Canton Biologics

BIOLOGICS CDMSO

One-stop Integrated Solution

Enhancing the Advancement of
Biologics Drug Development

Your Trusted Biologics CDMSO Partner

Reliable · Efficient · Innovative

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Leading Biologics CDMSO

Founded in 2016, Canton biologics is a one-stop international CDMSO company that focuses on providing bio-pharmaceutical development, manufacturing, and supply chain services for global innovative pharmaceutical enterprises. With excellent technology and reliable delivery, we accelerate the high-quality research and development of biologics for partners, reduce costs, and benefit public health and life.

We have five R&D Manufacture centers in China and own a team of more than 300 scientists with over 15 years of pharmaceutical experience. Furthermore, over 60% of our researchers and developers are masters and doctors. As a highly efficient company, we have created a new record that from DNA to CMC in only 7 months, which has played an important role in the rapid advancement of customers' products to clinical practice. In addition, we have 13+5 manufacturing lines complying with China, US and EU GMP standard (50-2000L, batch, fed-batch, perfusion) for DS and DP manufacturing.

300+ Scientists

80+ Global Clients

100+ Patents Application

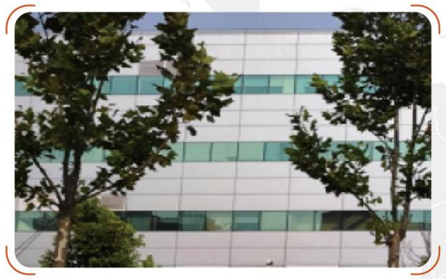
300+ Biologics Projects

50+ IND Experience

10+ BLA Expertise

Shanghai R&D + MFG center

(Shanghai Biologics 200L-2000L)



Global Clinical Service Center

(Shanghai - Biologics+)

CanCelltech MFG Site

(Guangzhou - CGT)

Bethlehem R&D Center

(Guangzhou - Biologics)

Kunlun MFG Site

(Foshan Biologics 50-2000LGMP)

Five sites in China 300+ employees

International Partnering

Global license in and out
International tech-transfer

Versatile platforms

Expertise in Cell line, Vector, Media for complex protein

High efficiency in delivery

CLD-2GMP in 7.5 months

One-stop Service Platform

Expediting your molecule from early stage to commercialization

Tech & Capacity

- Leading End-to-End Biologics CMC platform，including Antibody Optimization, Cell Line and Process Development, Physiochemical, Biochemical, Characterization, Tech-Transfer, and Clinical Bioanalysis
- 13+5 manufacturing lines complying with China, US and EU GMP standard, 50-2000L (batch, fed-batch, perfusion) DS and DP manufacturing

Service Offerings

- Biologics CDMO, covering Monoclonal Antibody, Bispecific Antibody, Fusion Protein, Recombinant Protein, Vaccine
- Cell and Gene Therapy（CGT）CDMO
- Global Clinical Supply manufacturing, packaging, storage, distribution

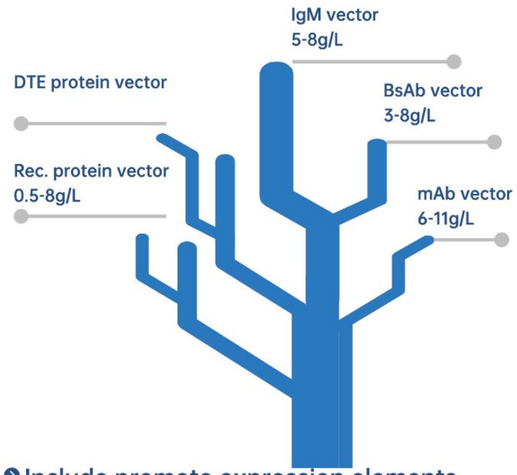
	Discovery	Pre-Clinical	Clinical Sample	Clinical Sample
Dis.	Molecule, Sequence, Protein Engineering Protein Expression, Feasibility			
CMC Development	CLD, Evaluation (CHO、HEK、GEX) USP, DSP development, Formulation Process Optimization, Scaling-up/down Analytical Method（PCAD, BAD） Analytical services，characterization study Cell bank characterization			
GMP-MFG QC/QA		Tech Transfer, MSAT Viral Clearance Studies Biologics cGMP DS Manufacturing Formulation, Fill & Finish (Vials, PFS) and Packaging Clinical Packaging and Supply Quality in Process, Quality Analysis Process Validation, Packaging Materials, Stability Quality System, Release, Regulatory (IND、BLA)		
CSS			Clinical Bioanalysis Clinical Supply Service	

