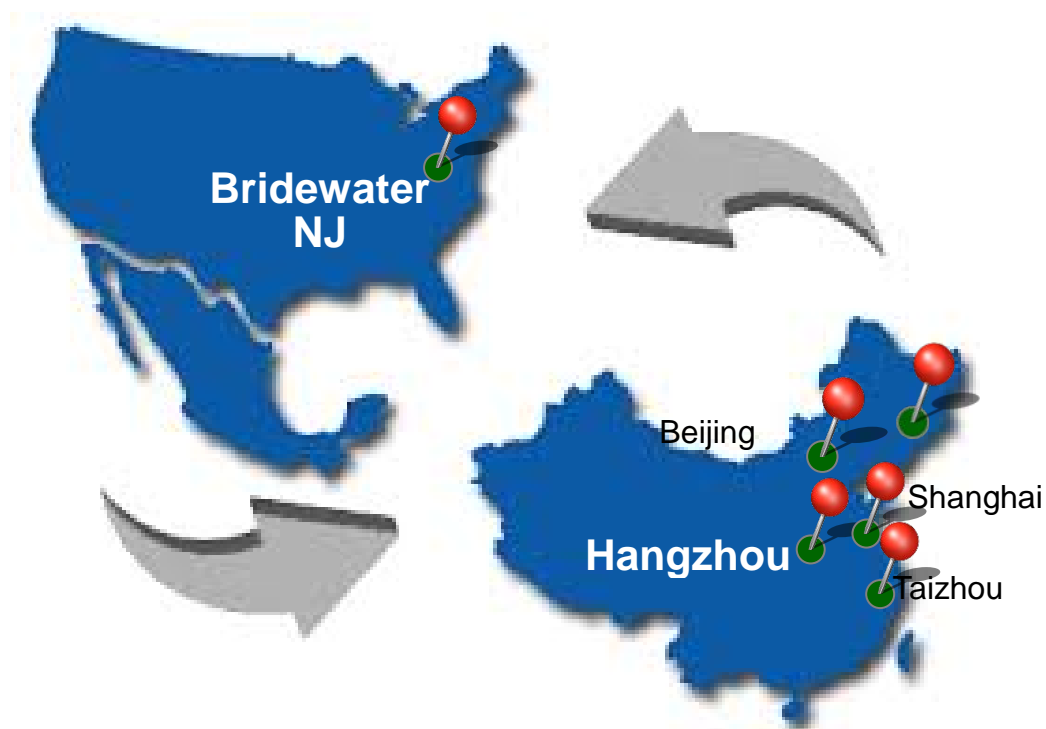


# HISUN Pharmaceuticals



Zhejiang Hisun Pharmaceutical Co. Ltd., established in 1956, is headquartered in Taizhou, China with more than 10,000 employees. Zhejiang Hisun Pharmaceutical Company is one of the largest Active Pharmaceutical Ingredient (API) manufacturers in China. Our API products are shipped to our partners throughout the world. Zhejiang Hisun Pharmaceutical also manufactures finished dosage pharmaceuticals – capsules, tablets and parenterals – for Anti-Infective, Cardiovascular, Oncology, CNS, Animal Health and other therapeutic areas. Zhejiang Hisun Pharmaceuticals also has Antibody Drug Conjugate (ADC) and biosimilar manufacturing facilities.

Hisun Pharmaceuticals USA, established in 2009, is an emerging pharmaceutical company committed to the development, manufacture and commercialization of pharmaceutical products for the US market place with a focus on APIs, Generics, Specialty and Animal Health Products. Hisun USA also provides contract manufacturing services through its parent company Zhejiang Hisun Pharmaceutical Co. Ltd.



## HISUN Research Institute



HISUN Research Institute, a state-certified High-tech center, employs 1200 staff scientists, including the 8 "national thousands of plans professors ", 19 "state thousands of plans professors ". The R & D annual expenditure is more than 8 % of HISUN annual revenue. The Institute is about 20,000 square meters; total investment was over 500 million RMB. The institute is closely linked to Hisun's manufacture platform. There are six branches covering multiple fields, such as, microbiology, biotechnology, enzyme engineering, and natural product screening. The center houses multiple laboratories and small-scale trial production workshops for novel products and new technology industrial development, plus, a management unit, Intellectual Property Department, Ministry of drug registration, maintenance and other supporting functions; in all 60 units.

HISUN's other research institutes are spread throughout Shanghai, Beijing and Hang Zhou. The research covers biotechnology, chemical synthesis, microbial fermentation and formulation; anti-tumor, anti-parasitic, blood fat, anti-infective, endocrine regulation, immune-suppressants, and antidepressants. HISUN openly cooperates with foreign research institutions and leading pharmaceutical companies in drug discovery, and actively responds to the global pharmaceutical industry needs and challenges.

