most of the Investigational New Drug (IND) support studies in-house, hence shorten the turnaround time for its R&D projects and help it become more cost efficient. Earlier, PEL used to conduct GLP studies externally. However, now with this in-house facility it will enable faster access to bio-analytical

and toxicology data and better control on project timelines.