

WuXi Biologics Suzhou Testing Centre Secures Fourth EMA GMP Certification

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The certification supports EU marketing authorization applications for 19 biologics across antibody, enzyme and fusion protein modalities.



WuXi Biologics' Suzhou Biosafety Testing Center has passed a European Medicines Agency Good Manufacturing Practice inspection with zero critical findings, marking the fourth EMA GMP certification for the facility.

The inspection supported European Union marketing authorization applications for 19 biologics from 13 clients. Most of the products were developed and manufactured through WuXi Biologics' integrated platform, covering modalities including antibodies, enzymes and fusion proteins.

This is relevant because biosafety quality control testing is a key part of biologics development and commercial readiness. For biologics seeking European market authorization, regulators need confidence that cell banks, commercial unprocessed bulk and related testing systems meet GMP expectations before products can move into commercial supply.

The four-day EMA inspection covered quality management, facilities and equipment, testing methods, standard operating procedures, computerized systems and personnel. WuXi Biologics said the Suzhou facility's quality system, infrastructure, technical capabilities, data integrity and organisational management were recognised by the EMA.

The certification strengthens WuXi Biologics' role as a global CRDMO supporting biologics development from early validation through commercial batch release. The company's Biosafety Testing Center operates facilities in Suzhou and Shanghai, offering services including cell bank characterisation for CHO, HEK293 and E. coli expression systems, biologics biosafety testing, GMP-compliant release testing for commercial products and GLP-compliant viral clearance studies.

The development reflects the importance of biosafety testing infrastructure in the biologics value chain. While manufacturing capacity is often the most visible part of CDMO competition, regulatory-grade testing can be equally important in helping products progress through clinical and commercial milestones.

As of December 2025, WuXi Biologics' Biosafety Testing Center had enabled more than 1,700 IND or BLA applications. The centre has also completed a U.S. FDA remote interactive evaluation and passed inspections or assessments by CNAS, NMPA, Health Canada, Australia's TGA and Japan's PMDA. It has also undergone more than 510 quality audits by global clients.

The milestone is commercially relevant because biologics developers increasingly rely on outsourced partners not only for manufacturing, but also for integrated analytical, biosafety and quality control capabilities. For companies seeking EU approval, a testing partner with repeated EMA inspection success may reduce regulatory execution risk.

Adoption of CRDMO platforms will depend on quality track record, global regulatory recognition, modality coverage, capacity, cost and client confidence in data integrity. As biologics pipelines become more complex, especially with multi-specific antibodies, fusion proteins and other advanced formats, testing infrastructure will remain a key differentiator.

The development reflects how Asia-based biologics service providers are becoming more embedded in global regulatory and commercial supply pathways. For the biopharma industry, the larger implication is that quality systems and inspection readiness are now central to competitiveness, not just operational compliance.