Global Platform.
One Vision.

Enabler of Innovation · Trusted Partner · Global Contributor

About Us

WuXi STA, a subsidiary of WuXi AppTec, is a leading pharmaceutical development and manufacturing company serving the life sciences industry with operations across Asia, North America, and Europe. As a premier Contract Research, Development, and Manufacturing Organization (CRDMO), we offer our worldwide partners efficient, flexible, and high-quality specialized services in drug discovery, development, and manufacturing to enable our clients to bring more innovative drugs to market faster.

Our Vision

Every drug can be made and every disease can be treated.

Our Mission

Become enabler of innovation and a global contributor to pharmaceutical development and manufacturing from discovery to commercial.

Expedite Your Project from Preclinical to Commercial

F2CS™
Fast to Clinical Supply

F4CL™
Fast for Commercial Launch

IEPP™
IND-Enabling Preformulation Package

Quality Risk Assessment
NDA-enabling

Regulatory Starting Materials
Justification & NDA-derisking

PRECLINICAL → CLINICAL → COMMERCIAL

API	Process R&D, API & Intermediates Manufacturing
Drug Product	Pre-formulation, Formulation & Process Development, Manufacturing
Analytical	Analytical Development, Quality Control, and Stability Studies
Regulatory CMC	CMC Dossier Preparation to Support Global Regulatory Filing

Exemplary Quality Record

We have an ingrained quality culture and adhere to the same quality and EHS (Environmental, Health, and Safety) standards across all sites globally, with a proven track record from all major regulatory agencies.

11 US FDA
2013 - 2023

4 EMA
2019 - 2022

4 SwissMedic
2018 - 2022

6 Japan PMDA
2019 - 2022

4 South Korea MFDS
2022

52 China NMPA
2015 - 2023

300+ Client audits
every year

56
ongoing commercial projects

105
country approvals for marketed drugs

Global Research, Development, and Manufacturing Network

China

Changshu, Jiangsu
Early Intermediate Manufacturing

Changzhou, Jiangshu
API | WuXi TIDES

Chengdu, Sichuan
WuXi TIDES

Shanghai Waigaoqiao
API | Drug Product | WuXi TIDES

Shanghai Jinshan
API

Taixing, Jiangsu
API | WuXi TIDES

Taixing, Jiangsu
Early Intermediate Manufacturing

Tianjin
API | WuXi TIDES

Wuhan, Hubei
API | WuXi TIDES

Wuxi City, Jiangsu
Drug Product | WuXi TIDES

U.S.A

Middletown, DE *Operational in 2025*
Drug Product | WuXi TIDES

San Diego, CA
API | Drug Product

Switzerland

Couvet, Neuchâtel
Drug Product | WuXi TIDES

Singapore

Tuas, Singapore *Operational in 2026*
API | WuXi TIDES

Our Unique CRDMO Model Covers the Full Life Cycle of New Drug Development

Our Achievements in the Past 12 Months

CRO »

424,938
DISCOVERY
compounds synthesized

Every **2,500** compounds yield **1** preclinical candidate

CDMO »

2,763
PRECLINICAL to PHASE III
drugs

We support **1** out of **7** global clinical programs

CMO

56
COMMERCIAL
projects

We produce **5** out of **10** top-selling small molecule drugs

TIME & COST SAVINGS
streamlined process and seamless technology transfer

REDUCED RISK
same high quality and EHS systems across all sites

IMPROVED EFFICIENCY
harmonized integrated CMC project management with us

Capability When You Need It

Over the years, we have built an industry-leading process chemistry team ensuring expertise at every level. Our process R&D laboratories in Shanghai, Jinshan, Changzhou, and San Diego are amply equipped with the most modern and cutting-edge instruments, offering unparalleled capabilities and flexibility to address even the most challenging project needs.

- "Fit for purpose" synthetic route design as well as process optimization, development and scale-up
- Develop control strategies for Regulatory Starting Materials (RSMs), advanced intermediates and APIs
- Process validation

With our globally renowned quality system, we are uniquely positioned to be your strategic manufacturing partner, providing reliable and cost-effective long-term supplies of intermediates and APIs, even from a few grams to metric tons.

