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LifeSan Clinical Research receives zero 483 observations from USFDA inspections

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LifeSan Clinical Research, the clinical research division of Centaur Pharmaceuticals was audited by the USFDA and was concluded with zero 483 observations which signifies compliance and conformance to applicable GCP regulations.

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It undertakes bioavailability/ bioequivalence studies, which are mandatory for generic drug approval process and phase II/III clinical trials. Since inception, LifeSan has submitted many studies to regulatory agencies of USFDA, EMA, MCC South Africa and TGA, Australia as well as CDSCO, the Indian Drug Regulatory Authority, including successful conduct of phase II and III clinical trial of a new chemical entity [NCE].

S.D Sawant, Managing Director, Centaur Pharmaceuticals said, “The zero 483 observations to our clinical research division, LifeSan Clinical Research is yet another feather in our cap. We are happy with this significant development not only for Centaur but also for the Indian pharmaceutical industry. In addition to USFDA accreditation, the said facility also conforms to MHRA (UK), TGA (Australia), Health Canada, MCC (South Africa) and WHO-GMP standards.”

Earlier in May 2019, Centaur Pharmaceuticals oral solid dosage facility in Pune had received no action indicated (NAI) compliance status with zero 483 observations from the USFDA. In addition to USFDA accreditation, the Pune facility also conforms to MHRA (UK), TGA (Australia), Health Canada, MCC (South Africa) and WHO-GMP standards.