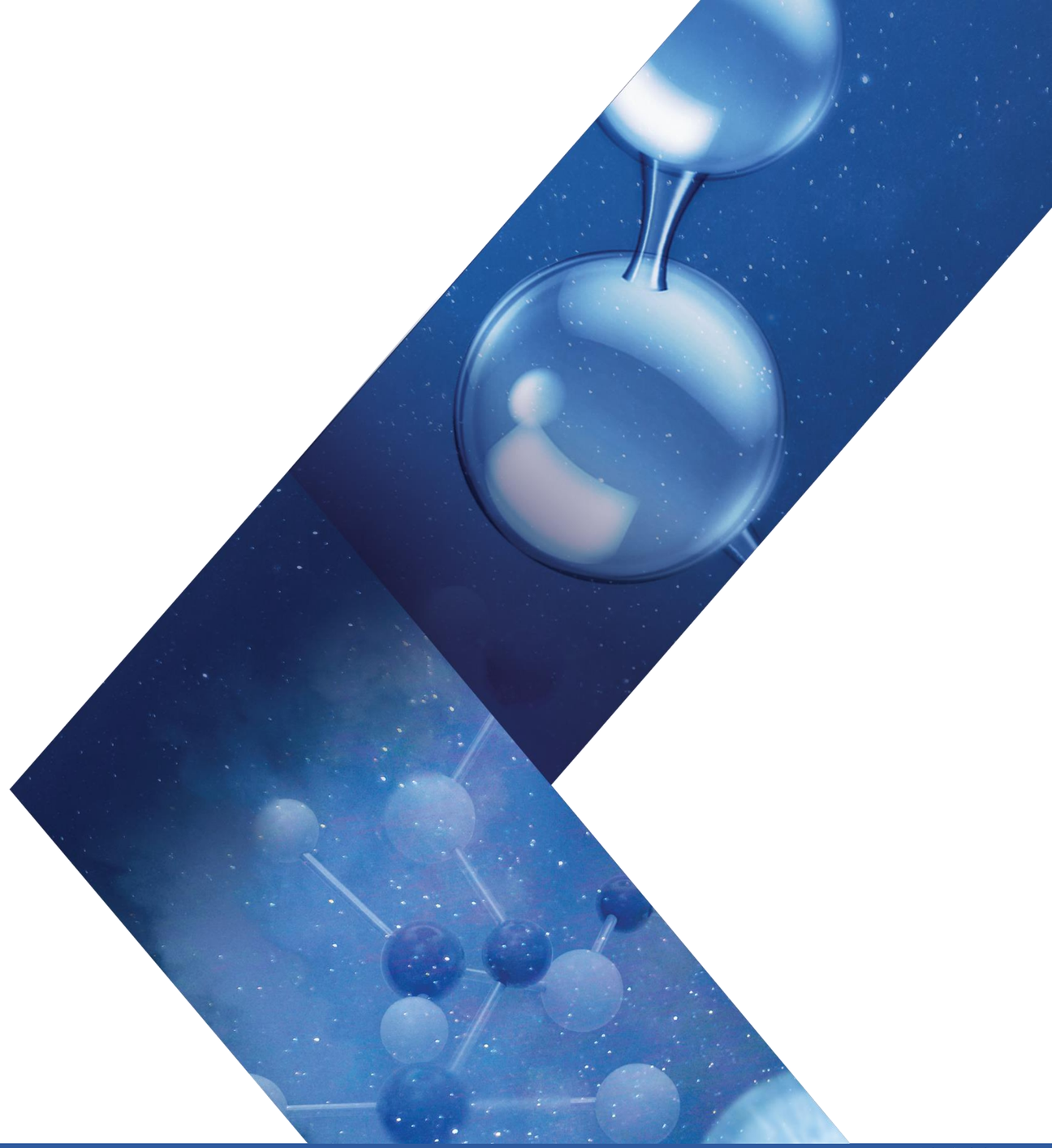
Asymchem Labs.



www.asymchem.com

Stock Code: 002821.SZ/6821.HK

Our Mission & Vision

Our mission

Is to become the most creative escort and participant in the research and development and supply of new drugs in the world. Be one of the fastest in the industry with innovative technology of sustainable development. In addition, be a leader and a partner for the global health industry.

Our vision

Be a partner in global drug R & D and production, starting from everyone, every product and every service.

IP Protection

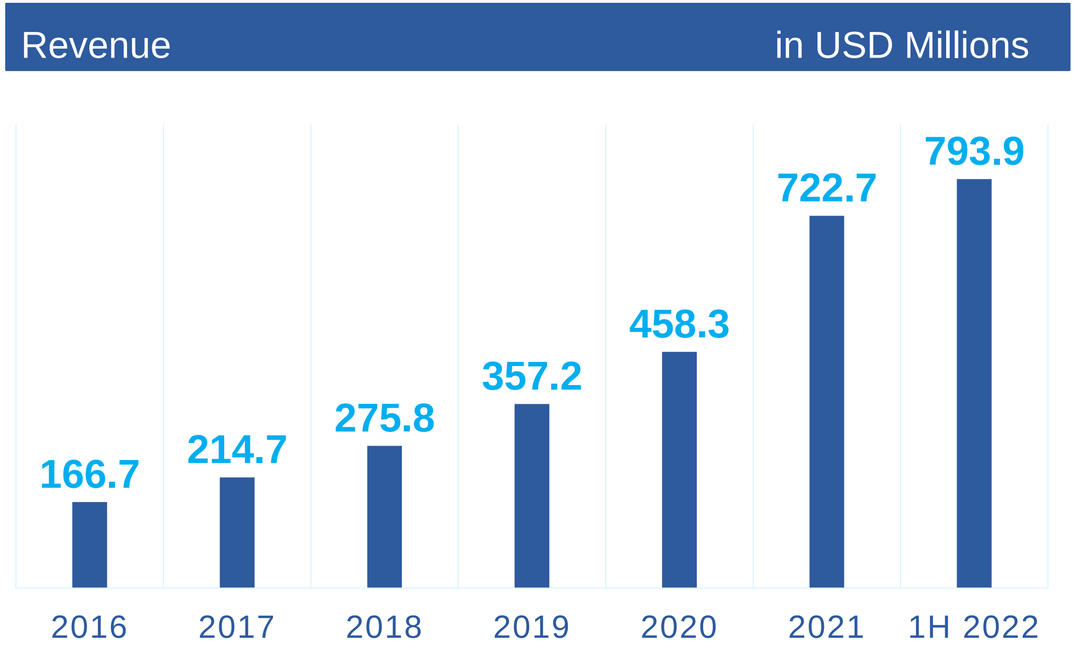
Asymchem is a pure CDMO

All IP developed as part of Asymchem’s services belongs to our clients

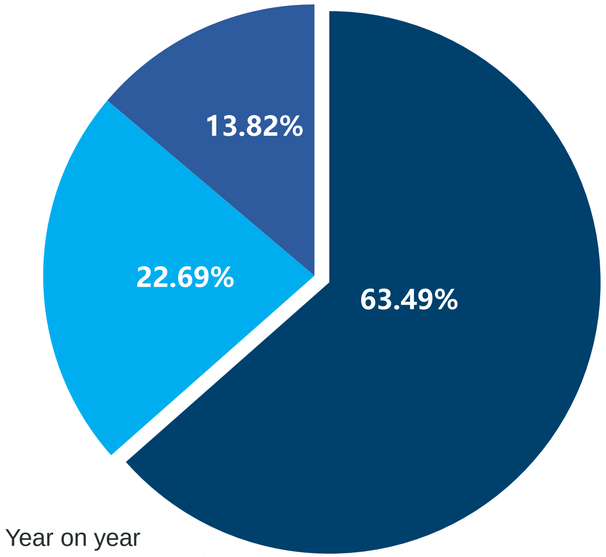
Asymchem never develops its own new drug products, nor does it provide services for early new drug discovery

About Asymchem

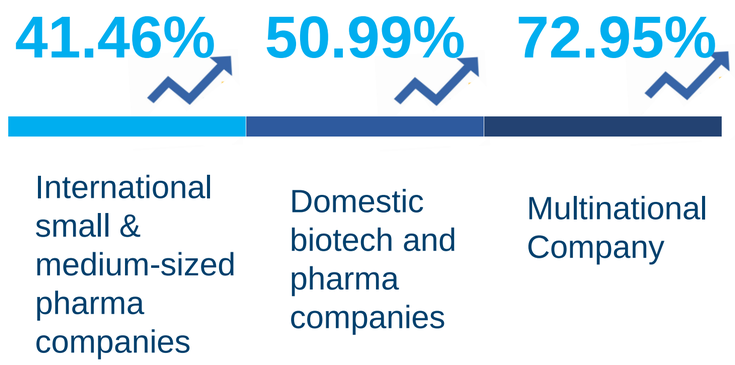
- Established in 1998 in Tianjin, China
- A+H: Shenzhen Stock Exchange listed company (SZ.002821), Hong Kong Stock Exchange listed company (HK.006821)
- The fifth largest innovative drug raw material supplier in the world. The largest commercial stage chemical drug DCMO in China.
- The market value of the company is about 15 Billion USD, the operating revenue in 2022 will be about 1.5 Billion USD.