Produced **7** out of **16** small molecules approved by US FDA in 2023 H1

Our integrated CRDMO service ensures knowledge retention throughout your product's life cycle, shortening your development timeline by eliminating the need for multi-company/ site transfers. Operating with over 500 reactors, from 5 L to 20,000 L, our global manufacturing facilities offer you short production lead times and ample flexibility.

Preclinical to Phase II

1,916 molecules
supported in 2022

2.5 weeks/step
process development and manufacturing for First-in-Human study

52
PPQs completed
2018-2022

40
PPQs ongoing

100%
success rate

Phase III to Commercial

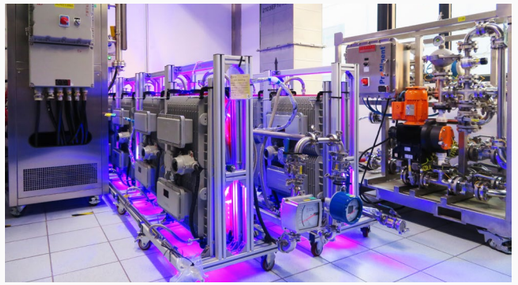
API Enabling Technologies

Continuous Processing

We offer advanced continuous processing enabling technology to overcome traditional batch-mode challenges, improving sustainability, safety, and economic viability. Our highly skilled team excels in developing flow processes and building customized lines accommodating a diverse range of reaction types, including:

- Aerobic oxidations
- Azide reactions
- Ozonolysis
- Photochemistry
- Dynamic kinetic resolution
- Enzymatic catalysis
- Hydrogenation
- Nitration
- High temperature/pressure
- Low temperature metallo-organic
- Centrifugal extraction
- Extraction using mixing setter

Photo Flow Reactor

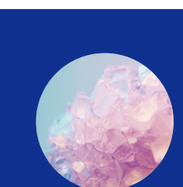


Biocatalysis

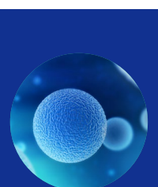
Biocatalysis enables cost-effective and sustainable processes for producing complex chiral molecules, meeting pharmaceutical manufacturing requirements. Our comprehensive services include enzyme screening, enzyme evolution, fermentation, process development, and cGMP production, ensuring efficient and eco-friendly solutions for your needs.

- 2,000+ enzymes in house
- Experience with 20 reaction types
- 1,400 m^2 laboratory that can handle 15 projects simultaneously
- 4,000 m^2 commercial fermentation workshop
- 500 L, 1,000 L ,and 2,000 L enzyme fermenters available

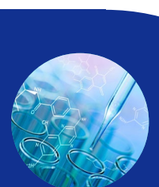
2,000 L Enzyme Fermenter



Crystallization & Particle Engineering

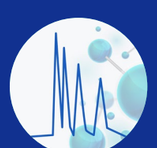


Biocatalysis



Chemo Catalysis

Continuous Processing



Preparative HPLC and SFC

Integrated High Potency Solutions

Meeting All Your Needs for APIs and Drug Products at Every Stage

3,000 L reactor

HP API Changzhou | Jinshan

- 10 m^3 total reactor volume
- 90+ projects supported in 2022
- Features R&D and kilogram scale laboratories, and plants with up to 3,000 L reactors
- Expertise in particle size reduction methods: wet, jet, pin, and hammer milling
- Offers both batch and flow mode operations

10 ng/m^3 OEL limit

HP Drug Product Wuxi City

Injectable

- 10 million vials annual capacity
- Automated filling system
- Two 20 m^2 lyophilizers
- Glass and steel vessels
- Single use bag

Oral

- 400 million tablets and 200 million capsules annual capacity
- Formulation processes include:
  - Wet and dry granulation
  - Tablet compression and coating
  - Capsule filling

Oral Solids Tablet Press

Injectable Filling Line

Formulation Development

We offer three signature formulation development packages to expedite your new drug development across all stages, bringing your molecules from preclinical to commercial launch with phase-appropriate risk assessments and fit-for-purpose control strategies.