## Professional Research Teams



HISUN continually recruits top research talent home and abroad to lead the various platforms in line with the current pharmaceutical industry trends. There are nearly 1,200 staff in HISUN's Research Institute; undergraduate and postgraduate account for more than 80%. HISUN's team was awarded "Zhejiang Science and Technology Innovation Team."

Chinese Academia are the core of Hisun's advisory team for technological innovation, playing an important supporting role. Over one hundred independently developed products have been approved and sold in more than 70 countries and regions world-wide. In more than 30 countries, HISUN has been granted over one hundred patents involving innovative molecules, crystal forms, synthetic techniques and new pharmaceutical compounds.

HISUN is cultivating our own R&D capabilities, extensively cooperating with scientific research institutions and leading pharmaceutical counterparts at home and abroad, in drug discovery, development of the manufacturing process, clinical research and other fields, to actively respond to opportunities and challenges under the changing structure of the global pharmaceutical industry.

## CRO/CMO/CDMO Manufacture Services

Hisun operates a globally integrated network of 4 manufacturing facilities. Our best-in-class facilities are built to manufacture and deliver a wide range of active pharmaceutical products (API) and finished dose products, to more than 60 countries. All facilities follow strict quality, safety, and environmental standards as upheld and outlined by government bodies and leading regulators such as US FDA, EMA, TGA and others.



**Taizhou Site:** located in Tai Zhou Medicine-Chemical Industry Park, Zhejiang, supplies active pharmaceutical ingredients and drug products for various therapeutic areas including oncology, cardiovascular, infectious, endocrine and immunosuppression. The drug products division is being upgraded and reconstructed in accordance with new national GMP and international cGMP standards and expects to earn RMB 2.5 billion in annual revenue upon completion.

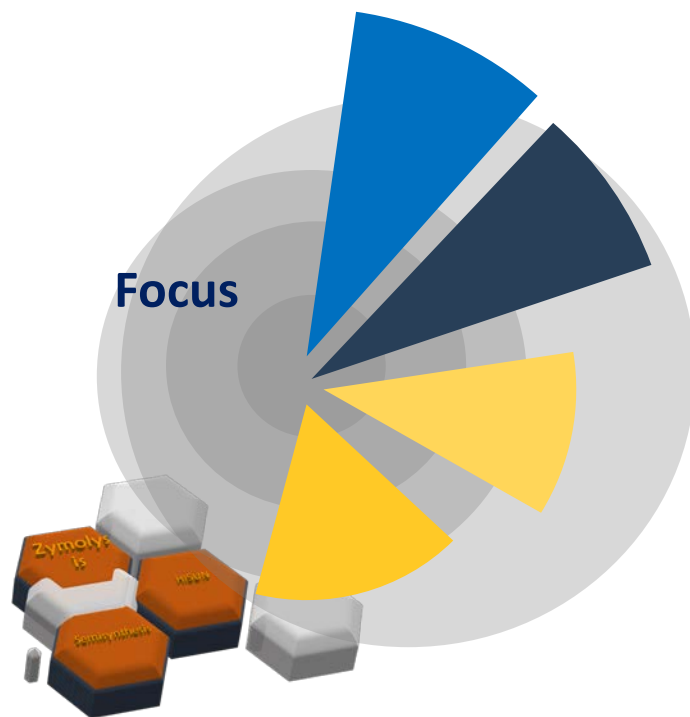


**Hang Zhou Site:** located in Fu Yang, started construction in 2005 with a total area of 800,000 square meters. The microbial fermentation production line has been in operation since 2009 and more lines for healthcare and animal health products are under expansion. Our drug product division maintains 20 lines for manufacturing multiple dosage forms including solid lyophilized powder, liquid injection, pre-filled injection and sterile powder injection. The lines are applicable both for small molecule and biotech products. The biopharmaceutical division accommodates mammalian cell and E.coli expression systems, as well as purification and formulation. Our product pipeline consists of recombinant proteins, mAb, recombinant vaccines, antibody-drug conjugates, covering multiple therapeutic areas such as autoimmune disease, cancer, diabetes and blood disease.



**Natong Site:** located in the High-Tech industrial Park, Rudong Economic Development Zone, Jiang Su, is a chemical synthesis and semi-synthesis production facility. Manufacturing at this site utilizes a large variety of reaction types and conditions including high pressure, and high/low temperatures. Products produced cover multiple therapeutic areas including anti-infection, cardiovascular & hypolipidemic, anti-parasitic and antibiotics.