Sales by Consumer Types

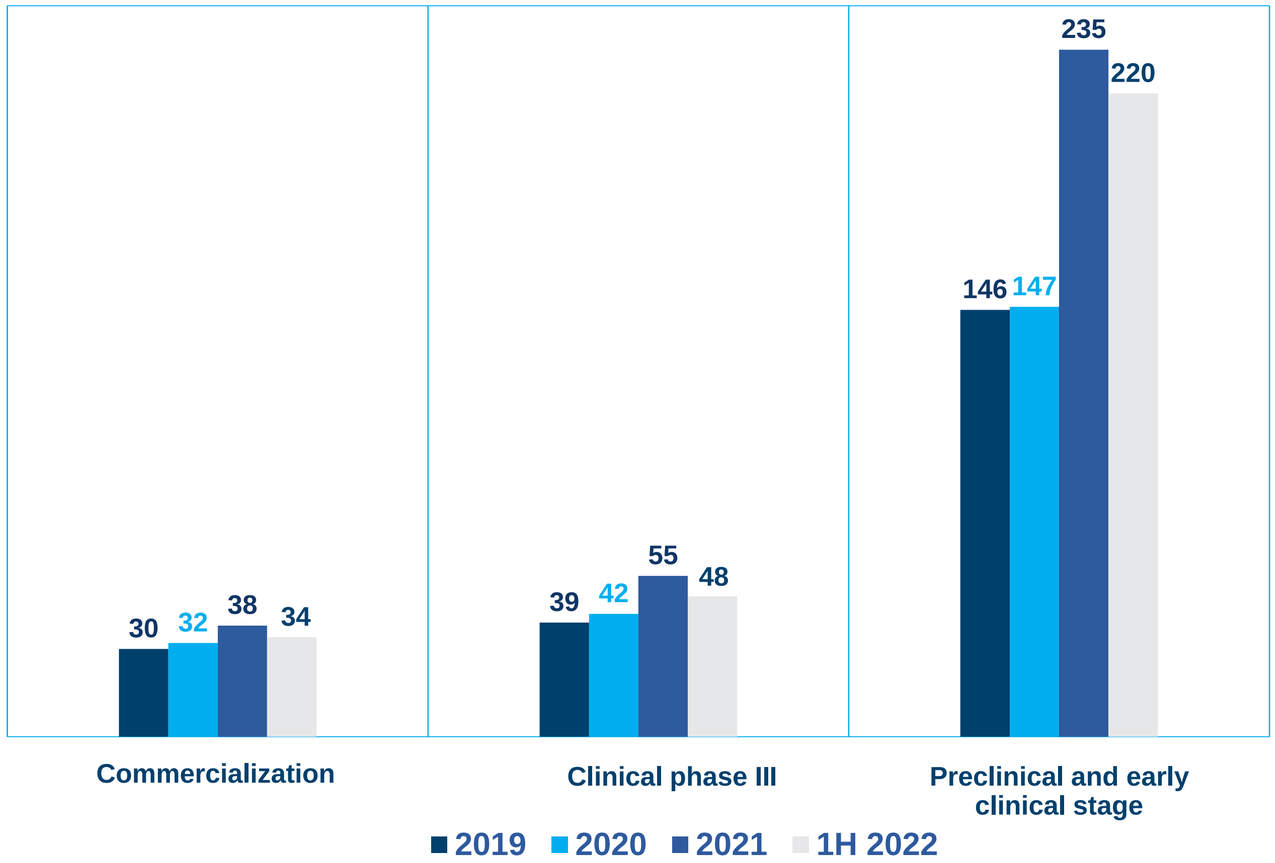


Year on year growth rate in 2021



Rich Project Experience from Early Stage to Commercialization Stage

Number of projects by phase of development, 2019-2021H1
Unit: Number



>30%

Participated in clinical phase II - III of **five major multinational pharmaceutical companies in the United States ,** Over 30% of small molecule candidate drugs.

17

Breakthrough blockbuster drug project. The annual or predicted peak sales of heavyweight **drugs exceed US $1billion.**

38

The total number of commercial projects has increased consistently. The operating revenue increased **by 51.7% year-on-year.**

Asymchem Global Layout

20+ Years

8 Manufacturing Sites

50 Successful Inspections From USFDA/NMPA/TGA/MFDS/PDMA

9800+ Employees

4200+ Scientists

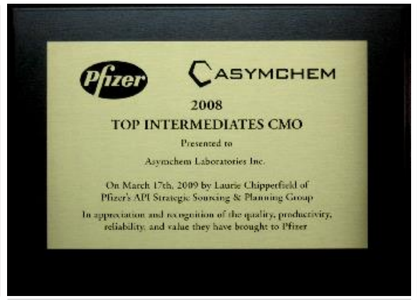
800+ Global Clients

600+ On-going Clinical Projects

30+ On-going Commercial Projects

Our Performance

Over the last 20 years, Asymchem has provided outstanding service for big pharmas such as Merck, Pfizer, Eli Lilly, and AbbVie in addition to leading Chinese bio-pharmaceutical enterprises including Zai Lab and Hutchison. Long term strategic partnerships has been established with these companies. Furthermore, Asymchem has been recognized as one of the preferred suppliers for numerous biotech and pharmaceutical partners.



One Stop CMC Service from Preclinical to Commercialization

Preclinical → IND → Phase I → Phase II → Phase III → NDA → Market

With more than 20 years of deep cultivation in the field of small molecule synthesis, we can synthesize and manufacture almost any small molecule drug. The volume of the reactor exceeds 5300m³

Chemical Small Molecule CDMO Business

Chemical Macromolecule CDMO Business

Have served more than 80 clients for more than 150 projects in total

Biosynthesis Technology R&D And Enzyme Production

- Total enzyme inventory exceeds 2300
- Own more than 800 IP
- Enzyme production capacity: mg - ton
- 5000L GMP fermentation; 1000L/week

Manufacturing process development of drug substance and drug product, GMP production of clinical/commercial supply
Drug substance production lines with 200L/500L/2000L pilot-scale bioreactor and drug product production lines
Capacity covers mAb, ADC, plasmid, mRNA etc. R&D and manufacturing

Bio Macromolecule CDMO Business

Innovative formulation R&D and production

- Crystal screen and selection, preformulation research, formulation and process development, analytical method development and validation, stability study.
- R&D and GMP production from clinical phase I till commercial production of oral immediate release and sustained release dosage forms, injections， eye drops and inhalation solutions
- Advanced complex formulation technical platforms and multiple solutions for insoluble drugs

Drug Registration Application And Regulatory Services

- The RA team with global application experience can provide IND, NDA/BLA, supplementary application and other registration services for domestic and foreign customers
- Provide CTD document writing services and have successfully delivered 100+ projects in total

Eight Innovation Technology Platforms Full Service for Optimal Solution

Capability & Capacities ---Chemistry R&D

R&D Capabilities

- Process Chemistry R&D
- Safety Assesment
- Full DoE study
- Flow Chemistry research
- Biotransformation
- High Potency compounds synthesis research