IEPP
IND Enabling Preformulation Package

IND Enabling Preformulation Package

Candidate selection to IND-ready formulation in 8 weeks

F2CS
Fast to Clinical Supply

Fast to Clinical Supply

Clinical trial materials ready in 8 weeks after receiving GMP API

F4CL
Fast for Commercial Launch

Fast for Commercial Launch

Process validation in 2 months

2,300+
formulation chemists

Preformulation Services

- Drug developability assessment
- Physical-chemical characterization
- Early physical form screening
- Preclinical formulation & drug delivery

Solid State Development

- Salt and polymorph selection
- Comprehensive polymorph study for NDA filing
- Single crystal cultivation and analysis
- Solid state characterization

Highlights in 2022

2,500+
molecules screened

3,500+
clinical and commercial batches manufactured

370+
integrated CMC projects

2,800+
batches with DP enabling technologies

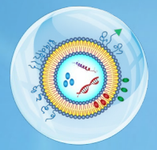
Drug Product Enabling Technology Portfolio

Currently, 90% of pipeline compounds face solubility challenges. Our bioavailability enhancement toolbox is designed to address these issues. We develop phase-appropriate formulations for clinical trials and beyond. Covering every stage from preclinical to commercial, our technologies enable the identification of compounds with the highest success rate.

PSD-3 ▸

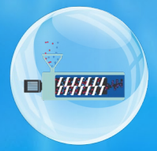
Two PSD-4 spray dryers will be operational in 2024 and 2025.

Lipid Nanoparticle



Spray Dried Dispersion

Hot Melt Extrusion



Nano Suspension

Liquid Capsules

End-to-End Lipid Nanoparticle Technology Platform

Novel Lipid Design and Synthesis

Injectable Dosage Form Development and Manufacturing

Formulation Development and Manufacturing

- Novel lipid design and synthesis at any scale
- Robust scalability and reproducibility starting from 5 mL
- Small particle size 80~100 nm and narrow PDI < 0.10
- Integrated formulation development, analytical, in vitro/in vivo evaluation
- Flexible scale, ranging from 10 L to 50 L per sub-batch

Drug Product Manufacturing, Packaging & Labeling

Oral Dosage

- Tablets, capsules, sachets, liquid orals, topical semi-solids, powder in bottles, sustained/delayed-release pellets or beads in capsules, and liquid-filled hard gelatin capsules
- Techniques: Dry blend, roller compaction, wet granulation, high shear granulation, fluid bed granulation, and encapsulation
- Compression: Efficient powder compacting
- Coating: Wurster and pan methods, over-encapsulation for blinded clinical supplies
- Pediatric formulations: Mini tablets, oral solutions/suspensions, beads
- Formulations also available for hygroscopic and light-sensitive compounds

Injectable Dosage

- Solutions, emulsions, suspensions, lyophilized powder, liposomes, and lipid nanoparticles
- Packaging: Vials, pre-filled syringes, cartridges
- Mixing, filtration, filling with sterile containers in an isolated system
- Fully automated and robotic operations

Packaging

- High-Density polyethylene bottles with induction sealing
- Bottles with screw caps, including Child-Resistant Caps
- Thermoforming Blisters (PVC/PVDC/Aclar/Trilaminates-Alu)
- Cold form foil blister packs
- Single-dose sachets

Clinical Supply

- Fast clinical supply enabled by our integrated CMC service, saving 6-8 months
- Full service for clinical supply lifecycle management, including packaging, comparator sourcing, and logistics
- Efficient and user-friendly blister wallet packaging solutions
- In-house clinical label design and printing services

Parenteral fill-finish line
Wuxi City site

Reliable Drug Product Supply

Inspection Track Records

Couvet, Switzerland

Oral Solid Manufacturing

- Commercial lines for tablets and capsules
- Blister & bottle packaging

Shanghai Waigaoqiao, China

Oral Solid R&D & Manufacturing Injectable R&D

- Dry and high shear wet granulation/ fluid bed drying
- Commercial lines for tablets and capsules
- Blister & bottle packaging

