

# WUXI APPTTEC RECEIVES THE 2023 COMPANY OF THE YEAR AWARD

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*Identified as best in class in the  
Global contract research, development,  
and manufacturing organization industry*

## Best Practices Criteria for World-Class Performance

Frost & Sullivan applies a rigorous analytical process to evaluate multiple nominees for each award category before determining the final award recipient. The process involves a detailed evaluation of best practices criteria across two dimensions for each nominated company. WuXi AppTec excels in many of the criteria in the contract research, development, and manufacturing organization space.

AWARD CRITERIA	
<i>Visionary Innovation &amp; Performance</i>	<i>Customer Impact</i>
Addressing Unmet Needs	Price/Performance Value
Visionary Scenarios Through Mega Trends	Customer Purchase Experience
Implementation of Best Practices	Customer Ownership Experience
Leadership Focus	Customer Service Experience
Financial Performance	Brand Equity

### ***WuXi AppTec: The Industry's Best Practices Benchmark***

Established in 2000, WuXi AppTec stands as a prominent player in the global pharmaceutical field, offering an all-encompassing suite of services spanning research, development, testing and manufacturing.

Known initially as WuXi PharmaTech, the company transformed, adopting the name WuXi AppTec after it acquired AppTec Laboratory Services in 2008. With a presence across Asia, North America, and Europe, WuXi AppTec contributes significantly to the global healthcare landscape, orchestrating clinical endeavors to usher in groundbreaking therapies that cost-effectively cater to patients' needs.

The company's business model is multifaceted, including diverse domains such as chemistry drug contract research, development, and manufacturing organization (CRDMO), biology discovery, preclinical testing, clinical research services, and cutting-edge cell and gene therapies (CGT), alongside contract testing, development, and manufacturing organization (CTDMO) capabilities.

WuXi AppTec's innovative spirit is reflected in its global workforce, which totals over 41,000 dedicated individuals, and its network of 32 state-of-the-art facilities worldwide. The company serves over 6,000 active clients from more than 30 countries.<sup>1</sup>

<sup>1</sup> Interview with Frost & Sullivan, August 2023.

WuXi AppTec's skill lies in its adeptness at constructing integrated platforms that facilitate drug discovery, laboratory analysis, and manufacturing processes. It has solidified its position as a cornerstone of progress in the pharmaceutical and healthcare ecosystem through its unwavering commitment to innovation and excellence.

### ***A Leader's Path: Navigating CRDMO Space***

WuXi AppTec's vision is "every drug can be made and every disease can be treated" using a comprehensive open-access platform that advances global healthcare innovation and accelerates the discovery,

*"As an enabling platform, the company [WuXi AppTec] envisions a future where breakthrough treatments are more accessible to address a range of medical conditions, ultimately improving the quality of life for patients worldwide. Through its CRDMO and CTDMO business models, WuXi AppTec facilitates the seamless integration of drug discovery, development, and manufacturing processes."*

***- Azza Fazar  
Best Practices Research Analyst***

development, and manufacturing of transformative pharmaceuticals and therapies. This platform overcomes barriers that hinder drug development, such as cost, time, and complexity, by providing researchers and companies with a collaborative ecosystem.

As an enabling platform, WuXi AppTec envisions a future where breakthrough treatments are more accessible to address a range of medical conditions, ultimately improving the quality of life for patients worldwide. Through its CRDMO and CTDMO business models, WuXi AppTec facilitates the seamless integration of drug discovery, development, and manufacturing processes. By bringing together expertise, data-driven insights, and state-of-the-art tools, this approach offers an efficient

and collaborative environment for researchers, enabling them to make informed decisions and drive innovation in healthcare.

### ***An Integrated, Open-Access Platform***

WuXi AppTec stands out as a rarity among open-access platforms within the industry, with comprehensive capabilities that span the entirety of the new drug research and development value chain. The organization extends a wide-ranging array of research and development (R&D) and manufacturing services, empowering the global pharmaceutical and healthcare sector to advance discoveries and introduce groundbreaking treatments to patients. Its comprehensive services cover drug chemistry CRDMO services, biology discovery, preclinical testing, clinical research, and CTDMO for cell and gene therapies. This comprehensive offering aids clients in enhancing the efficiency and cost-effectiveness of advancing healthcare products.

WuXi AppTec is well-equipped to address various customer needs, both in terms of technological requirements and service coverage. The organization maintains vigilant oversight of new drug R&D projects and continuously broadens the range of services available to clients throughout the development stages of each project.