Chemical Small Molecule
CDMO Business

Technology Platform DoE

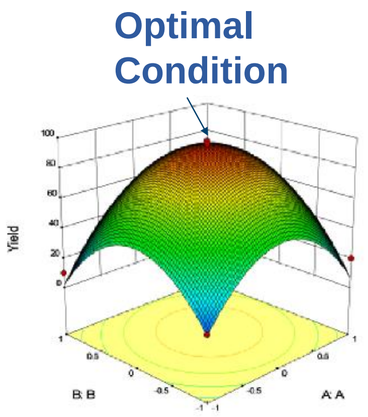
DOE (experimental design) is an efficient technology for rapid process optimization to obtain the optimal conditions, and it is also the main tool for the implementation of the QBD research and development concept of drug development in the CMC research process. Asymchem has the ability to provide these two DOE services:

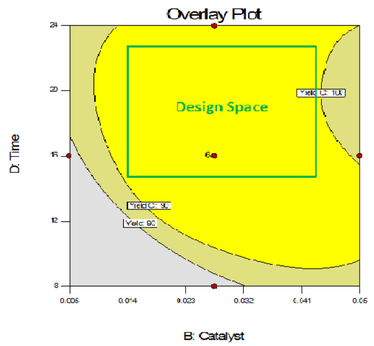
Process optimization: quickly and accurately determine the optimal process conditions

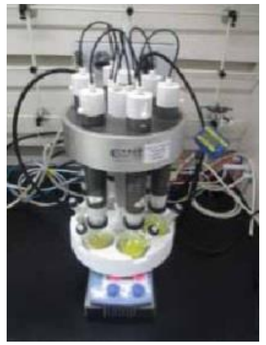
- Factorial Design
- Response Surface Design
- ……
- Screening Design
- Custom Design

CMC research: ensure drug declaration and production demand

- API Specification Evaluation
- RSM Justification
- Intermediate Specification
- PAR/NOR Study
- CPP/KPP Identification
- GTI Study and Control Strategy

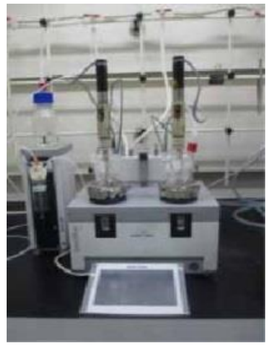






Parallel Reactor

Parallel Reactor



EasyMax 102

Jacket Cylinder Reactor

Chemical Macromolecule
CDMO Business

Technology Platform High Potency APIs

High Potency API Development

- Asymchem has a dedicated research and development laboratory, kilogram production laboratory and production workshop.
- Asymchem has the ability to operate compounds with OEL (occupational exposure limit) ≤ 0.01ug/m³. The production workshop passed the audit of USFDA in 2014，2019 and the on-site inspection of NMPA in 2021. It can produce highly active APIs and provide relevant services for global customers.

Overview of HP Capabilities

Function	Equipment/Capability	OEL Rating
HP R&D Lab	4 labs：18fume hoods+2Isolators	≤0.01μg/m³
HP Kilo Lab（Class D）	6 Labs: 6 isolators, 2-20 L glass reactors (-80-150 ℃) 1 Freeze-drying Lab: 2 m² lyophilizer DAC150□DAC200, Nanofiltration, 2.5-10 m² TFF 1□ lyophilizer	≤0.01μg/m³
HP Plant（Class D）	3 Modules: 200-1000 L glass-lined reactor / stainless steel reactor (-20-120 ℃), 100 L Reaction Region: flexible isolator, 2-20 L glass isolator (-80-150 ℃) Solid material charging Isolator, discharge/sampling isolator, jet milling, wet milling	≤0.05μg/m³
Analytical	1 QC Lab: 1 isolator 1 Microbiology Lab: 1 isolator (Class A)	≤0.02μg/m³

Our advantages

- **High performance sealing technology, excellent engineering control**
- **Good isolation control strategy**
- **Verify the particle sealing performance of the equipment according to ISPE guidelines**

Chemical Macromolecule
CDMO Business

State-of-the-Art Manufacturing Facilities

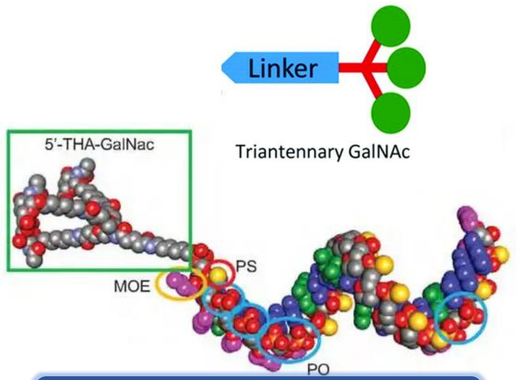
5,300 m^3 in total

World class production facilities

Single quality system across all manufacturing sites

Chemical Macromolecule
CDMO Business

Chemical Macromolecules CDMO Service Scope

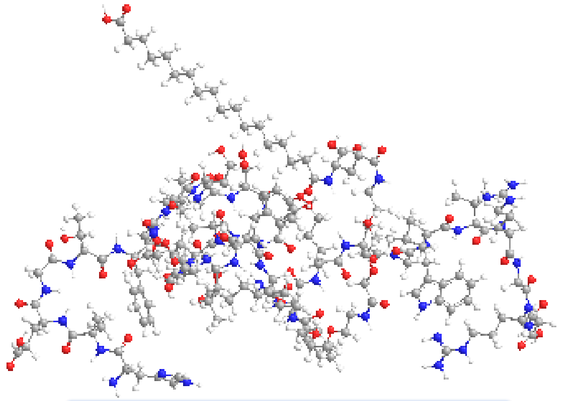


Oligonucleotides

Antisense oligonucleotides,

Small interfering RNA, lock nucleic acid,

Aptamer, CPG



Peptides

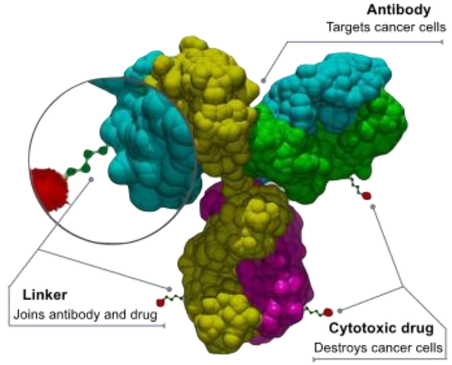
Solid/Liquid/Hybrid Strategies

Up to 40+AA peptide

Modification of natural peptides: enzymatic hydrolysis, lipidation, pegylation,

N - methylation, etc

Peptide-drug conjugates, Radionuclide Drug Conjugates Precursor

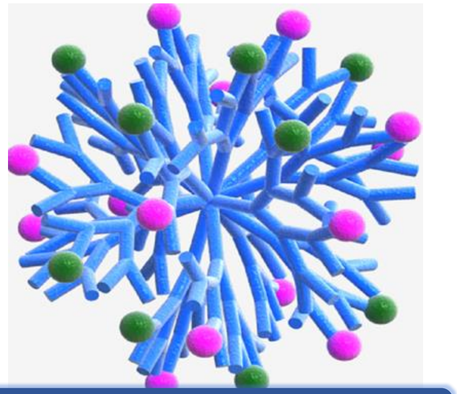


Payload Linkers

Payload: Dolastatins, Camptothecins, PBD.

Linker: Peptide Linker, PEG Linker, Multivalent Linker (Trident Linker, Dendrimer Linker, Polymer Linker)

Payload-Linkers in marketed ADCs and their analogs



Polymers / Excipients

Polymers (polyether, polyesters, polyamides, polypeptide),

Dendrimers (PAMAM, Gn-poly(L-lysine))

Polymer-drug conjugate synthesis

Natural Polysaccharides Modification ,GalNAc and derivatives

Phospholipids, PEG-lipids, Cationic lipids

Other Excipients: Pharma grade SBECD (USP), SNAc

300+ process chemists (30+ Ph.D.)

100+ active clients with dedicated team

300+ Analysts, Engineers, QA, and RA

300+ project experience from pre-clinical to NDA stage

The dedicated site (12000 m² R&D center, and 16000 m² GMP plant) for CMMD.

Chemical Macromolecule CDMO Business

Oligonucleotides: Research And Production Capacity

Currently — **20** sets of Synthesizers (From OS10 to OS1000)

By Jan 2023 — **35** sets of synthesizers (From OS10 to Oligoprocess)

OS synthesizers were designed, produced, and validated by Asymchem with shorter lead time (6 Months by Asymchem vs 15 Months by the key supplier).

