

# SGS's Shanghai Health Science Laboratory Completes US FDA Inspection with Zero 483 Observations

GENEVA, SWITZERLAND, October 1, 2024 /EINPresswire.com/ -- SGS, the world's leading testing, inspection and certification company, has set a new benchmark for third-party pharmaceutical testing laboratories in China following an outstanding inspection by the US Food and Drug Administration (FDA) of its Shanghai Health Science Laboratory.



For a third consecutive time, the facility was not issued a Form FDA 483 at the conclusion of the US FDA's comprehensive inspection (Zero 483 inspectional observations), becoming the first third-party pharmaceutical testing laboratory in China to achieve this accolade.

In the global pharmaceutical market, international recognition of pharmaceutical quality systems is critical for companies to gain market access. As a globally recognized regulatory authority, the US FDA protects public health by ensuring the safety, efficacy and security of human and veterinary drugs, biological products and medical devices. To this end, GMP on-site inspections evaluate whether a company's operations quality management system meets international standards.

Over four days in September 2024, US FDA inspectors undertook a full-scope GMP compliance inspection of SGS's Shanghai facility. Its focus included quality management, chemical and microbiological quality control laboratory management, sample management, personnel training, hardware/software system validation, method validation, documentation and records, electronic data management and data integrity.

Additionally, inspectors conducted on-site reviews of actual tests in physical, chemical, microbiological and sterile testing laboratories.

Dr. Sandy Hao, Managing Director of SGS in China, said: "Our Shanghai Health Science Laboratory's successful completion of the US FDA GMP on-site inspection with a zero 483 observations result is not only a testament to our long-standing commitment to excellent laboratory management practices but also a further consolidation of our authority and

professionalism in the third-party pharmaceutical testing field.

“Our team continuously embraces SGS’s ‘Quality First’ mission to further enhance pharmaceutical brand reputation and customer confidence. With SGS support, Chinese pharmaceutical product manufacturers will continue to improve market reputation and customer trust, and readily access global markets. In partnership with our global pharmaceutical customers, we aim to drive the long-term, high-quality development of the healthcare industry in China.”

SGS provides analytical services spanning the entire drug development life cycle, including GMP-compliance QC testing, bioanalysis and clinical research, formulation development. We cover all segments such as chemical drugs, biopharmaceuticals, medical devices and pharmaceutical packaging materials.

SGS is committed to providing higher quality services to pharmaceutical companies in China and globally, helping products to be marketed efficiently and safely, and offering a solid guarantee for the health of patients worldwide.

#### About SGS

We are SGS – the world’s leading testing, inspection and certification company. We are recognized as the global benchmark for sustainability, quality and integrity. Our 99,600 employees operate a network of 2,600 offices and laboratories around the world.

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