Development

Proprietary Cell Lines-owns full commercial license

- **CHOzen® (CHO-K1), CHOExpress ®**
  High-producing CHO host cell line
- **CHOFlow®**
  Fucosyltransferase 8 knock out CHO line, enhanced ADCC effect.
- **CHO GSKO**
  Glutamine synthetase knockout cell lines, no need to add MSX during screening
- **GLYCOEXPRESS ® (GEX®)**
  For expression of complex proteins, viruses, specially tailored proteins. Human cell lines are required for different glycosylation and modification.

Canvector®-High Expression Vector Series

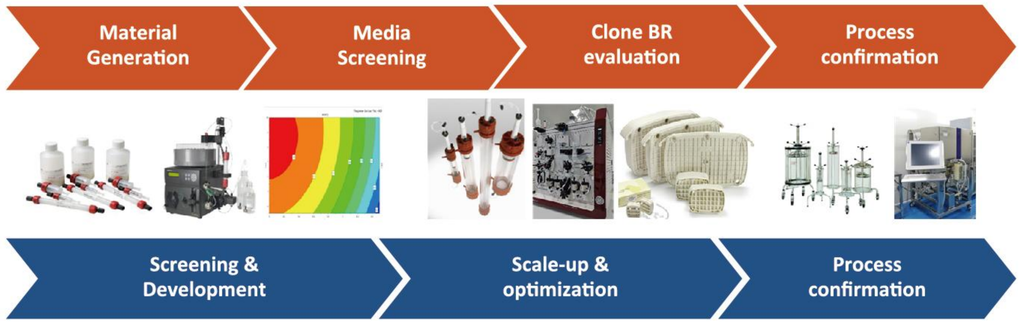


- **Include promote expression elements**
- **Integration into transcription active sites, higher copy number**
- **High productivity RCB in 12 weeks**

We offer an extensive upstream and downstream process development expertise shaped by multidisciplinary projects, including mAb, BsAb, recombinant/fusion proteins, vaccines, coagulation factors, growth factors, exosomes. CBoost® process increases titer by 50%-200%, and 22 g/L is achieved in mAb molecule.

Flexible Cell Culture Platform

Host Cell: CHO, GEX, HEK, SP2/0, Hybridoma
Process: Perfusion, Fed-batch, Intensified Fed-batch



Complete process development up to 15 L in 4 months

Manufacturing

We offer 50L/200L/500L manufacturing services to support Tox, IND submission and clinical trial batches domestically and globally. Multiple batches can be handled simultaneously and disposable systems have been applied to minimize the risk of cross-contamination and allow rapid replacement.

Our commercial manufacturing team has >10 years of GMP manufacturing experiences and strong track record in tech transfer and manufacturing for several commercially launched innovative and biosimilar biologics within and outside China.