Annual capacity up to 500 Kg/Year

OS10/50, OP100

(20 mg~20 g/batch)

OP400 (2 sets)

（20~200 g/batch)

OS1000, OP2000 (5 sets)

(200~1000 g/batch)

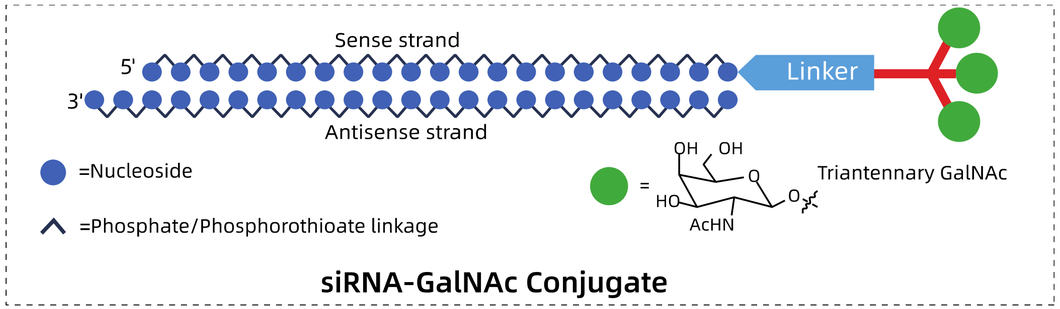
OS Kilo, Oligoprocess (3 sets)

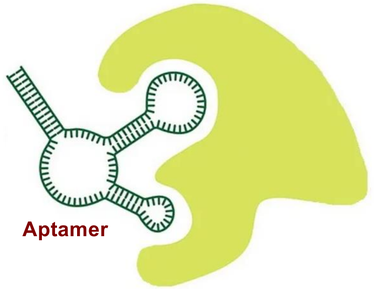
(1~10 Kg/batch)

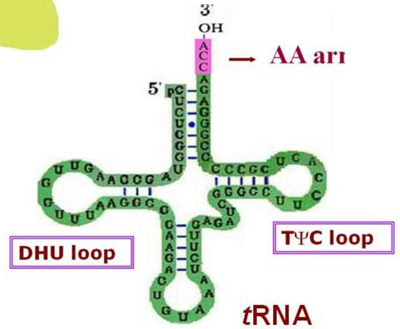
Chemical
MacromoleculeCDMO Business

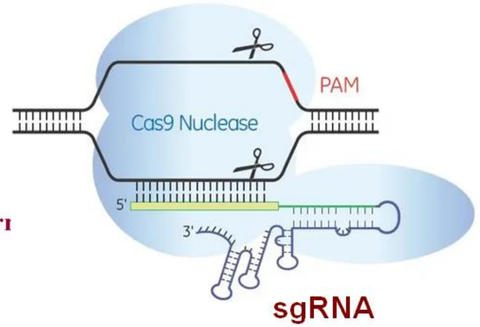
Capabilities For Oligonucleotides

17~30 nt.: ASO, siRNA, CpG-ODNs, etc.
(Nature DNA, RNA, and variants with 2-OMe, 2-F, 2-MOE, LNA)









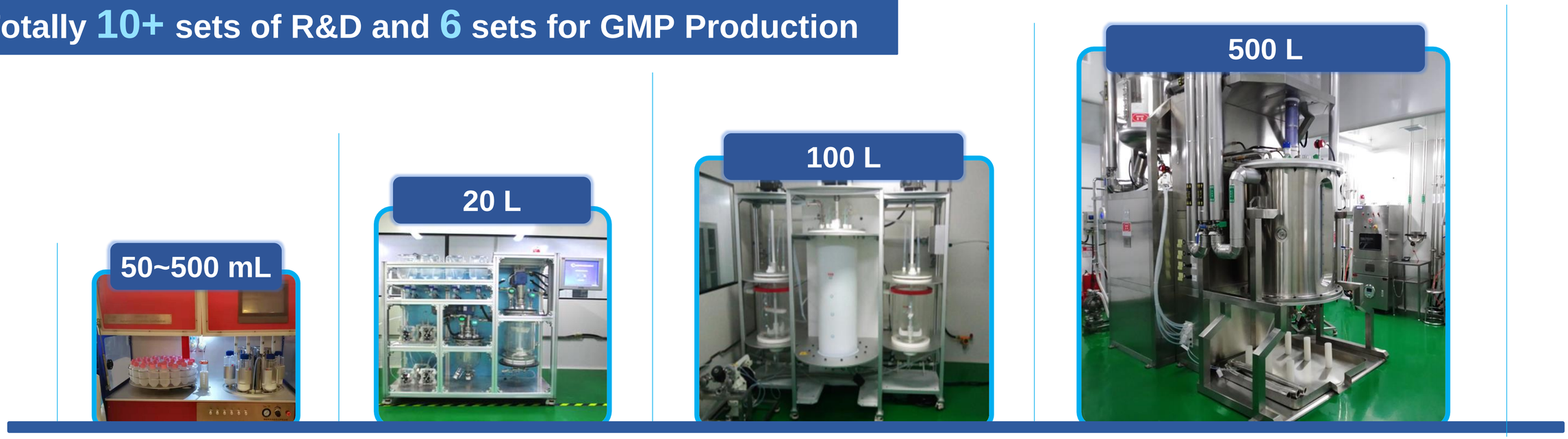
17 nt. **We are here!** **>100 nt.**

- **Well establish solid phase platform for “quick and dirty” synthesis of <100 g scale sample with up to 60 nt**
- **High purity of reference standard (≥97.0%) synthesis with different purification strategies**
- **GMP production of DS + DP with well established specification sheets, quality control & test procedures**
- **Reliable supply chain for amidites and supports (including in-house manufacture with higher quality and lower cost)**
- **10+ IND & 4 Pre-PPQ project experience**
- **PAT (Process Analytical Technology) application for moisture control, solid phase synthesis and purification**

Chemical
MacromoleculeCDMO Business

Solid Phase Peptide Synthesis Capacity

Totally 10+ sets of R&D and 6 sets for GMP Production



- 30+ Project experience including 10+ Phase II/III projects with up to 10 Kg/batch
- Strong Know-how at impurity controls including mis-AA, epimerization, oxidation, re-arrangement, and hydrolysis
- Combination of purification technologies in RP-Prep-HPLC, Ionic Exchange, and SEC chromatography
- Fast delivery (<3-month) for early phase project (10~40 AAs)

Chemical
Macromolecule CDMO Business

Toxin-Linker High Production Capacity

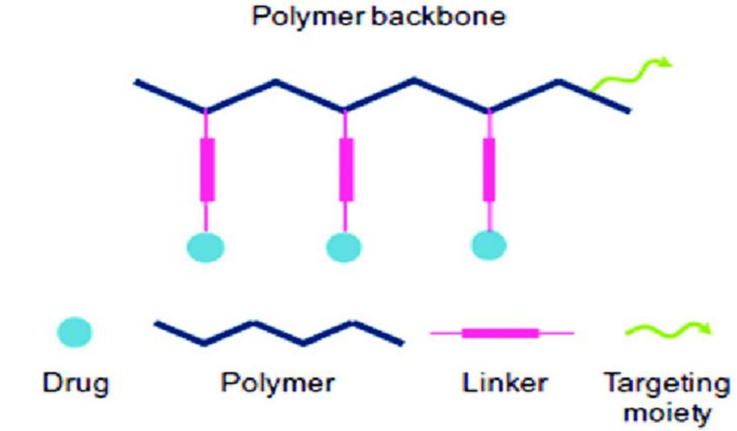
- Capable of operating OEL≤5 ng/m^3 (OEB5) chemicals
- USFDA (2014 & 2019) certified facility
- 8 sets isolators to support >10 projects in parallel
- 30+ projects experience including 4 PPQ