### ***Comprehensive Cell and Gene Therapy Support***

WuXi AppTec's subsidiary, WuXi Advanced Therapies (WuXi ATU), is dedicated to transforming discovery, development, testing, manufacturing and commercialization of cell and gene therapies. WuXi ATU currently has operations in the United States, China, and United Kingdom, with an upcoming facility in Singapore poised to further amplify its capabilities.

WuXi ATU collaborates with biotech partners as early as the process development phase to fine-tune quality performance benchmarks like cell yield and purity. Further value is delivered to the customers through the optimization of cost-effective current Good Manufacturing Practice (cGMP) manufacturability and assurance of quality compliance via customized tests. For example, WuXi ATU's proprietary TESSA™ manufacturing platform enables the production of adeno-associated viruses in serum-free human embryonic kidney 293 cells, at a scale ranging from 250 milliliters (research grade) to 200 liters (cGMP). Through this platform, the potential improvement in AAV yield is ten times compared to conventional triple-transfection method.

*“Cell and gene therapies play a critical role in helping treat and prevent many severe and rare diseases, which is why WuXi ATU is committed to growing our comprehensive one-stop service platform specifically dedicated to the gene and cell therapy field. By expanding our global footprint, we will provide enhanced cell and gene therapy manufacturing services for our customers worldwide and better enable them to deliver more effective and accessible advanced therapies to patients.”*

– Dr. David Chang, President and CTO, WuXi ATU<sup>2</sup>

WuXi ATU and Singapore's Agency for Science, Technology, and Research Bioprocessing Technology Institute partnered to accelerate the CGT sector's expansion in the Asia Pacific region in April 2022. This collaboration fosters scientific innovation and introduces a joint professional development program to train and cultivate the next generation of scientists and engineers specializing in GMP manufacturing.

WuXi ATU also works with WuXi Testing, another branch of WuXi AppTec, to offer complete solutions for preclinical needs, including long-term toxicology, drug metabolism and pharmacokinetics during development, and clinical bioanalysis. These solutions are customized to speed up the process from DNA to antibiotics for biopharmaceutical companies.

As an example of how WuXi ATU can support our partners towards success, Hemogenyx Pharmaceuticals achieved a significant milestone of an Investigational New Drug (IND) submission to the US Food and Drug Administration (FDA) for its lead HEMO- chimeric antigen receptor (CAR-T) cell candidate designed to treat acute myeloid leukemia. This submission marked the culmination of Hemogenyx Pharmaceuticals' successful efforts in ensuring the product's manufacturability, quality, and safety by utilizing WuXi ATU's plasmid and lentiviral vector manufacturing platforms.

Another illustration is Juventas Cell Therapy, who received clearance from China's National Medicinal Products Association (NMPA) to proceed with clinical trials for its cell therapy injection targeting relapsed and refractory lymphoblastic leukemia and refractory non-Hodgkin lymphoma.

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<sup>2</sup> <https://www.wuxiapptec.com/news/wuxi-news/4882>

In South Korea, WuXi ATU was crucial in helping TiCARos, a biotech firm creating immune anti-cancer treatments, move forward with its CAR-T cell therapy. WuXi ATU expedited the preparation of TiCARos' IND application preparation for phase I and II clinical trials.

### **Expanding Plasmid Manufacturing Capacity**

WuXi ATU's CTDMO plasmid platform offers personalized services, including plasmid engineering, clone screening, strain libraries development, and production for research, clinical, and commercial purposes. This streamlined approach capitalizes on OXGENE's proprietary technology, effectively reducing costs and accelerating the manufacturing timeline for clinical viral vectors. The plasmid manufacturing process is free from antibiotic-free and uses single-use consumables.

*“WuXi ATU collaborates with biotech partners as early as the process development phase to fine-tune performance benchmarks like cell yield and purity. The focus extends to optimizing cost-effective current Good Manufacturing Practice (cGMP) manufacturability and ensuring quality compliance through tailor-made quality tests.”*

**- Azza Fazar**  
**Best Practices Research Analyst**

WuXi ATU's facilities strictly adhere to the rigorous standards set forth by regulatory bodies, including the US FDA, European Medicines Agency, and China's NMPA. At the end of 2022, WuXi ATU supported over 60 top pharmaceutical companies, biotech firms, and research organizations, delivering over 200 batches of GMP plasmids to enhance the development of new medical treatments.

Frost and Sullivan expects the market outlook for WuXi AppTec to remain highly promising, underscored by its comprehensive CTDMO platform and its commitment to adhering to stringent regulatory standards. With the

company's innovative approach, diverse service portfolio, and demonstrated success in serving a broad clientele, WuXi AppTec plays a pivotal role in shaping the future of advanced therapies and viral vector manufacturing.