Wuxi City, China

Oral Solid & Injectable R&D and Manufacturing

- Two R&D centers on-site with 500+ scientists
- Dry granulation process
- Commercial lines for tablets and capsules
- Blister & bottle packaging
- Fully automated parenteral fill-finish

Annual Capacity

8.5
billion oral doses

24
million injection units

WuXi TIDES

End-to-End CRDMO Services for Oligonucleotides and Peptides

WuXi TIDES provides comprehensive, high-quality solutions for the drug development of oligonucleotides, peptides and related synthetic conjugates ("TIDES" drugs). We greatly simplify the TIDES drug development by providing all discovery, CMC development, and the entire manufacturing supply chain under one roof.

Our team of over 1,100 scientists across 10 R&D and manufacturing sites offers a wide range of services. These include compound screening and synthesis, process development and manufacturing of novel monomers, linkers and ligands, oligonucleotides, peptides, and complex synthetic conjugates at any scale.

WuXi TIDES

Discovery, CMC Development, and the entire manufacturing supply chain under one roof

from **nmol** to **mol**

Target to hit → Hit to lead → Lead to PCC → Preclinical → Phase I → Phase II → Phase III → Commercial

Oligonucleotide

Monomer/Ligand
- Novel Amidite
- GalNAc
- Nucleoside | Nucleotide
- mRNA NTP
- Capping Reagent
- Linker | Spacer | CPG

Oligonucleotide
- siRNA | ASO
- saRNA | microRNA
- PMO | sgRNA
- circRNA | Hairpin oligos
- CpG ODN | Aptamer
- Degenerate oligonucleotides

Conjugate
- GalNAc-Oligos
- Lipid-Oligos
- Peptide-Oligos
- 'Drug'-Oligos
- Dye-labelled oligonucleotides

Peptide

Unnatural Amino Acid
- α,β,γ-substituted
- N-alkylated
- Glyco

Peptide
- Long Linear
- Cyclic
- Modified
- PEGylated
- Peptidomimetics

Conjugate
- Oligos-Peptides
- Peptide-PMO
- Peptide drug conjugates

Our State-of-the-Art Oligonucleotide and Peptide API Manufacturing Facilities

74 acres
campus
Changzhou Site, Jiangsu, China

169 acres
campus
Taixing Site, Jiangsu, China

Oligonucleotide Discovery

Library Synthesis

- High-throughput synthesis from nmol to µmol scale
- 48/192-channel synthesizers coupled with chromatography columns
- Advanced purification methods including high-throughput RP-HPLC and Oligonucleotide Purification Columns™
- Rapid delivery of 200 double-stranded RNA in 10 days

Amidite Synthesis

Support from Discovery to Commercial Scale

- Experience with 1,000+ customized amidite molecules
  - sugar backbone (LNA, cEt, UNA, GNA, TNA amidite etc.)
  - phosphorus backbone (PACE, PS2, chiral amidite)
  - 2′/3′/5′ modified amidite
  - base modified amidite (tRNA base, deaza base)
- Catalog products
  - 300+ amidite in stock
  - 30+ with hundreds of kg scale (DNA, 2′-F, Ome, MOE, LNA, PMO monomer)
- Large-scale amidite manufacturing capacity
  - capacity: 10 MT/year
  - dedicated plant for amidite production

Custom Synthesis

- µmol to mmol scale by 12-channel synthesizers, OligoPilot™10 , OligoPilot™100, and ÄKTA oligosynt™
- Highly modified synthesis enabled by channel synthesizers with up to 32 amidite ports
- Extensive experience in synthesizing long-chain oligonucleotides, including both single-stranded RNA and double-stranded RNA
- Expertise in oligonucleotide conjugates such as ASO with phosphorothioates, RNA with 3'/5'-GalNAc, lipid modifications, and PEGylation
- Standard <0.5 EU/mg endotoxin level; <0.1 EU/mg can be requested