Chemical Macromolecule
CDMO Business

Polymers & Polysaccharides

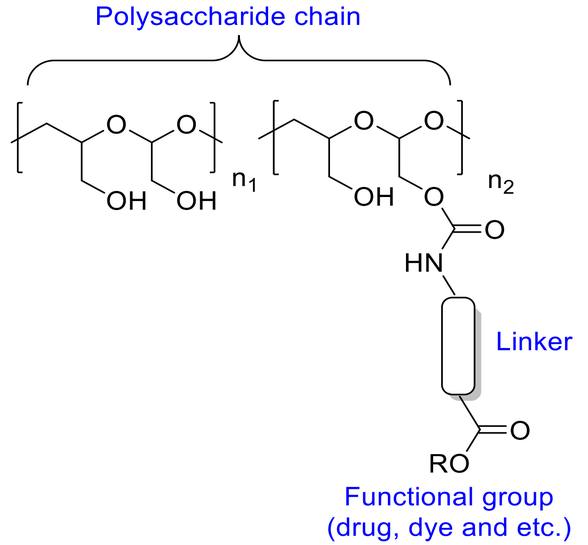
Polymers for Drug Delivery

- Polyamides for nucleic acid delivery such as Poly(b-amino)esters (PBAEs)
- Polyesters such as PLGA
- Dendrimers (G2~G6 with high purity)
- Polymer-drug conjugates (HPMA based, PEG based, conjugation to targeting moieties. Mw: 10~50 KDa)



Polysaccharides

- **SBE-β-CD** (US DMF: 029379), HP-β-CD
- Synthetic complex & conjugated carbohydates such as GalNAc derivatives
- Modification of natural polysaccharide (dextran, Chitosan, Hyaluronic acid, Pullulan and etc., Mw: 5~100 KDa)
- Carbohydrate based vaccine adjuvants (MPLA, Globo-H)



Chemical
Macromolecule CDMO Business

Purification & Isolation Platform

Prep-HPLC Systems

- DAC 150/300 /450/600
- ÄKTA process 350/600

R&D: 30+ sets
GMP Production: 10+ sets

Membrane Systems

- TFF: 1 ~ 30 ㎡
- NF: 1812/2540 /8040

R&D: 20+ sets
GMP Production: 10+ sets

Lyophilization

- 1/2/5/10/20 ㎡
- Total 60 ㎡

R&D: 10+ sets
GMP Production: 10+ sets

Spray Drying

- 1~50 L/h
- Total 120 L/h

Totally 6 sets

Drug Product Service Scope

Pre-formulation

- Polymorph, salt and cocrystal screening
- Stable form selection
- Physicochemical and Pharmaceutical profiling
- Compatibility study
- Pre-clinical formulation development

Formulation & Process dev.

- Oral immediate release and modified/extended release formulation and process development and optimization
- Parenteral and eye drops formulation development and optimization
- QbD-based process development, scale-up and optimization

Production & Registration

- Clinical supply to support different clinical phase needs
- Commercial scale cGMP production
- Dossier drafting for IND/NDA (ANDA) submission in compliance with China and US regulatory requirement

Analytical development

- Analytical method development, transfer and validation
- Microbiological method development and validation
- Stability study as per ICH guideline
- Analytical troubleshooting support

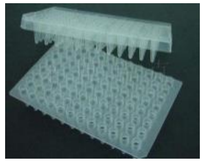
Solid State Science & Pre-formulation Research

Solid State Science

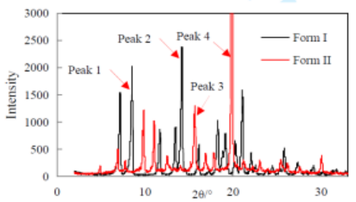
- Salt/co-crystal/polymorph screening and selection
- Solid State Characterization
- Single crystal preparation and quantitative analysis of polymorph

Pre-formulation Research

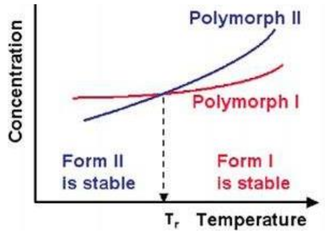
- Chemical and Pharmaceutical Profiling
- Solubility and Stability Study
- Excipient compatibility study
- Preclinical Formulation Development
- Amorphous solid dispersion for solubility enhancement



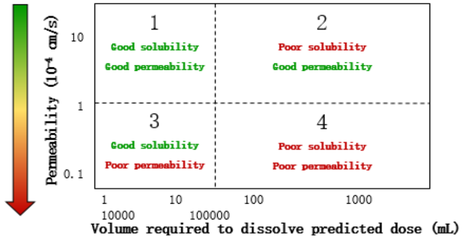
High throughput screening



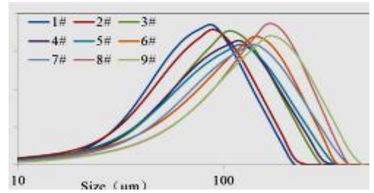
Crystal characterization



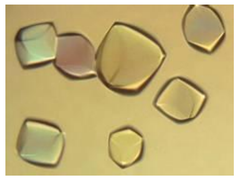
Crystal form interconversion



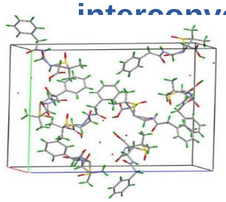
BCS classification



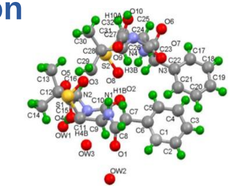
PSD optimization



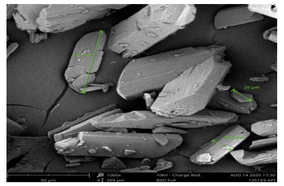
Single crystal

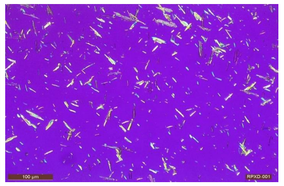


Crystal cell



Structure analysis





Solid state Characterization

OSD Production cGMP Capacity

A variety of state-of-art equipment for pilot and commercial-scale cGMP production			
Workshop	**Area**	**Dosage form**	**Batch Size (units)**
OSD-1	341 M^2	Tablets/ Capsules/ Granules/ Pellets	3,000-50,000
OSD-2	1472 M^2		100,000-1,000,000
OSD-3	2150 M^2		80,000-1,250,000

Solid Dispersion Capacity (Spray dryer and Hot melt extrusion)	
Model	**Capacity**
Spray Dryer BP-290	Water: 1 L/h, 6.7 t/year Organic solvent: ~3 L/h, 20 t/year Can handle OEB4 compound
Spray Dryer PSD-1	Water: 3 L/h, 20.2 t/year Organic solvent: 10~15 L/h, 66-99 t/year Can handle OEB4 compound
Spray Dryer SCOC-25(T)	Water: 20 L/h, 132 t/year Organic solvent: ~28 L/h, 185 t/year Can handle OEB4 compound
Hot melt extrusion Pharma 11	2.5kg/h, 15t/year Can handle OEB4 compound

