WuXi AppTec's New EU Batch Release Services: What This Means for European Biotech

Shanghai, China Sep 15, 2025 (Issuewire.com) - WuXi AppTec has achieved a key milestone for EU pharmaceutical market access: WuXi STA, its subsidiary, marks the official launch of EU batch release (Qualified Person, or QP Certification). Through WuXi AppTec's Munich site's successful GMP inspection by Germany's Federal Institute for Drugs and Medical Devices (BfArM), the company has received Manufacturing/Import Authorization (MIA) and EU-GMP certification – unlocking key advantages for our partners with EU-facing programs, including the direct QP certification for batch release in the EU, streamlined importation process, and shorter timelines for patient access.

Understanding QP Certification and WuXi AppTec's Achievement

Rooted in the EU's pharmaceutical regulatory framework (Eudralex Volume 4) and GMP guidelines, each batch of finished product must be certified by a Q.P. within the EC/EEA (European Community / European Economic Area) before being released for sale or supply in the EC/EEA or for export. For biotech and pharma clients, partnering with a QP-certified CRDMO like WuXi AppTec shortens time-to-market by eliminating the need for external QP services.

This success shows that the company is very critical in adhering to the European regulatory standards and is in a position to perform any official EU batch release services. This is good news to biotech companies as they can expect a more efficient import process and quicker delivery to patients.

How WuXi AppTec Earns Continued Trust from Industry Leaders

WuXi AppTec has established its reputation on quality, regulatory compliance, and customer-focused service. From the start, it has followed international regulatory standards, meeting and often exceeding client expectations.

One of the main elements of this strategy is WuXi AppTec's unwavering commitment to high quality. The company runs the overall Quality Management System (QMS) that works beyond the industry standards. The 2024 ESG Report shows that the company has an effective system ensuring quality at every phase of research, development and production.

The combined CRDMO (Contract Research, Development, and Manufacturing Organization) model further ensures consistent quality, with the company controlling every production phase—from raw materials to final product release.

Proven Results in Regulatory Compliance and Quality

The quality practices at WuXi AppTec have been confirmed by a good record with the regulatory authorities. The company has successfully passed the inspection of large agencies such as the US FDA, EU EMA, China NMPA, and Japan PMDA. The QP certification and various awards & recognitions add another layer of regulatory assurance, particularly for European operations.

In 2024 alone, WuXi AppTec passed 802 global customer, regulatory, and third party quality audits and inspections, with a 100 percent pass rate. More than 80% of its main sites are certified with globally accepted quality standards such as GMP, GLP, GCP, ISO 9001, ISO 13485 or other equivalent systems - affirming high-quality standards across drug development and production.

Consistent quality performance gives the clients the confidence that WuXi AppTec is capable of complying with regulations and can provide reliable services. Pharmaceutical and biotech enterprises will be able to concentrate on innovation and research, knowing that regulatory and manufacturing activities are completely supported.

WuXi AppTec partners with global customers—from startups and small firms to large corporations. It delivers R&D and manufacturing services that meet the most stringent regulatory and quality requirements. With a presence in over 20 countries, it currently collaborates with around 6,000 clients as a trusted partner of the global life sciences ecosystem.

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