GalNAc Synthesis

Support from Discovery to Commercial Scale

- Over 100 different GalNAc compounds synthesized, spanning all molecule types such as Mono-GalNAc, Tri-GalNAc, Tetra-GalNAc, GalNAc amidite, GalNAc PFP ester, GalNAc N3, and GalNAc-PEG conjugates
- Specialized in GalNAc PS/CPG conjugates with general loading of 150 µmol/g (for PS resin) and up to 210 µmol/g
- Stock of more than 10 known GalNAc molecules or CPG/PS resins, enabling quick start of oligo synthesis
- Over 30 GalNAc building blocks readily available, ensuring swift delivery of GalNAc compounds
- Corresponding analytical tests based on oligo CMC requirements are included

100,000+ oligonucleotide molecules synthesized yearly

20+ classes of oligonucleotide conjugates delivered

40+ ribose & **10+** backbone modifications

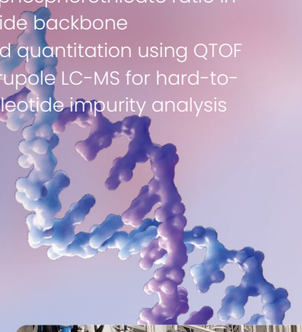
Up to **138 nt** long oligonucleotides

Development and Manufacturing Capacity

- 29 production lines including 4 large-scale commercial lines
- 6.1 mol total synthesis capacity
- 3 injectable lines including 1 high potency line for integrated CMC projects

Specialized Oligonucleotide Analytical Instruments

- Waters 2D UPLC coupled with Xevo G2-XS Q-TOF; Thermo Orbitrap Elite; Bruker MALDI-TOF/TOF HRMS for precise molecular weight and sequence determination
- Identification by 31^{P} NMR to determine the phosphate and phosphorothioate ratio in the oligonucleotide backbone
- Identification and quantitation using QTOF HRMS and quadrupole LC-MS for hard-to-resolve oligonucleotide impurity analysis



Oligonucleotide CMC

Support **69** preclinical to phase III drug candidates and **1** commercial product

Novel Technologies

- Biocatalysis
- Thin film evaporation
- Spray dried dispersion

Recent Experience Highlights

- Completed 100 batches of 900 mmol DNA production including PPQ enabling studies and PPQ campaign in 9 months; delivered 400 kg in total
- Completed 3x1.6 mol ASO production in 2 months
- 20+ ongoing siRNA projects with modifications at 5′-end or 3′-end such as GalNAc and cholesterol modifications, including 11 integrated CMC projects

1,800 mmol synthesizer with 800 mm column

Peptide Discovery

Highlights in 2022

Served **300+** customers

Delivered **20,000+** peptides, from mg to kg scale

Delivered **15,000+** custom UAAs

Library Synthesis

- High-throughput synthesis from μmol to mmol
- 36/48/96-channel synthesizers for parallel synthesis
- 12-channel microwave synthesizer with up to 5 min/AA for sequential synthesis

Typical Timeline for a 48-Peptide Parallel Synthesis Project

Length	< 10 AAs	10-20 AAs	20-30 AAs
Delivery Time	< 12 days	< 15 days	< 20 days

Custom Synthesis

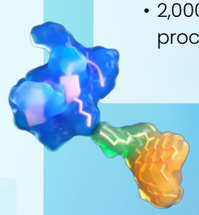
- Single solid-phase peptide synthesis length up to 70 AAs
- Ligation length up to 200 AAs
- Experience in 100,000+ cyclic peptides, including thioether, disulfide bridge, bicyclization, lactam, RCM monocyclic, lactone, and click chemistry
- Experience in 50,000+ linear and highly modified peptides, including phosphorylation/glycosylation/sulfation, lipidation, isotopic labeling, PEGylation, and dye modification
- Expertise in 10,000+ advanced peptides, including ligated peptide, peptidomimetics, peptoid, peptide nucleic acids, branched peptide, and dendrimers

