

# BLA Service

Late Stage Process Development & Commercial Manufacturing Service



- BLA Readiness in 14 Months
- Powerful Process Optimization
- Fast Process Characterization
- Quality System Recognized by Global Customers
- Commercial DS Manufacturing Enables Cost Savings
- Commercial Fill/Finish Delivers Premium Products



# BLA Readiness in 14 Months

## One-stop solution for process optimization, process characterization, and process validation

GenScript ProBio offers a one-stop BLA solution for late stage process development and commercial manufacturing. The service includes tech transfer, process optimization, pivotal clinical sample manufacturing, process characterization (PC), process validation (PV), BLA documentation prep of the CMC section, pre-approval inspection (PAI), and commercial manufacturing. It takes only 14 months\*\* from the initial tech transfer to the completion of process validation.



### Fast Process Characterization

PC completion in 4 months



### Global Quality System

100+ client audits globally



### Powerful Process Optimization

Cost reduction of up to 70%



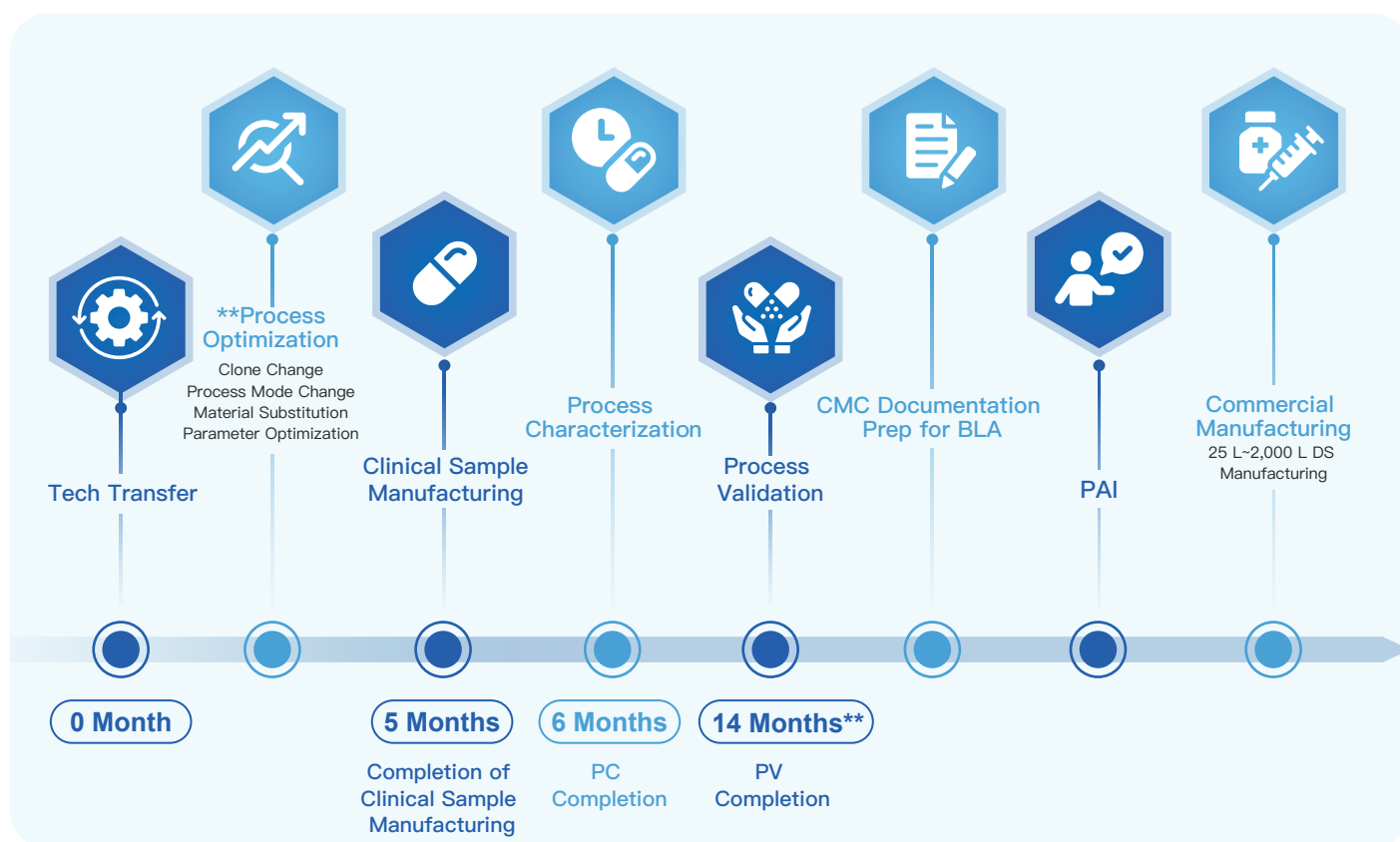
### Prompt Communication

E-mail response within one business day



### Cost Savings

2,000 L GMP manufacturing price <\$100/g\*



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

