Bioworkshops

www.bioworkshops.com

CELL LINE DEVELOPMENT

High quality
Stable and robust
Royalty-free commercial licenses
Global freedom to operate
Full traceability
Clonality and safety assured

Bioworkshops CLD Platform------
Fast Stable Pool Ready in Just 6 Days

How Fast Can You Go from DNA to IND-Ready Material?

How Can You Build a Stable Pool in Just 6 Days ?

Timepoint	Milestone
Day 0	Electroporation with vector + supplemental transfection reagent
Day 6	**Stable pool generated—fastest recovery enables seed expansion for fed-batch**
Day 20	Harvest ~150 mL of supernatant with antibody titer reaching 2–4 g/L — suitable for evaluation and further CMC development

Lower Cost
Cost-effective for large-scale material generation

Faster Timeline
Stable pool ready in **6-13 days**

High Yield
3–6× higher than **transient expression**

Commercial Ready
Same host cell (ATCC CHO-K1) & electroporation as commercial production

Regulatory-Backed Host Cell Platform

ATCC CHO-K1

DMF

Cell Line Regulatory Readiness
FDA DMF Filing Completed

FDA

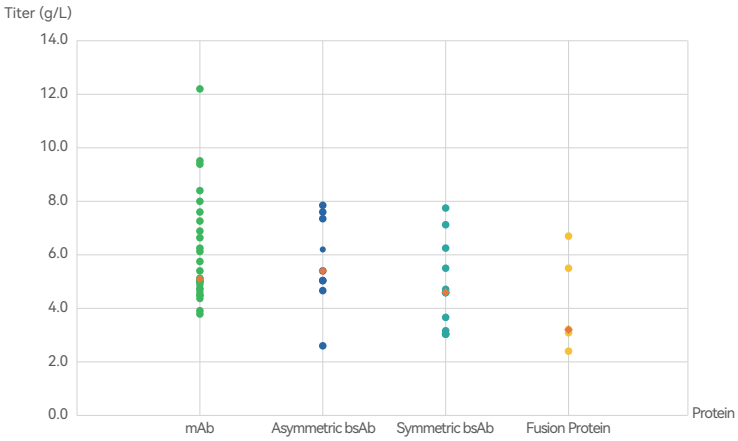
DMF NO.041600 | Type II -Cell Substrate Master File

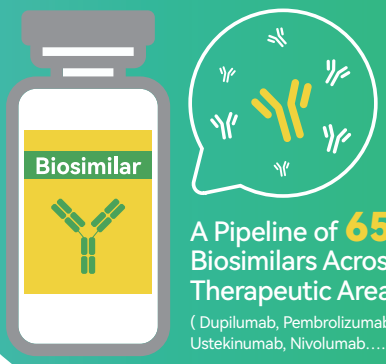
Beyond ATCC CHO-K1, our platform includes several in-house CHO expression systems.

ECACC •--------• CHO-K1
Thermo •------• ExpiCHO (transient)
Thermo •-------• Expi293 (transient)
Merck •-----• CHOZN-K1
HorizonC •--• HD-BIOP3
Thermo •----• CHO DG44
Thermo •---------• CHO-S

Expression Power That Drives Biosimilar Success

High-Expression Across All Biologics Formats





A Pipeline of **65+** Biosimilars Across Multiple Therapeutic Areas

(Dupilumab, Pembrolizumab, Ustekinumab, Nivolumab.....)

High Expression Meets High Consistency

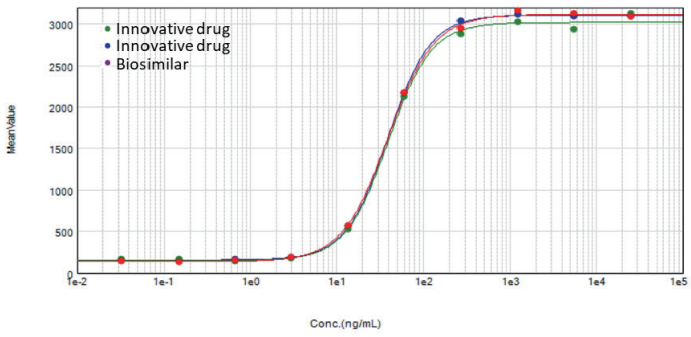
High-expression **biosimilar** cell lines ensure cost -effective and scalable manufacturing — without compromising similarity.

Case Study: Daratumumab

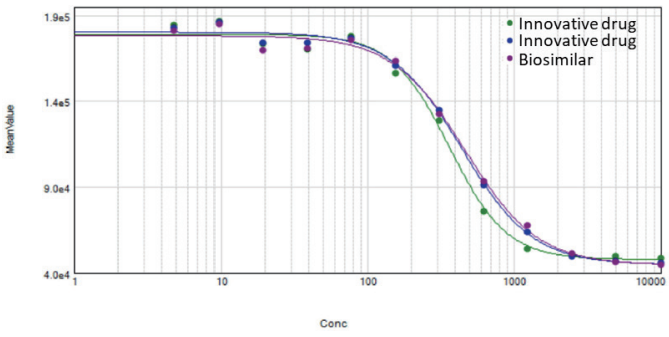
Sample Name	Titer (g/L)	Yield (%)	Galactosylation (G1+G1F+G2F)%	High Mannose (Man5+Man8)%	Afucosylation (G0N+G0+G1)%	Sialylation (G1FS1+G2FS1+G2FS2)%
16 batches of Innovator ±3SD	N/A	N/A	17.5~30.9	0~1.8	2.1~4.0	0~1.9
3 batches of **Biosimilar**	5.11~5.99	92~98	18.0~20.0	1.6~1.7	3.0~3.2	0.7~1.6

Sample	SEC(%)		iCIEF-CPB (%)				CE-NR (%)		CE-R (%)
	Agg	Mon	Acid	Main	Basic	pI	LMW	Main	LC+HC
16 batches of Innovator ±3SD	0.0~2.4	97.5~100.2	25.0~32.8	61.4~70.5	4.2~6.1	8.7	1.3~3.5	96.2~98.9	98.4~99.2
3 batches of **Biosimilar**	1.0~1.3	98.5~98.7	25.2~26.0	69.4~70.7	4.1~4.6	8.676	2.1~2.8	97.2~97.9	98.3~98.6

ADCC activity



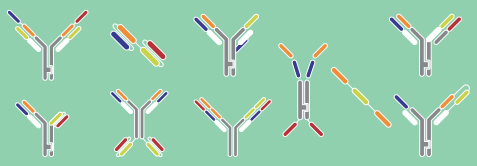
CDC activity



65+ Biosimilars---Ready for development and licensing

Starting at target discovery stage Bioworkshops CMC service platform can help screen candidate molecules and shorten the development period. Our experience in clinical manufacture reduces risks in the later development stages, and delivers both a highly productive cell line and a robust manufacturing process to speed molecules into clinical development.

Bioworkshops have developed highly efficient cell lines for mAbs, bsAbs (symmetric + asymmetric), multispecifics, fusion proteins and other therapeutic proteins with robust process, high expression, scalability and excellent cell line stability.



Bioworkshops is a one-stop CDMO for antibody products. Bench to BLA for mAbs, bsAbs, ADC, and fusion proteins with 13,000L of cell culture capacity and 3 aseptic filling lines. Bioworkshops has proven compliance with US and EU regulatory requirements.

24 7/24 project management

Reliable supply chain

Quality is the way we work

200+

developed >200 stable single clone cell lines

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