We pride ourselves in exceptional R&D capability and robust project execution. Combining high productivity and cost-effective resources, along with unmatched regulatory and technical know-how.



#### **Valuable complex intermediate/compounds**

- Complex intermediates are prepared using multi-technology combinations
- Rare impurities are prepared using multistage series industrial separation technology

#### **Innovation medicine**

- Modify macromolecules to develop ADC cytotoxic payloads and drug conjugates

#### **Specialty generic APIs and FDFs**

- Develop generic pipeline of extremely challenging molecules

#### **Veterinary drug/pesticide**

- Develop non-toxic and environment-friendly veterinary drugs/pesticides



## R&D/API Manufacturing Capability

- Multi-step synthesis
  - High potency molecules
  - Cytotoxins
- Fermentation
  - Complex small molecule
  - Downstream processing
  - Bacteria, yeast, Filamentous Fungi, Mammalian
- Natural Product
  - Extraction
  - Chemical modification
- Protein Engineering
  - Cell line development
  - Cloning
  - Protein expression



## Biologics Manufacturing Capability

- Monoclonal Antibody
- Recombinant and Fusion Protein
- Peptide
- Cell Factor
- Vaccine
- Antibody Drug Conjugates



## Manufacturing Capacity

### Fermentation

- Lab, Pilot, Commercial scale
- >240 fermenters from 20L to 8000L.
- Industrial scale: 33 extraction product lines; 8,000 m<sup>3</sup> of fermentation volume.
- A wide range of fermenter, extraction and purification capacities contribute to the flexibility for a variety of product campaigns.

### Synthesis

- More than 10 workshops, 50 chemical synthesis production lines.
- Over 680 reactors with a capacity of about 900m<sup>3</sup>.
- Advanced techniques such as enzyme transformation, new oxidant and catalyst application, controlled chemical reactions under low temperature, high pressure and hydrogenation.

## Sample Reaction Types

<b>Acetylation</b>	<b>Crystallization</b>	<b>Grignard</b>	<b>Oxidation</b>
<b>Acidification</b>	<b>Cyanation</b>	<b>Hydrazine cyclization</b>	<b>Peroxide oxidation</b>
<b>Alkylation</b>	<b>Cyclization</b>	<b>Hydrogenation</b>	<b>Phosgenation</b>
<b>Amination</b>	<b>Diazotization</b>	<b>Hydrolysis</b>	<b>Phosphorus trichloride</b>
<b>Decarboxylic</b>	<b>Enzymatic esterification</b>	<b>Iodization</b>	<b>Reduction</b>
<b>Bromination</b>	<b>Epoxidation</b>	<b>Lithiation</b>	<b>Sulfonation</b>
<b>Butyl lithium</b>	<b>Esterification</b>	<b>Methoxylation</b>	<b>Sulfur derivatives use</b>
<b>Chlorination</b>	<b>Ethylene oxide</b>	<b>Methyl hydrazine reaction</b>	<b>Suzuki</b>
<b>Coupling</b>	<b>Fluorination</b>	<b>Nitration</b>	<b>Zinc reduction</b>
<b>Cryogenic reaction</b>	<b>Friedel Crafts</b>	<b>Nucleophilic aromatic (SNAr)</b>	

## Methods & Conditions

<b>Distillation, Chromotagraphy</b>	<b>Evaporators- short path &amp; thin film</b>	<b>Temperature: -100°C to 300°C</b>	<b>Pressure: Up to 100 bars</b>
-------------------------------------	--	-------------------------------------	---------------------------------

# Hisun Products and Markets

## Oral



- Immediate-release
- Sustained and controlled release

## Injection



- Normal injection
- Depot injection
- Targeted drug product
- Nanoparticles
- Nanomicelles
- Liposomes

## Transdermal



- Transdermal patch
- Implant

## Inhalation



- Atomizing products
- Aerosol products
- Dry powder inhalation
- Nasal spray products

## Products

100+

- Therapeutic areas:
- Anti-tumor
- Cardiovascular
- Anti-infection
- Anti-viral
- Autoimmunity
- Digestive system

## Customers overseas

400+

- Cooperate with the top ten pharmaceutical companies in business, projects, and strategy.