\*\*The time of process optimization varies depending on the project. The period of 14 months excludes process optimization.



# Powerful Process Optimization

Improve process performance and cost efficiency in multiple ways

Substitution of High-Cost Material	Development of High-Density Inoculation Process	Process Parameter Optimization	Clone Change
Time <b>2 Months</b>	Time <b>6 Months</b>	Time <b>6 Months</b>	Time <b>8-12 Months</b>
Cost Reduction <b>Up to 20%</b>	Cost Reduction <b>Up to 40%</b>	Cost Reduction <b>Up to 40%</b>	Cost Reduction <b>Up to 60%</b>

GenScript ProBio has extensive experience in process optimization for late-stage clinical projects. Our experienced process development team is capable of performing substitution of high-cost materials, process mode changes, process parameter optimization, and other kinds of customized process optimizations. Efficient process optimization significantly reduces expense and improves the product quality of your late-clinical projects.

## Case Study:

Item	Final process cost compared to the original process (%)
Material	100
Manufacturing service	113
Fill/Finish	26
Release and stability studies	48
Packaging	11

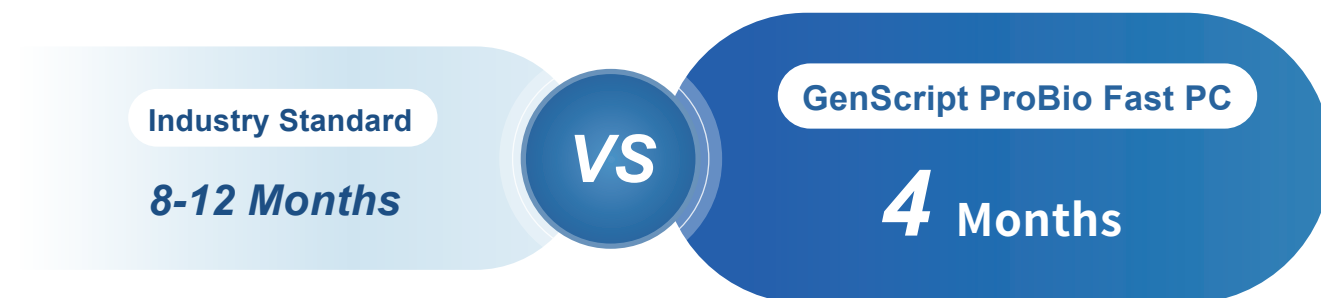
A project whose fill/finish and DS/DP release cost of its original process accounted for 50% of total manufacturing cost. ProBio substituted high cost materials and optimized the process parameters.