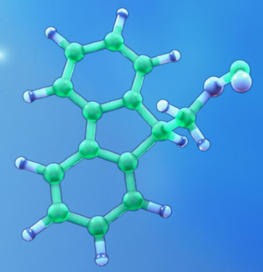
- **Most peptides under 30 AAs at mg scales delivered in two weeks**
- **Over 98.5% on time delivery**
- **Purity up to 99.9%**

UAAs Synthesis

Support from Discovery to Commercial Scale

- 2,300+ catalog products in house
- Experience in 800+ UAAs not commercially available
- Rapid production of α/β-substituted and aromatic/homo amino acids with a 1-10 g delivery in 2-3 weeks
- Process development and non-GMP production for large-scale orders, up to metric tons
- 2,000+ UAAs custom synthesis and process development experience



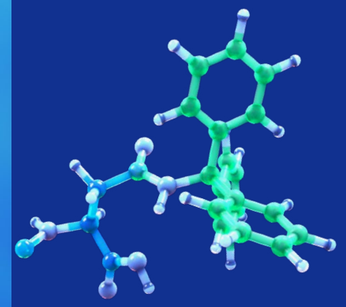


Development and Manufacturing Capacity

- 32,000+ L total reactor volume of solid-phase peptide synthesizers
- 20+ production lines at various scales with up to 3,000 L reactors
- 10 L – 20,000 L cleavage & isolation vessels
- 10 cm – 80 cm DAC HPLC columns
- 0.5 m^2 – 20 m^2 tray lyophilizers
- 3 injectable lines including 1 high potency line for integrated CMC projects

Specialized Peptide Analytical Instruments

- Agilent 1260/1290, Waters ACQUITY H-Class/I-Class/Premier UPLC, Thermo Flex Vanquish UHPLC, Waters SQD2/BioAccord LC-MS, Agilent 6125/6135/6470 LC-MS and QQQ-MS for accurate identification and quantification
- Waters Xevo G2-XS/G3, Agilent 6545XT, Thermo Orbitrap Exploris 240 HRMS for detailed impurity identification, quantification, sequencing, and circular dichroism (CD) for advanced structural identification
- SEC-UV/RID-MALS and MALDI-TOF for precise molecular weight distribution characterization in PEGylated peptides
- Bruker 400/600 MHz NMR for thorough structure elucidation



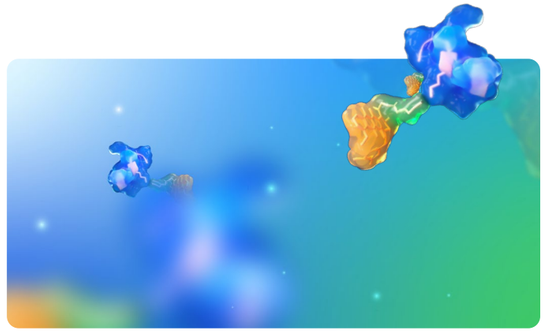
Peptide CMC

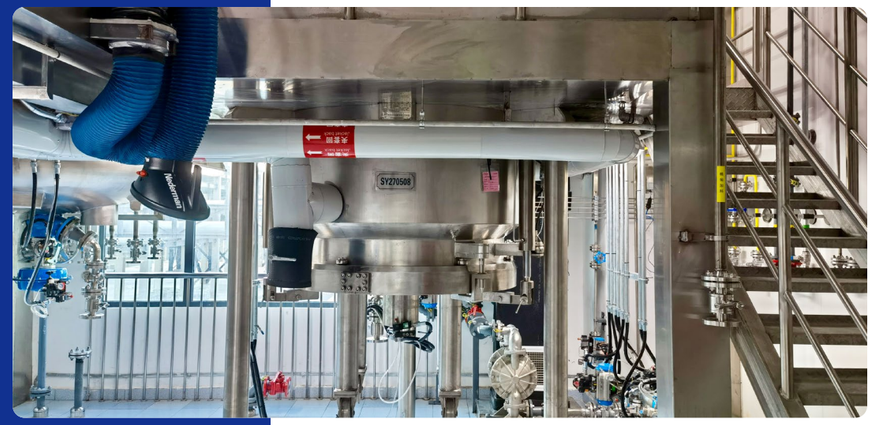
Support **46** preclinical to commercial projects