### **Digital Transformation through eClinical Solutions**

Committed to driving digital transformation and harnessing data for enhanced efficiency, WuXi AppTec possesses a wealth of expertise in electronic data capture, interactive web response systems, and electronic patient-reported outcome (ePRO) systems and has developed a proprietary Clinical Data Management System, Clinical Trial Management System, and an artificial intelligence (AI) coding system. With a specialized focus on decentralized clinical trials (DCT) capabilities, the company provides tailored digital solutions for clinical trials, including e-recruitment, e-consent, e-writing, e-Source, remote monitoring, tele-visit, direct-to-patient, direct-from-patient, and wearables.

Demonstrating a proven track record, WuXi AppTec successfully executed over 20 hybrid DCT projects and completed 700 remote visits within the past three years, with four studies utilizing its hybrid DCT modules receiving regulatory approval. The company has introduced an integrated digital-clinical trial operating platform encompassing resources, projects, people, financial and business management, training, site initiation, and a patient recruitment performance database, effectively enhancing the efficiency and quality of clinical trial execution.<sup>3</sup>

<sup>3</sup> Interview with Frost & Sullivan, August 2023.

Moreover, WuXi AppTec developed the "Medicine Searching" e-patient recruitment platform, facilitating suitable new drug treatment opportunities for patients and their families and streamlining registration for clinical trials.

An automated Suspected Unexpected Serious Adverse Reaction (eSUSAR) reporting system eliminates manual steps, reduces errors, and optimizes the process of eSUSAR reports, ultimately saving time and costs for clinical sites. These platforms elevate internal personnel management and team capabilities and significantly augment medical monitoring and data review efficiency, eventually leading to improved service delivery and exceptional customer experience.

### ***Roadmap to Success: Customer-centric, Continuous, Proactive***

WuXi AppTec's approach exceeds its extensive expertise and best-in-class capabilities, with customer value as a strategic imperative. Through the years, the company has earned a sterling reputation supporting clients' paths toward achieving objectives.

### ***Customized Bioanalytical Testing***

WuXi AppTec's global bioanalytical service within its Laboratory Testing Division provides customized solutions for worldwide drug R&D. The company specializes in personalized preclinical and clinical bioanalytical strategies, using advanced technology to analyze drug effects, safety, and biomarkers across different treatment types. The team's expertise in testing methodologies, supported by cutting-edge technologies, provides essential insights for effective drug development.

With over 1,800 validated methods, WuXi AppTec's bioanalytical services have invested in more than 3,000 global clinical trials while maintaining high regulatory compliance standards. As a dedicated partner for nearly two decades, the company ensures swift turnaround, unwavering quality, and reliability in line with rigorous quality benchmarks.<sup>4</sup>

Frost & Sullivan believes WuXi AppTec's efforts in bioanalytical testing offer a significant edge in an increasingly competitive landscape within the biologic therapies outsourcing market. This competence is particularly relevant for sectors such as vaccines and cell and gene therapies, where specialized bioanalytical capabilities are essential. Consequently, industry participants are directing their attention toward securing these specialized technologies through strategic acquisitions.<sup>5</sup>

WuXi AppTec builds its technology, collaborating closely with various stakeholders and partners to evolve alongside market needs and trends. Its transparent and seamless methodology and close client relationships establish it as a preferred partner. The company is uniquely poised to navigate complex ventures and drive innovation in the industry.

### ***Positioned for Growth***

Since its inception, WuXi AppTec's positive reputation and customer-centric framework have led to its coveted preferred partner status. Over the years, it added a range of new facilities to its established base. In June 2022, WuXi STA, another WuXi AppTec subsidiary, expanded its manufacturing capabilities by

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<sup>4</sup> Interview with Frost & Sullivan, August 2023.

<sup>5</sup> *Global Bioanalytical Testing Services, 2021–2027, Acquisition of Disruptive Technologies will be the Key to Driving Growth*, Frost & Sullivan Global Information & Communications Technologies Research Team, August 2022.

inaugurating a new high-potency active pharmaceutical ingredient (HPAPI) production facility in China. Located at the Changzhou site in Jiangsu, China, this latest addition to WuXi STA's facilities boasts 250 to 3,000 liters reactors and incorporates advanced flow chemistry and milling technology.<sup>6</sup>

With both the Changzhou and Shanghai sites, WuXi STA is well-equipped to support the development and manufacturing of HPAPIs, each hosting multiple high-potency processes, R&D laboratories, and kilo labs, along with the capacity to handle linkers, oligonucleotides, and peptides for complex conjugate modality therapies developed by CDMO customers.

