WuXi AppTec Strengthens Global Trust With Excellent Regulatory Audit Record and Expanding Quality Certifications

SHANGHAI, SHANGHAI, CHINA, September 19, 2025 / EINPresswire.com/ -- In the pharmaceutical and life sciences industries, quality is paramount. A lapse in drug development or manufacturing quality can have catastrophic consequences, directly impacting human lives. This profound responsibility makes an unwavering commitment to quality an ethical imperative, ensuring every step, from research to production, adheres to the highest standards for public health.

WuXi AppTec, a leading global CRDMO, supports thousands of partners across over 30 countries in their mission to deliver breakthrough treatments. Its vision, "every drug can be made and every disease can be treated," for this vision to be realized responsibly, effective treatments must first be safe, reliable, and consistently manufactured. This means that quality must be the absolute foundation, ensuring that every scientific advancement is translated into a safe and dependable therapeutic for patients.

Concurrently, as global new drug R&D evolves towards a more efficient and rapid model, CXOs are increasingly involved in the new drug development process. WuXi AppTec, a globally renowned CRDMO enterprise in the pharmaceutical and healthcare industry, has continuously expanded its global facilities over the years to meet growing R&D demands. This has further accelerated clients' drugs entering global markets, while also meaning WuXi AppTec's quality and

compliance systems must meet the stringent requirements of various countries and regions worldwide.

The company consistently adheres to the highest global quality and regulatory standards across all operations, from raw material procurement to R&D, production, and quality management. It has a proven track record of successfully passing inspections by major global regulatory authorities, including the US FDA, EU EMA, China NMPA, and Japan PMDA. Over 80% of its main facilities are certified to GMP, GLP, GCP, ISO 9001, and ISO 13485.

Demonstrated Success in Global Regulatory Audits and Certifications

Couvet, Switzerland: This site, specializing in clinical and commercial-scale oral solid dosage production, has an impeccable record of no Form 483s nor any observations from three FDA inspections (2019, 2020, and June 2023). This "no 483s" record is a gold standard, signifying a deeply ingrained, proactive quality culture. The site also achieved ISO 14001 and ISO 45001 recertification in 2024 and supplies products to major global markets.

Munich, Germany: This site successfully passed GMP inspection by the German BfArM, earning its Manufacturing/Import Authorization (MIA) and EU-GMP certification. This launched WuXi AppTec's EU Qualified Person (QP) release services, simplifying import procedures and accelerating patient access in the EU.

Changzhou and Taixing, China: These two API manufacturing sites successfully passed U.S FDA inspections back-to-back in March 2025, both without a single observation and with no Form 483 issued. The API site at Changzhou underwent a GMP surveillance inspection by the FDA, while the API site at Taixing completed a Pre-Approval Inspection (PAI) for the commercial manufacturing of a peptide-based therapeutic, with no observation.

The sheer volume and consistent success of these audits are compelling. In 2024, the company received 802 quality audits and inspections conducted by global customers, regulatory authorities and independent third parties, again achieving a 100% pass rate with no critical findings. This demonstrates the robustness of the Quality Management System (QMS) under intense scrutiny, building immense trust with clients and regulators.

Furthermore, WuXi AppTec extends its quality commitment to data security. 24 of its main operating sites, including all main sites in China, are ISO/IEC 27001 Information Security Management System certified. In 2024, the company successfully passed 58 information security

audits by global customers with no critical findings.

So, how does WuXi AppTec rapidly "replicate" its high-standard quality system across these new operational bases and facilities?

WuXi AppTec's remarkable ability to rapidly "replicate" its high-standard quality system in new facilities is central to its global expansion. This capability stems from a pervasive company-wide quality culture, systematic training, and robust supply chain quality control, forming a synergistic ecosystem where quality is intrinsic from day one.

Fostering a Pervasive Quality Culture

At WuXi AppTec, quality is deeply ingrained in the organizational DNA, from the lab bench to the boardroom. A strong quality culture means quality is inherent in every employee's approach.

Leadership commitment is paramount, with the Board of Directors providing top-level quality oversight, signifying it as a strategic imperative. This top-down emphasis creates an environment where all employees are vigilant about quality. Quality is thus seen as an accelerator, enabling faster, more reliable drug development, with all-member participation ensuring collective responsibility.

Systematic Training and Continuous Competency Development

To translate this quality culture into consistent execution, WuXi AppTec implements a comprehensive, year-round quality training plan. All personnel involved in product and service quality receive continuous education covering quality management standards, process improvement, QMS training, and specific R&D/production skills.

The Quality Assurance (QA) department is held accountable for conducting internal inspections, preparing for customer audits and regulatory inspections, and addressing findings through corrective and preventive measures.

Rigorous Supply Chain Quality Control

Quality extends throughout the entire value chain. WuXi AppTec has a robust assessment and qualification process for all suppliers, ensuring quality is built into the supply chain from inception. Key suppliers undergo regular audits to assess product supply quality and long-term

capabilities.

All incoming raw materials are subjected to stringent testing and certification, with continuous quality monitoring. WuXi AppTec is dedicated to fostering mutually beneficial collaborations with our suppliers to jointly enhance the management of quality of products and services.

Global high-quality standard layout is a key strategy for WuXi AppTec to become a trusted partner for global clients. This is underpinned by a robust, globally harmonized QMS, a pervasive quality culture, systematic training, stringent supply chain controls, and unwavering commitment to intellectual property and data security.

In the competitive CRDMO market, WuXi AppTec's consistent, globally recognized, and independently audited quality performance is a powerful differentiator. This deep embedding of quality positions WuXi AppTec as a low-risk, high-assurance partner—an invaluable asset for pharmaceutical companies navigating immense regulatory scrutiny and patient safety responsibilities.

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