- **1** commercial drug with 4 metric ton produced in 2022
- **12** Peptide Drug Conjugate (PDC) development projects
- **6** peptide-PMO (PPMO) development projects
- Multiple metric ton scale peptide batches

Novel Technologies

- Convergent process in combination with isolation of API through direct precipitation approach
- Liquid phase peptide synthesis
- Spray dried dispersion
- Biocatalysis
- Continuous flow chromatography
- Normal phase and ion-exchange chromatography





1,000 L peptide synthesizer

Global Regulatory CMC Filing

376

CMC submission packages written to support global IND and NDA filings

2019-2022

Regulatory CMC Support

- Comprehensive CMC dossier preparation with detailed technical reviews
- Assistance with IND, NDA, and Clinical Trial Application (CTA) submissions to global regulatory authorities, customized for regional standards
- Gap analysis for evaluating document readiness for filing
- High-quality document preparation for regulatory submissions
- Strategic consultations for planning, feasibility, CMC updates, and regulatory contributions

Streamlined CMC Writing

Project Initiation
Provide regulatory consultations tailored to project phase and regions

Project Execution
Offer filing templates, collect testing data, and tailor CMC documentation to suit different phases of drug development

Conduct regular data reviews with clients to address potential risks promptly

Project Completion
Deliver submission-ready CMC dossiers within a 4-6 week timeframe

Commitment to Excellence

9 times
2012-2023

CDMO LEADERSHIP AWARDS by Life Science Leader

Quality | Expertise | Capability | Reliability | Compatibility | Service

At WuXi STA, our belief is firm: dedication to excellence is the foundation of success. Excellence isn't just a principle for us - it's exemplified in every facet of our operations. Whether we're swiftly delivering solutions, pioneering the latest in innovative technologies and services, or staying true to our mission, our every move is geared towards setting the benchmark in the industry.

But we don't stop at just offering services. We aspire to be more than service providers; we aim to be trusted partners for our customers. This ambition underscores our commitment to not only meet but exceed the expectations set by our industry and clientele. In doing so, we prioritize addressing our customers' needs, ensuring every step we take is both efficient and in their best interests.

150
client awards from 92 customers

Our ESG Targets by 2030

Compared to the 2020 baseline

GHG Reduction Target

30% ⬇

GHG intensity reduction

Energy-saving Target

25% ⬇

energy consumption intensity reduction

Water-saving Target

45% ⬇

water consumption intensity reduction

Waste Management Target

Be landfill-free

for all productive hazardous wastes

Highlights of Our ESG Awards

CDP

- "A-" in the CDP Climate Change rating
- 2022 CDP"Environmental Leadership Award

CDP DISCLOSURE INSIGHT ACTION

DJSI

- Included in the 2022 DowJones Sustainability World index
- Included in the 2022 Dow Jones Sustainability Emerging Markets index

Member of Dow Jones Sustainability Indices Powered by the S&P Global CSA

MSCI

Received AA rating for a second consecutive year: 2021 2022

MSCI ESG RATINGS AA

CCC | B | BB | BBB | A | AA | AAA

Sustainalytics

- Evaluated as "Low Risk" in 2022
- 2022 "ESG Industry Top Rated" Company

SUSTAINALYTICS ESG REGIONAL TOP RATED 2023

EcoVadis

Our four sites received Silver Awards for Business Sustainability Rating: Changzhou, Couvet, Shanghai Waigaogiao, Wuxi City

SILVER 2022 ecovadis Sustainability Rating

SILVER 2023 ecovadis Sustainability Rating

Middletown Delaware site to be operational in 2025

190 acres
campus

- Formulation development
- Clinical and commercial drug product manufacturing
- Packaging, labeling, and distribution

