

What Drives WuXi AppTec's 25-Year Compliance Record, and Why Does It Matter for Global Partnerships?



Natick, Massachusetts Apr 14, 2026 ([Issuewire.com](https://www.issuewire.com)) - As a global company operating in a highly regulated pharmaceutical and life sciences industry, [WuXi AppTec](https://www.wuxiapp.com) places compliance, transparency, and responsible business conduct at the center of its operations.

From customer onboarding to project execution, the company maintains rigorous internal controls designed to ensure that all business activities meet applicable international regulations, industry standards, and ethical requirements.

These compliance mechanisms reflect the company's commitment to operating as a trusted and accountable partner within the global healthcare ecosystem.

Rigorous, Multi-tiered Due Diligence Work for Partnerships

As a Contract Research, Development, and Manufacturing Organization (CRDMO), WuXi AppTec provides integrated services that support partners across every stage of the drug development process. To ensure responsible business conduct, the company undertakes rigorous, multi-tiered due diligence work for all partnerships, which includes comprehensive Know-Your-Customer (KYC) and Know-Your-Supplier (KYS) procedures.

Why are KYC and KYS procedures important? KYC and KYS are critical processes that companies should implement to verify the identity and assess the risk of their customers and suppliers.

They are designed to ensure that all business relationships meet strict compliance standards.

How does WuXi AppTec implement these mechanisms? Taking KYS as an example, WuXi AppTec has established a formal and rigorous assessment and qualification process to manage all suppliers. Such a process encompasses supplier selection, ongoing evaluation, and regular performance reviews. The company also conducts periodic audits to review supply quality and stability.

Similarly, the robust KYC framework underpins WuXi AppTec's work with customers across more than 30 countries, **ensuring that all partnerships are with commercial pharmaceutical and biotechnology organizations and meet strict compliance standards.**

As an innovation enabler and key contributor to the industry, WuXi AppTec joined the Pharmaceutical Supply Chain Initiative (PSCI) in 2025 as a Supplier Partner, underscoring the company's enduring commitment to responsible business practices and support for supply chain resilience across the sector.

Operating in A Highly Regulated Industry

Drug development and manufacturing are among the most highly regulated activities in the world. Companies operating in this industry must comply with strict regulatory standards established by authorities such as the U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMA), China's National Medical Products Administration (NMPA), and other global regulatory bodies. WuXi AppTec's quality system is evidenced by a strong track record of global regulatory recognition from these major bodies. Its facilities across the globe hold multiple accreditations and maintain rigorous compliance with Good Laboratory Practice (GLP), Good Manufacturing Practice (GMP), and other high-level standards.

For over 25 years, WuXi AppTec's focus has been, and remains, serving as a trusted partner to global customers. The company has always welcomed oversight and has consistently met these standards, successfully passing audits and inspections across jurisdictions—including U.S. government scrutiny—demonstrating a long-standing commitment to compliance, quality, and safety.

All of the company's facilities and operations undergo regular oversight from customers, regulators, and third parties. Below is its track record of quality audits in 2025 alone:

- **Total number of quality audits:** WuXi AppTec completed a total of 741 quality audits and inspections.
- **Breakdown:** These comprised 680 audits performed by customers, 56 inspections by regulatory authorities, and 5 audits by independent third parties.
- **Key results:** The company fully met audit compliance standards with zero critical findings.
- **Site certifications:** In 2025, WuXi AppTec's 20 main sites were also ISO/IEC certified.

In addition, data privacy and security is one of WuXi AppTec's highest priorities. The company has maintained a strong track record based on a rigorous and multi-layered internal process since its founding. Key practices and results include:

- **Framework and guidelines:** The company operates under a robust framework for data privacy and intellectual property protection, ensuring strict adherence to applicable laws, regulations, and industry standards across the jurisdictions in which it operates. For example, in the U.S., WuXi AppTec maintains stringent compliance with the guidelines set by the U.S. Department of Health & Human Services, Federal Trade Commission, and Food & Drug Administration.

- **Data compartmentalization and security:** All project data is compartmentalized by customer and accessible only to authorized personnel. U.S.-based project information is stored exclusively in U.S.-based facilities and IT systems, separated by robust firewalls from operations in other countries.
- **Key results:** In 2025, there were 60 information security audits by global customers with zerocritical findings.

These layers of oversight demonstrate clearly that **WuXi AppTec operates transparently, responsibly, and exclusively within the global pharmaceutical and life sciences industry, with its 25-year track record of regulatory compliance and transparency that speaks for itself.**

For WuXi AppTec, compliance is not simply a regulatory requirement—it is a fundamental part of operating responsibly within the global healthcare ecosystem. Through rigorous customer due diligence, strict internal controls, and openness to regulatory oversight, the company continues to ensure that its work supports the advancement of legitimate biopharmaceutical innovation worldwide.

WuXi AppTec remains committed to maintaining the high standards of compliance and transparency as it partners with the global pharmaceutical and life sciences community to help bring new medicines to patients.

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