Roller Compactor

Tablet Compression Machine

Capsule Filling Machine

Bottle Packaging Machine

Spray drying

R&D And Production Of Innovative Formulations

GMP Manufacturing of Injectable

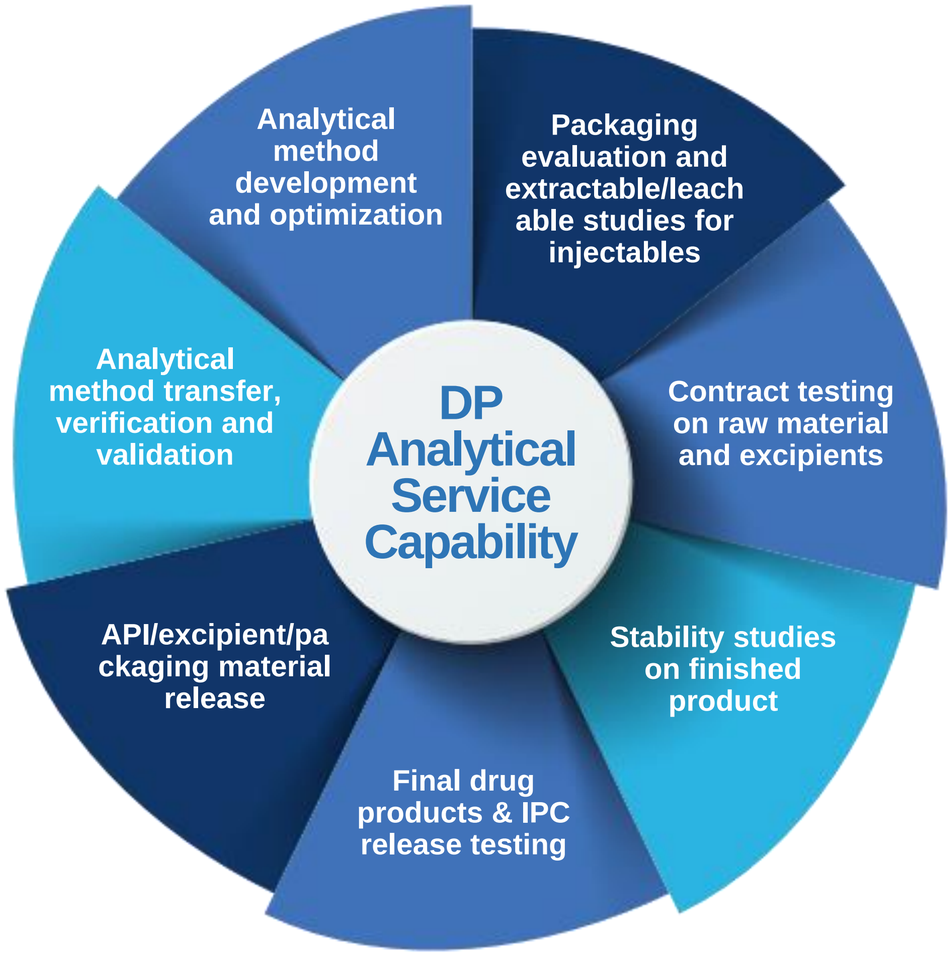
Workshop	Dosage form	Size	Batch Size
Injectable-1 (Glass Ampoule)	Sterile solution	1-20ml	20,000-66,000 units
Injectable-2 (Vial)	Sterile solution	2-50ml	8,000-60,000 units
	Sterile lyophilized powder		5,000-30,000 units
Injectable-3 (Vial & Plastic ampoule)	Sterile solution	2-30ml	1,500-10,000 units
	Sterile lyophilized powder		500-1,800 units
	Ophthalmic drops (BFS)	0.4-20ml	10000-20800 units
	Sterile solution(BFS)	0.4-20ml	10000-20800 units

Filling and Stoppering machine

Mini KUFill

BFS

DP Analytical Service Capability



Materials Control

- DS
  - Identity
  - Microbial testing
- Excipients
  - Identity
  - Microbial control
  - Bacterial endotoxins
- Primary packaging
- Secondary packaging

IPC

- Bu
- CU
- pH
- Osmolality
- Particulate matter
- Assay
- Bioburden (TAMC, TYMC)
- Density

Release Testing

- Appearance
- Identity (IR, HPLC, LCMS)
- Dissolution
- Disintegration
- Water content
- pH, osmolality, clarity
- Particulate matter
- Purity
- Assay
- Bacterial endotoxins
- Sterility

Stability Study

- Stress testing
  - High temperature
  - High humidity
  - Light
- Accelerated stability
- Intermediate stability
- Long-term stability
- Low-temp stability
- Freeze- thaw durability
- In-use stability

R&D And Production Of Innovative Formulations

Major Analytical Instruments

- HPLC, UPLC (Agilent & Waters)
- HS-GC (Agilent)
- Dissolution Tester (Distek, Logan & Agilent)
- UV-VIS

- Osmometer (OSMOMAT 030)
- Residual Oxygen Analyzer (TMI)
- Clarity Tester
- Particulate Matter Instrument
- TGA/DSC/DVS/PSA/SEM

- FT-IR
- Turbid meter
- LC-MS(MS)/ICP-MS/ICP-OES/XRD
- Stability Chamber
- Advanced instrumentation

Agilent HPLC

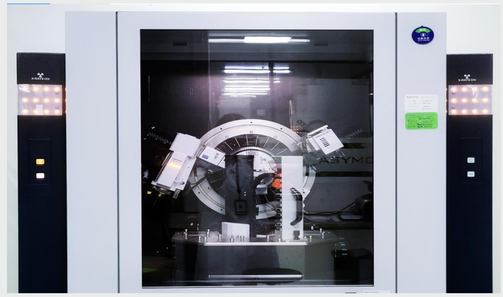
Waters HPLC

Agilent dissolution tester

Agilent GC

Thermo QE LC-MS/MS

Waters LC-MS/MS



Bruker D8 XRPD

Binder stability chamber

Overall Layout of Asymchem Biologics

Jinshan Shanghai

- **Jinshan site (Shanghai)**
  - Covering the R&D and production of pre-clinical, clinical and commercial products of recombinant protein, mAb, ADC and other products

Fengxian Shanghai

- **Fengxian commercial site (Shanghai)**
  - Commercial production capacity of antibody (monoclonal antibody and double antibody)
  - Commercial production capacity of ADC products

Suzhou Industrial Park

- **Xinsufang&Biobay (Suzhou)**
  - Plasmid (PD+GMP) pilot and commercial production;
  - mRNA/LNP (PD+ GMP) pilot and commercial production;
  - Virus vector (PD+GMP) pilot and clinical supply

Asymchem Biologics CDMO
Business for biologics

Protein Antibody /ADC CDMO One-stop Service Capability

One Stop CDMO For Antibody / Recombinant Protein Product

ADC One Stop CDMO

- **Antibody**
- **Payload-linker**
- **Conjugation**

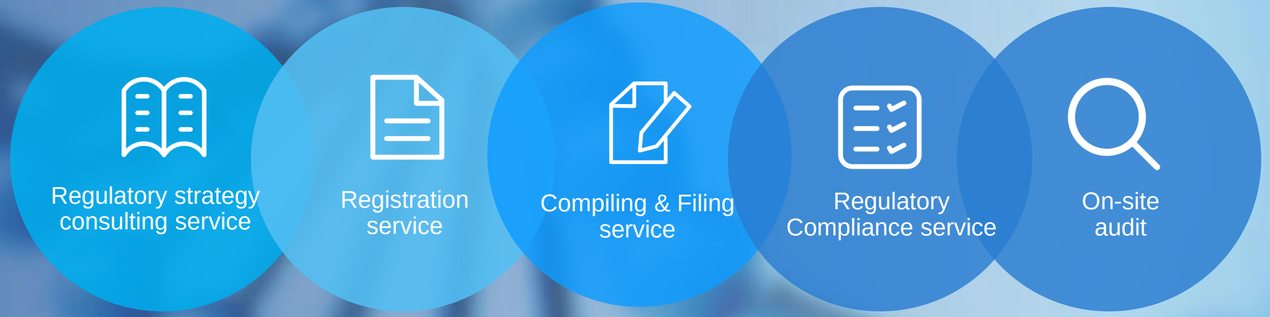
Candidate Molecule Preparation Developability assessment	Manufacturing Process Development	Early Stage Clinical Production	Late Stage Clinical Production Commercial Production
• Cell line transient and stable transformation platform • Developability assessment platform	• High-expression CHO host cell with clear source • 200l/500l/2000l disposable bioreactor, covering pilot scale to early commercialization capacity • cGMP compliance facilities	• Process development and scale up • Clinical supply • Release testing	• Late stage clinical and commercial production • Production risk management • Product maintenance • Regulatory affairs support
• Preparation of ADC candidate molecules • Reserves of different conjugation technologies • Rich project experience with payload linker • ADC developability assessment platform	• Traditional conjugation technology: lysine and cysteine based • Site-specific conjugation technology: thiomab technology, thiobrige technology, sortase enzyme coupling technology	• Process development and scale up • Clinical supply • Release testing	• Late stage clinical and commercial production • Production risk management • Product maintenance • Regulatory affairs support

Asymchem Biologics CDMO
Business for biologics

Drug Registration Ability

Registration team:

- The core members of the registration team have more than ten years of drug registration experience and rich project management experience;
- Wide knowledge of regulatory affairs in drug development, CMC,, analytical chemistry and clinical research. Very familiar with the regulatory requirements, technical guidelines, evaluation and approval processes.



Project experience

- The RA team has assisted customers to complete **150+ IND projects and 20+ NDA projects** application documents preparation and submission, some of which are both filed to US FDA and NMPA.
- Independently complete the documents preparation and submission of **15 US DMF**.
- Currently EU ASMF for DCP application preparation is in progress.

Asymchem undertakes more than **30** IND and NDA projects application each year.

NMPA: With NMPA and CDE have perfect communication channels to consult and communicate on technical and regulatory issues.

