

# How WuXi AppTec Keeps Quality Consistent Across Its Global Sites



**San Diego, California Oct 9, 2026 ([Issuewire.com](https://www.issuewire.com)) - Key Takeaways**

- WuXi AppTec runs a single "One Global Quality System" across every site it operates, instead of letting each location set its own local standards.
- In the three most recent reporting periods, WuXi AppTec completed 802 quality audits in 2024, 741 in 2025, and 465 in the first half of 2026, all with no critical findings.
- Case Study: WuXi AppTec's Couvet, Switzerland site took over a client's Phase 3 manufacturing within five months, and the same site later passed inspection by three separate regulators, Swissmedic, the FDA, and Brazil's ANVISA, without pausing production.

Ask a CDMO for one clean audit report, and most can produce one. Ask whether that same result holds at every site they run, and the answers get far less consistent. From 2024 through the first half of 2026, WuXi AppTec completed 2,008 quality audits and inspections conducted by global customers, regulatory authorities, and independent third parties, without a single critical finding. For a biotech or pharma company handing off a program, that record is what determines whether they can trust the

receiving site without having to verify it themselves.

## **WuXi AppTec Addresses Inconsistency Through One Global Quality System**

WuXi AppTec addresses variation across its global network through its “One Global Quality System,” which aligns quality standards, procedures and training across sites. Global computerized systems support consistent documentation and oversight, while standardized GMP procedures establish common expectations for daily operations. At its Couvet, Switzerland, manufacturing site, for example, the company adopted the same global procedures, computerized systems and training used across the network. Quality assurance leaders from other sites worked alongside local teams to map existing processes to the global framework.

This approach addresses a practical challenge of global collaboration. Growth through new builds, acquisitions and joint ventures can bring together sites with different operating histories, equipment, documentation practices and interpretations of GMP requirements. Without deliberate alignment, those differences can lead to gaps in how teams document work, manage changes and demonstrate that employees are qualified for their roles.

Harmonized procedures, shared quality management systems and common training requirements help translate global standards into consistent daily practice. They give teams a common basis for recording activities, reviewing decisions and identifying issues as programs move between locations. The challenge is sustaining that discipline as the network grows, so that each site meets the same expectations.

## **WuXi AppTec Helps Customers Navigate Transitions Between Sites**

[According to Dirk Tormans](#), WuXi AppTec’s Head of QA, a qualification audit at an API facility may allow customers to reduce the time spent reviewing same quality elements at a downstream drug-product site.

That benefit matters when a program moves into a new development stage, requires additional capacity or expands production to another region. Customers need to assess whether the receiving site can perform the work and maintain the program’s quality requirements. Familiarity with the broader quality framework helps them concentrate on the questions specific to that transition, including equipment suitability, process transfer and analytical readiness.

## **WuXi AppTec’s Site Examples Demonstrate Quality in Practice**

WuXi AppTec’s Couvet, Switzerland, site illustrates how an established manufacturing operation can support a time-sensitive transition. In one program, the site took over manufacturing of a Phase 3 drug previously produced at the client’s own facility. Teams worked in parallel on equipment compatibility assessments, analytical method validation and procurement of raw and packaging materials. The process transfer and scale-up were completed within five months, helping the client submit its New Drug Application on time.

Separately, Couvet's integration into the global quality framework provides an example of consistency under regulatory scrutiny. Inspections by Swissmedic, the U.S. FDA and Brazil's ANVISA proceeded without interrupting production following the site's alignment with the global system.

The company is also incorporating quality into new facilities before operations begin. At Middletown, Delaware, and Singapore, WuXi AppTec applies an approach that embeds leaders early and establishes quality systems ahead of production. These examples address two practical tests of a global network: preparing work into an existing facility and preparing new capacity to operate within the same quality framework from the outset.

### ***WuXi AppTec's Quality System Lets Programs Move Fast Without Losing Trust***

A quality system proves its worth when something has to move fast.

WuXi AppTec's Couvet, Switzerland site is one example. The site took over Phase 3 manufacturing that a client had previously run at its own facility, absorbing an unfamiliar process into an already-audited quality framework rather than building oversight from scratch. Multiple teams completed the equipment compatibility checks, analytical method validation and materials procurement the transition required within five months, and the client submitted its NDA on time.

That transition held up under outside scrutiny too. Switzerland's Swissmedic, the U.S. FDA, and Brazil's ANVISA, all three regulators inspected the site afterward, and in each case, production continued through the inspection instead of pausing for it.

[WuXi AppTec](#) is applying the same logic to sites that have not opened yet. At Middletown, Delaware, and at its Singapore site, quality leadership and systems are already in place before the first batch is ever run, so the new facility starts inside the global standard instead of being folded into it later.

That kind of transfer only works if the receiving site's quality system is already trusted. A client should not have to verify it from zero once the clock is running.

The same logic underpins WuXi AppTec's oral peptide work, where the company has supported more than 70 preclinical and over 10 clinical-stage programs without each one requiring its own separate quality build-out. For a company choosing a manufacturing partner, global quality has to mean a system that lets a program move between teams, sites and stages without losing the standard it started with.

That is the standard a biotech or pharma company is checking for when it evaluates a partner: a quality system with an actual track record behind it.

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