Middletown, DE, USA

Singapore Tuas site to be operational in 2026

50 acres
total area

7
plants planned

Phase I

R&D Center

Green Chemistry Center of Excellence

Research chemistry: small molecules, oligonucleotides, peptides, conjugates

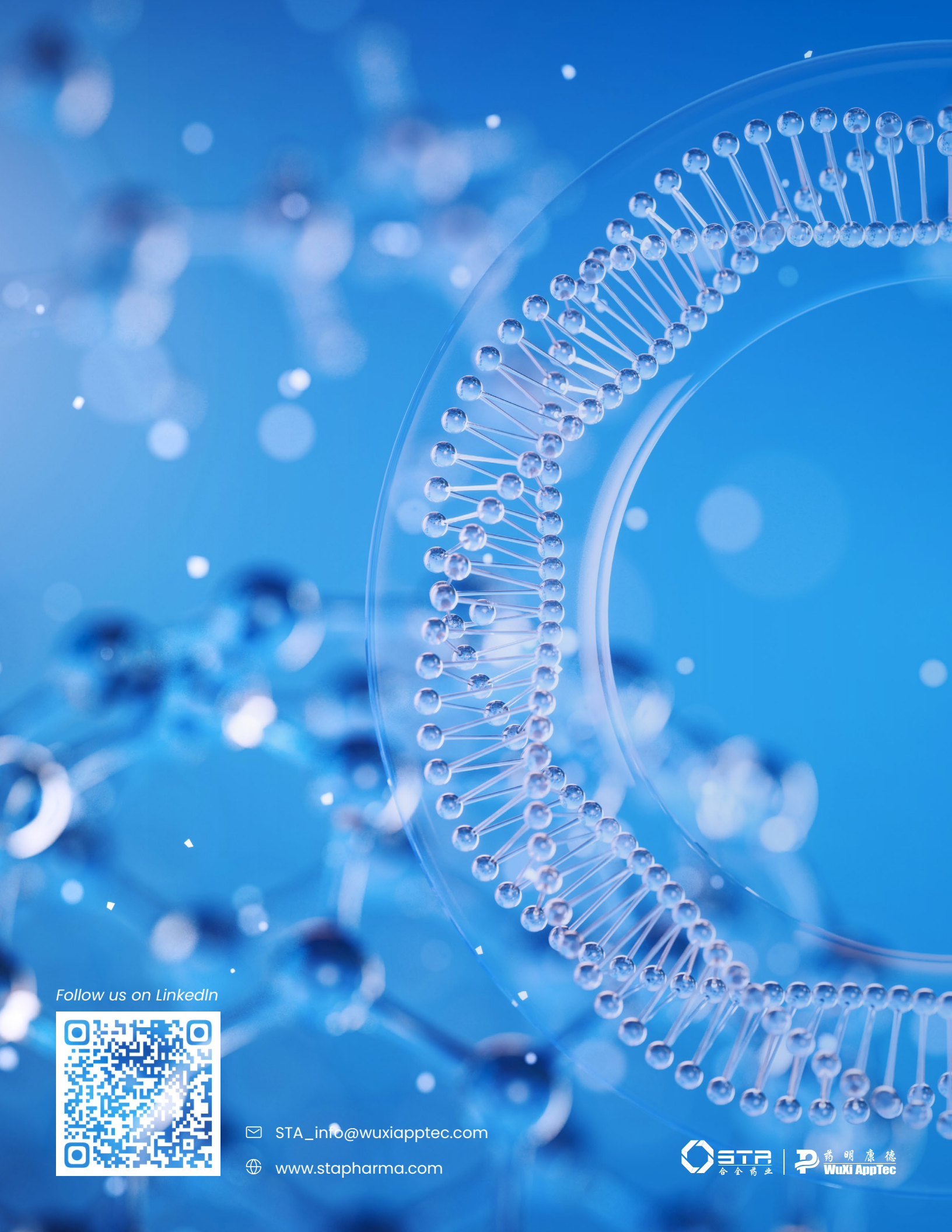
Manufacturing

2 small molecule plants

1 TIDES (oligonucleotide and peptide) plant

"End-to-end" supply chain for oligonucleotide therapies including amidites, oligonucleotides and conjugates

Tuas, Singapore



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