



# GMP Manufacturing Solution for Antibody & Protein Drug

Drug substance GMP manufacturing & aseptic fill/finish  
from pre-clinical development to commercialization



GenScript ProBio has both pilot-scale and commercial-scale GMP manufacturing facilities in China for antibody and protein drugs. Our diversified facilities satisfy the needs of drug substance GMP manufacturing and aseptic filling at all scales, from IND to commercialization.

GenScript ProBio's overall capacity for drug substance manufacturing has exceeded 20,000 liters. Our upstream production lines are equipped with single-use bioreactors ranging from 50L to 2,000L, allowing us to meet the manufacturing needs of various projects.

GenScript ProBio boasts two fully automated aseptic filling lines for liquid injection, lyophilized injection, prefilled syringe, and nasal spray filling. All of the core equipment of the two filling lines is from global top-tier companies, ensuring the delivery of high-quality products.

90+

CMC/CMO projects

120+

GMP batches successfully delivered

2

PPQ projects

As of April, 2024

## Quality System

### Comply with FDA, EMA, and NMPA GMP Regulations

Client  
Audits#

**160** client audits, including US & EU clients  
**1** PAI from BPOM (Indonesian food and drug authority)

#### Observations

- No** critical Observations
- Pass EU QP audits **4** times

#### CAPA Completion

- On schedule**

#### Certificate

- Drug Manufacturing Certificate** issued by NMPA\*

# External Audit History of GenScript ProBio (2019.7-2023.12)

\* NMPA refers to China's National Medical Products Administration

## Drug Substance GMP Manufacturing

### Phase I/II Drug Substance Manufacturing



#### Fully Single-Use System

- Cytiva XDR, Thermo Fisher HyPerforma single-use bioreactor
- AKTA Ready single-use chromatography system
- Mobius single-use filtration system



#### Zero-Crossover Production Lines

- Unidirectional flow design
- Physical segregation of production lines

★ Capacity: 2 × 50L, 6 × 200L, 3 × 500L

### Phase III & Commercial Drug Substance Manufacturing



#### 50L-2000L Flexible DS Manufacturing

- 1 × 50L Bioreactors
- 1 × 200L Bioreactors
- 2 × 500L Bioreactors
- 8 × 2000L Bioreactors

#### 2,000L GMP Manufacturing Price<\$100/g\*

- Stainless steel buffer preparation system for materials not in direct contact with the drug
- 8,000 L harvest tank supports scale-out manufacturing mode such as 2×2000L or 3×2000L per batch

\* DS unit price (a. Fed batch process in 2000L SUB, b. 7g/L, 70% yield, c. annual batch number≥ 20 batches), including FFS and material cost

# Aseptic Fill/Finish



## Top-tier equipment

- SYNTEGON filling line\*
- Ross freeze-thaw machine
- KYOWAC lyophilizer
- SEIDENADER visual inspector

## Filling capability for multiple dosage forms

- Vial liquid filling
- Vial lyophilized powder filling
- Pre-filled syringes filling
- Nasal spray filling

### Pilot Scale FF Line 30 K pcs/batch (2R)



### Commercial Scale FF Line 192 K pcs/batch (2R)



2R, 6R, 10R, 20R  
(0.3-20 ml filling volume)



1 ml  
(0.3-1 ml filling volume)



All sizes of snap-on  
bottles  
(0.3-20 ml filling volume)

\* SYNTEGON (former Bosch Packaging Technology)

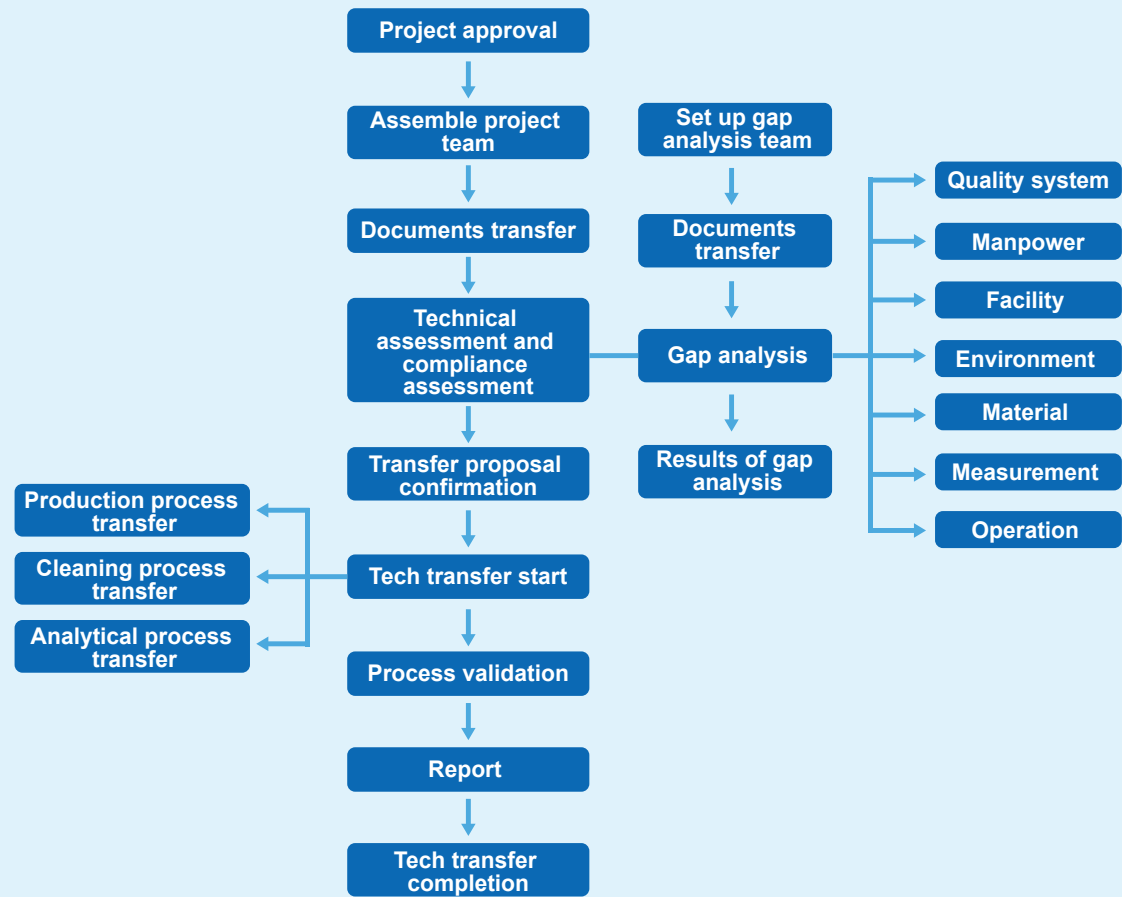
Tech Transfer

Comprehensive and Refined  
Technology Transfer Process

Parameter Conversion  
Model for Different  
Equipment



Comprehensive Risk  
Management and  
Control



## **Contact us**

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