FDA/EMA : Asymchem's overseas company also assists with communications and provide regulatory support

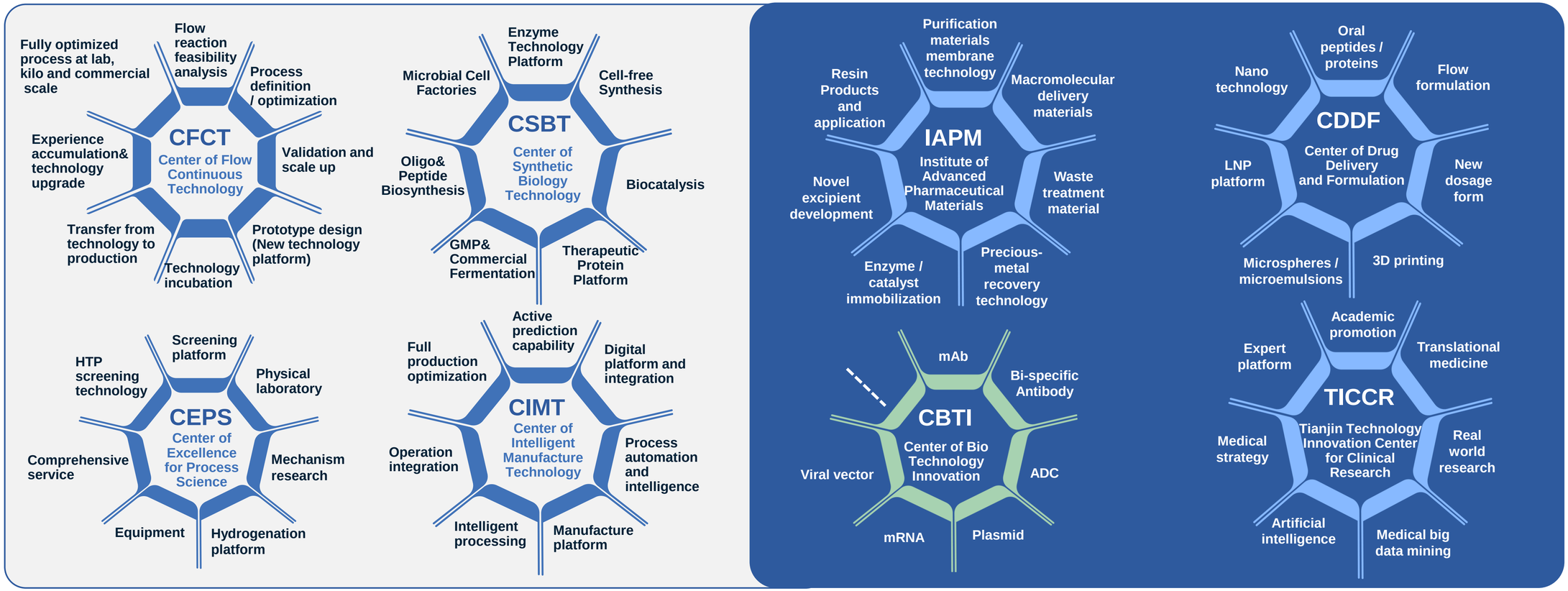
Expert resources

Asymchem has its own team of expert consultants who can provide with support and advise on technologies, regulations, reviews, strategies and so on.

Advanced And Continuously Evolving R&D Platform, Increased R&D Investment

- **Continuous R & D Investment:** in 2021, R & D investment was CNY **387 million**, a year-on-year increase of **49.64%**, accounting for **8.35%** of the revenue in the same period, which is one of the highest in the global CDMO industry

- **Application of new technology:** projects applying continuous reaction and enzyme technology account for more than **30%**

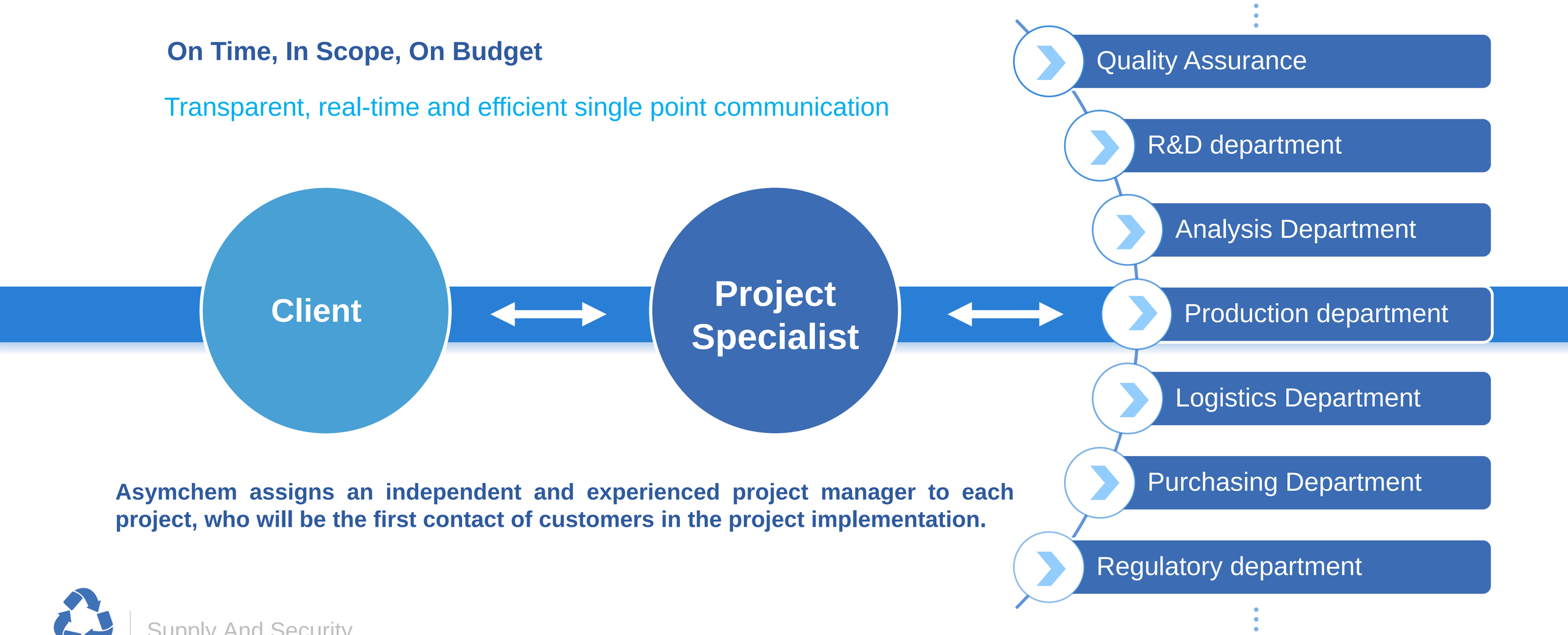


ASYMCHEM Eight Innovation Platforms

Project Management System

On Time, In Scope, On Budget

Transparent, real-time and efficient single point communication



Asymchem assigns an independent and experienced project manager to each project, who will be the first contact of customers in the project implementation.