Flexible facilities

Foshan, China

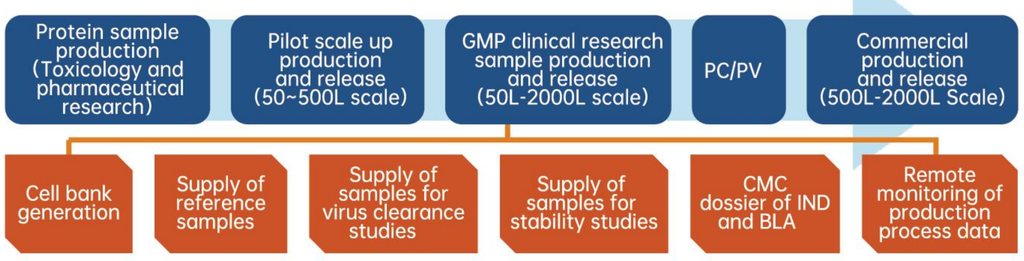
14,000L

2,000L x5
50-500L x14

Shanghai, China

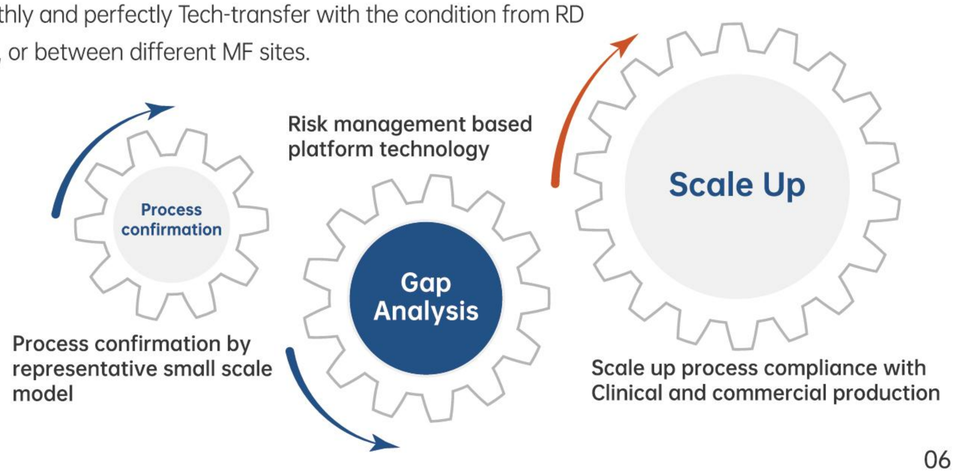
4,400L

2,000L x2
200L x2



MSAT Platform

Smoothly and perfectly Tech-transfer with the condition from RD to MF, or between different MF sites.



Aseptic fill/finish

Various formulation development platforms

Lyophilization

High concentration

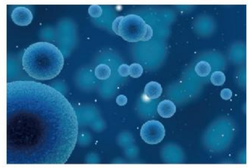
Vaccine

Semi-solid formulation

Inhalation

Nasal spray

Eye drops



Exosomes

Fill & Finish Capacity

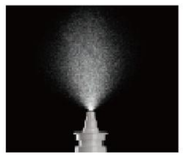
Sterile vials production line

- Compatible with 2R, 6R, 8R, 10R, 14R, 20R, 50R penicillin vials
- Automatic filling production line with isolator system, ensure good levels of sterility and particle control
- Filling speed up to 15,000 vials per hour

Sterile pre-filled syringe production line

- Compatible with 1ml standard, 1ml slender, 3ml pre-filled syringes
- Automatic pre-filled syringe filling production line with isolator system , ensure good levels of sterility and particle control
- Filling speed up to 8,000 syringes per hour

Nasal spray/ throat spray line



- Compatible with 2R, 6R, 8R, 10R, 14R, 20R, 50R penicillin vials
- Automatic filling production line with isolator system, ensure good levels of sterility and particle control
- Adding Spray cap speed up to 6,000 bottles per hour

Analytical Method Development

We understand the importance of a well-planned strategy that combines sensitive, specific, and qualified analytical assays to assist development decisions in bringing a promising drug candidate to market. Therefore, Canton Biologics is well-equipped with leading-edge technologies, state-of-the-art techniques and highly trained scientists to support a plethora of analytical services, offering solutions to support every phase of drug discovery and development.