## Markets

70+

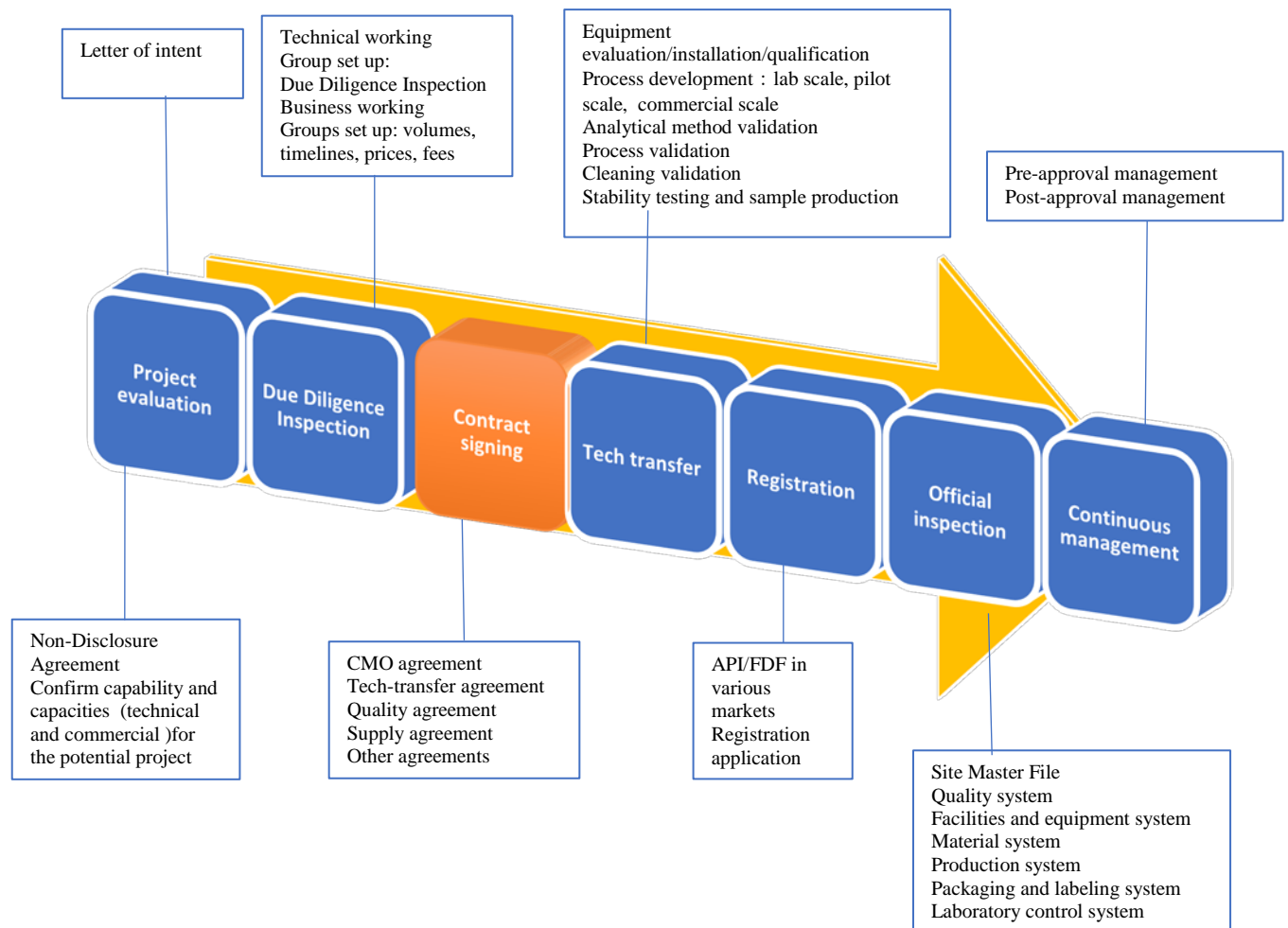
- 80% of the API revenue comes from overseas market, sales cover 70+ countries

## Medical customers

5000+

- Domestic FDF sales, products sales in 5000+ hospitals

# CRO/CMO/CDMO Project Management





## Our Service...

- Full service package from Complex Intermediates to API and Drug Product, from fermentation to synthesis, from chemical drugs to biopharm, flexible production capacities and well trained qualified staff, as well as supporting functions.
- State of the art facilities covering various kinds of products such as cytotoxic and sterile products. With a strong investment in environmental protection measures and skills.
- Well-established quality system, which has passed through a series of official inspections and customer audits. Quality management covers the entire chain – R & D, purchasing, manufacturing, logistics and marketing.
- World-wide CMO partners include major pharma and animal health companies such as, Lilly, Dow, Merck, Pfizer.

**... your reliable CMO service partner**

For More Information Please Contact:

**Peggy Albanese**

Executive Director, Business Development

Hisun Pharmaceuticals USA, Inc.

200 Crossing Blvd, 2nd Floor

Bridge, NJ 08807

Office: 609-454-0237

Email: [Peggy.Albanese@hisunusa.com](mailto:Peggy.Albanese@hisunusa.com)