After optimization

- Cost per vial decreased by **60%**
- Fill/Finish cost decreased by **74%**
- Release and stability cost decreased by **52%**
- Packaging cost decreased by **89%**

# Fast Process Characterization

Advance your project to the PPQ\* stage in 4 months  
Boost your product with accelerated approval pathways



## CPP/CQA Evaluation

- Data collection & risk assessment

## Upstream Process Characterization

- Scale-down model establishment and validation
- DOE
- Worst-case condition confirmation

## Downstream Process Characterization

- Scale-down model establishment and validation
- DOE
- Worst-case condition confirmation

## The scope of Fast PC

GenScript ProBio offers 2 process characterization services- **Fast PC and Standard PC**, to meet the needs of various projects. Fast PC is appropriate for products with accelerated approval pathways or monoclonal/symmetrical bispecific antibodies in liquid formulation. Standard PC is appropriate for all products, particularly complex molecules such as proteins and asymmetric bispecific antibodies.

\*PPQ- Process Performance Qualification

# Quality System Recognized by Global Customers

Comply with FDA, EMA, and NMPA GMP Regulations

**76** client audits,  
including US & EU  
clients

Nanjing  
Campus  
Client  
Audits

Zhenjiang  
Campus  
Client  
Audits

**85** 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





# Commercial DS Manufacturing Enables Cost Savings

**25 L~2000 L flexible DS Manufacturing**

**20,000 L  
DS Commercial  
Manufacturing Capability**

- 5 x 25 L Wave Bioreactors
- 3 x 50 L Bioreactors
- 7 x 200 L Bioreactors
- 5 x 500 L Bioreactors
- 8 x 2,000 L Bioreactors

**< \$100/g\*  
Antibody Unit Cost under  
Fed-batch Process**

- Stainless steel buffer preparation system for materials not in direct contact with the drug.
- 8,000 L harvest tank supports scale-out manufacturing modes such as 2x2,000 L or 3x2,000 L per batch.

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



# Commercial Fill/Finish Delivers Premium Products

## Liquid Injection/Lyophilized Injection/Prefilled Syringe/Nasal Spray

### Nanjing FF Line

	Liquid Filling	Lyophilized Powder Filling	Syringe Filling	Nasal Spray Filling
Filling system	SYNTEGON Filling Line	SYNTEGON Filling Line TOFFLON Lyophilizer	ORABs filling line from SYNTEGON	Flexicon Filling pump Aptar sealer
Filling volume	0.3–20 ml	0.3–20 ml	0.3–1 ml	0.3–20 ml
Container Size	2R, 6R, 10R, 20R	2R, 6R, 10R, 20R	1 ml	All sizes of snap-on bottles
Batch Capability	30,000 pcs/batch	22,200 pcs/batch	28,880 pcs/batch	6,000 pcs/batch
Filling Speed	125 pcs/min	125 pcs/min	120 pcs/min	/

### Zhenjiang FF Line

	Liquid filling	Lyophilized Powder Filling
Filling system	SYNTEGON Filling Line	SYNTEGON Filling Line KYOWAC Lyophilizer
Filling volume	0.3–20 ml	0.3–20 ml
Container Size	2R, 6R,10R, 20R	2R, 6R, 10R, 20R
Batch Capability	192,000 pcs/batch	192,000 pcs/batch
Filling Speed	400 pcs/min	400 pcs/min

\*SYNTEGON (former Bosch Packaging Technology)



# PROBIO

GenScript ProBio - Innovation Through Collaboration  
Together, we transform the world with science & innovation

## Contact us

🌐 [www.genscriptprobio.com](http://www.genscriptprobio.com)

📞 +1-732-885-9188 (US)

📍 GenScript ProBio USA Inc. 20 Kingsbridge Rd, Piscataway, NJ 08854, USA

✉ USA: [cdmo.us@genscriptprobio.com](mailto:cdmo.us@genscriptprobio.com)

China: [cdmo.cn@genscriptprobio.com](mailto:cdmo.cn@genscriptprobio.com)

APAC: [cdmo.apac@genscriptprobio.com](mailto:cdmo.apac@genscriptprobio.com)

Europe: [cdmo.eu@genscriptprobio.com](mailto:cdmo.eu@genscriptprobio.com)

Japan: [cdmo.jp@genscriptprobio.com](mailto:cdmo.jp@genscriptprobio.com)

South Korea: [cdmo.kr@genscriptprobio.com](mailto:cdmo.kr@genscriptprobio.com)