- **Exosomes**
- **Concentration**
- **Purity and impurities**
- **Glycan and post-translational modifications**
- **Primary and higher-order structure**
- **Cell-based potency**
- **Binding potency**
- **Affinity analysis**
- **Biomarkers for CGT and exosome**
- **Gene analysis**
- **Residual analysis**
- **Safety analysis**
- **Product characterization**

Regulatory Support

We provides efficient and specialized registration support, including domestic and foreign IND (CTA)/BLA(MAA)/conversion and other declaration services. Our registration and regulatory team has rich experience in US and European registration filings, fully understands the laws and regulations and communication mechanisms of various regulatory agencies and can comprehensively provide support strategy and planning for CMC, preclinical, and clinical study design for customers throughout the life cycle of drug development.

- **Experience:** rich domestic and international former FDA CMC professionals and industry operators, dozens of domestic and international successful filing experience;
- **Technology:** proficient in domestic and international regulations and guidelines, effectively solving problems in R&D and filing process;
- **Efficient:** standardised registration and declaration service process, accurate and fast development of registration and declaration strategy;

Clinical Supply

Best Solution of Quality, Speed and Cost

Global Supply Center

Your Well managed Global Clinical Supply Network

Shanghai Free Trade Zone main facility

China and Global Supply 6,000m² Building

Clinical Service Mgt

- Design Clinical Pack and Kit based on the Clinical Trial protocol
- Plan the packaging Campaign based on study parameters
- IRT initial setup and ongoing update
- Act as unblind person
- Training

Manufacturing & Packaging

- Primary packaging for chemical and biological products
- Secondary packaging based on the Pack and Kit design of the clinical study
- Labelling for blind and open studies
- Commercial Packaging

Storage & Distribution

- Clinical storage for various temperature ranges
- Distribution clinical sites
- International depot and distribution network
- Specialty & Cold Chain handling

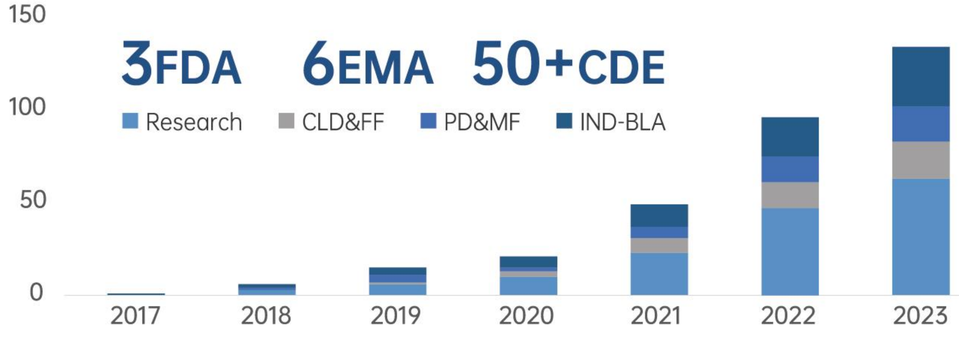
Comparator Sourcing

- Consulting for China and global commercial drug sourcing
- Comparator sourcing
- Chemo drug sourcing
- Ancillary sourcing
- Sourcing of Medical Devices
- Other equipment for CT

Why us?

Canton Biologics is an international, technology-driven, biologics CDMSO, fully dedicated to offer comprehensive biologics development and manufacturing services for our clients.

Accumulated Project No.



Case Study: Biosimilar

Experience on Biosimilar

- **Format type**
  - · mAb IgG
  - · Fc-fusion protein

Fast development timeline

- **Biosimilar development platform**
  16 to 18 months from DNA to IND

High Titer/ Yield/ Purity

- **Titer**
  >6 g/L (after Process developoment)
- **Yield**
  35 to 80 %(Depends on formats)
- **Purity**
  SEC>99%

Project	Format	CLD	PD	MCB	Tox batch	GMP batch	IND
C1	mAb IgG						
C2	Fc-fusion						
C3	Fc-fusion						

Empower Future with Biotechnology

For innovative development need and high quality of life, to create value for human and society

- Monoclonal Antibody
- Recombinant Protein
- Plasmid/Viral Vector
- **Bispecific Antibody**
- Fusion Protein
- Probiotics