Quality System And EHS

Audit history

- US FDA (12) 2011/2014/2017/2018/2019/2021
- TGA (3) 2015/2017/2022
- PMDA (3) 2017/2018/2019
- MFDS (1) 2017
- NMPA (28) 2012/2015/2016/2017/2018/2019/2020/2021/2022

Annually

100+ audit of customers and official institutions

200+ customer visits

- **The first batch of enterprises selected into the "green factory" of the Ministry of industry and information technology**
- **Widely use green Pharmaceutical Technology**
- **Passed the EHS audit of PSCI**

U.S. FOOD & DRUG ADMINISTRATION

Australian Government Department of Health Therapeutic Goods Administration

国家药品监督管理局 National Medical Products Administration

식품의약품안전처

pmda 独立行政法人 医薬品医療機器総合機構 Pharmaceuticals and Medical Devices Agency

Supply And Security

Create A New GXP One-stop Service Engine

Asymchem CDMO+CARO ecosystem，
providing one-stop CMC services for the full lifecycle of drug development

01 Evaluate dosage / dosing requirements from the point of pharmacokinetics and toxicology (pharmacokinetics and toxicology study)

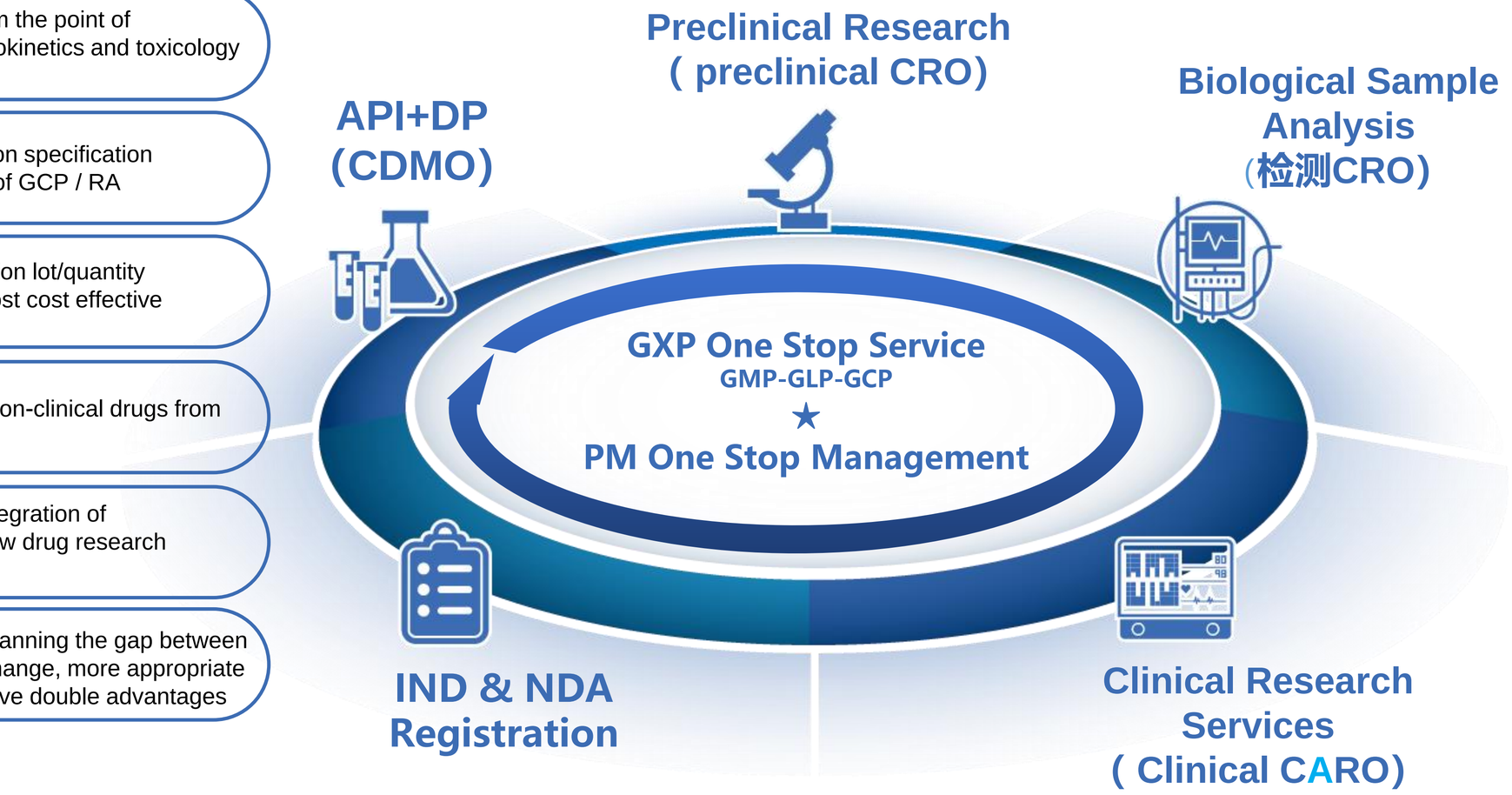
02 Evaluate the dose calculation and preparation specification requirements in clinical trials from the point of GCP / RA

03 Evaluate the API specifications and production lot/quantity requirements from the perspective of the most cost effective formulation

04 Evaluate the specification requirements of non-clinical drugs from the perspective of raw material synthesis

05 One-stop GXP service system, seamless integration of originally scattered modules with making new drug research and development services more "soul"

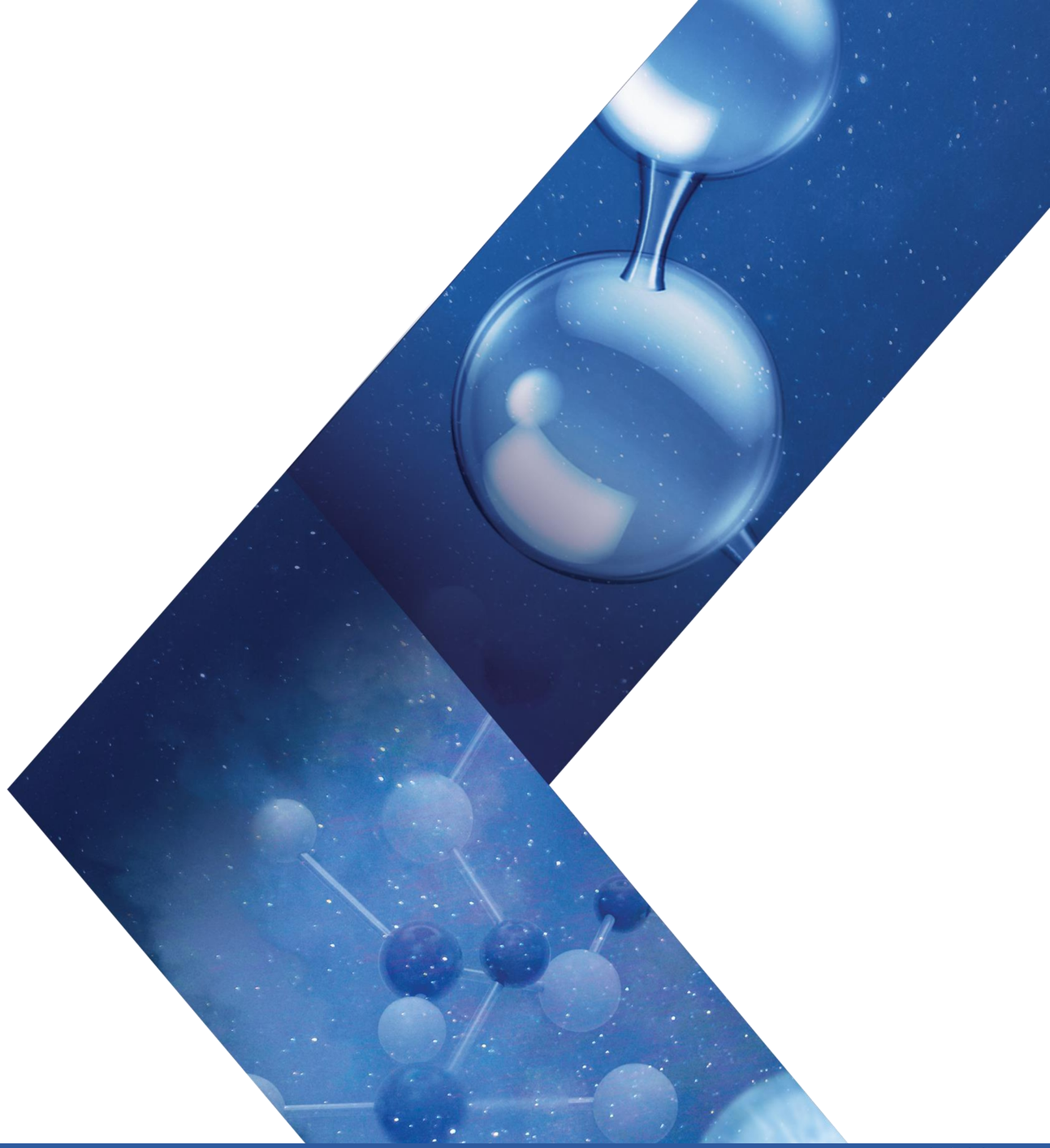
06 Virtual project management matrix mode, spanning the gap between entity modules, more timely information exchange, more appropriate service content, time/economic cost to achieve double advantages



Integrated Service Capability

凯莱英医药集团
Asymchem Labs.

Thanks for your time!



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