Through its exceptional customer service, WuXi AppTec garnered the trust and assurance of its clientele, cultivating robust customer relationships and propelling business expansion. In 2022, the company achieved remarkable growth, noting a 71.8% year-over-year increase in revenue. This achievement underscores the efficacy of its distinct CRDMO and CTDMO business models, enabling the organization to effectively address the escalating requirements of its global customer base. As of the first half of 2023, the company has engaged with over 6,000 active customers globally, all working collaboratively to enhance the well-being of those in need.<sup>7</sup>

Frost & Sullivan believes WuXi AppTec is well-positioned to drive the CRDMO space into its next growth phase, capturing market share and sustaining its leadership in the coming years.

## Conclusion

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WuXi AppTec's vision centers on creating a comprehensive open-access platform that accelerates global healthcare innovation by connecting deep domain knowledge, operational expertise, and advanced technology. Its platform aims to break down barriers hindering drug development, fostering collaboration, knowledge sharing, and access to cutting-edge technologies.

WuXi AppTec's extensive service portfolio spans the entire drug research and development value chain, offering fully integrated models, including contract research, development, and manufacturing organization (CRDMO) and contract testing, development, and manufacturing organization (CTDMO) capabilities globally. Overall, the company addresses unmet needs with a strong leadership focus that incorporates client-centric strategies and implements best practices.

For example, WuXi ATU contributes to expanding the cell and gene therapy sector, while at the same time collaborating with institutions like Singapore's Agency for Science, Technology, and Research Bioprocessing Technology Institute aim to promote scientific innovation. Other comprehensive innovations in plasmid manufacturing, eClinical solutions, and customized bioanalytical testing position WuXi AppTec as a leader in the industry, driving innovation and accessibility in healthcare.

The company remains a trusted partner with a reputation for offering the best in the market. With its strong overall performance, WuXi AppTec earns Frost & Sullivan's 2023 Company of the Year Award in the global contract research, development, and manufacturing organization industry.

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<sup>6</sup> <https://www.fiercepharma.com/manufacturing/wuxi-debuts-another-high-potency-api-production-facility-china>

<sup>7</sup> Interview with Frost & Sullivan, August 2023.

## What You Need to Know about the Company of the Year Recognition

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Frost & Sullivan's Company of the Year Award is its top honor and recognizes the market participant that exemplifies visionary innovation, market-leading performance, and unmatched customer care.

### Best Practices Award Analysis

For the Company of the Year Award, Frost & Sullivan analysts independently evaluated the criteria listed below.

#### *Visionary Innovation & Performance*

**Addressing Unmet Needs:** Customers' unmet or under-served needs are unearthed and addressed by a robust solution development process

**Visionary Scenarios Through Mega Trends:**

Long-range, macro-level scenarios are incorporated into the innovation strategy through the use of Mega Trends, thereby enabling first-to-market solutions and new growth opportunities

**Leadership Focus:** Company focuses on building a leadership position in core markets and on creating stiff barriers to entry for new competitors

**Best Practices Implementation:** Best-in-class implementation is characterized by processes, tools, or activities that generate a consistent and repeatable level of success

**Financial Performance:** Strong overall business performance is achieved in terms of revenue, revenue growth, operating margin, and other key financial metrics

#### *Customer Impact*

**Price/Performance Value:** Products or services provide the best value for the price compared to similar market offerings

**Customer Purchase Experience:** Quality of the purchase experience assures customers that they are buying the optimal solution for addressing their unique needs and constraints

**Customer Ownership Experience:** Customers proudly own the company's product or service and have a positive experience throughout the life of the product or service

**Customer Service Experience:** Customer service is accessible, fast, stress-free, and high quality

**Brand Equity:** Customers perceive the brand positively and exhibit high brand loyalty



## About Frost & Sullivan

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Frost & Sullivan's proprietary model to systematically create ongoing growth opportunities and strategies for our clients is fuelled by the Innovation Generator™.

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### Key Impacts:

- **Growth Pipeline:** Continuous Flow of Growth Opportunities
- **Growth Strategies:** Proven Best Practices
- **Innovation Culture:** Optimized Customer Experience
- **ROI & Margin:** Implementation Excellence
- **Transformational Growth:** Industry Leadership



## The Innovation Generator™

Our 6 analytical perspectives are crucial in capturing the broadest range of innovative growth opportunities, most of which occur at the points of these perspectives.

### Analytical Perspectives:

- **Mega Trend (MT)**
- **Business Model (BM)**
- **Technology (TE)**
- **Industries (IN)**
- **Customer (CU)**
- **Geographies (GE)**

