



Bioworkshops

www.bioworkshops.com

Bioworkshops

A full-service biologics CDMO
The partner of choice for your antibody
development and manufacturing projects
Accelerating your progress to market



INTERNATIONAL DEVELOPMENT



Bioworkshops

We assure approval in the highly-regulated markets of USA, China, EU and Australia as well as other regions.

EFFICIENT, RELIABLE SERVICES WITH A COMMITMENT TO CONTINUOUS IMPROVEMENT

OUTSTANDING TEAM



Simon Kwong , PhD

Chief Executive Officer

Bioworksshops is dedicated to working with selected global partners to achieve rapid approval of clinical and commercial biologics by applying our expertise in development and manufacturing.



Nick Kotlarski , PhD

President

Our vision is to bring biologics to market reliably and efficiently.

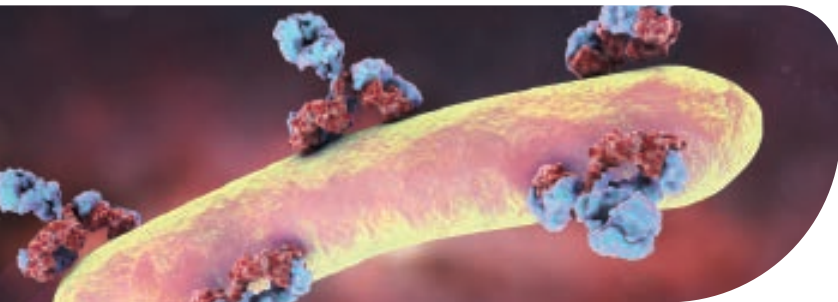
28,000m²

Bioworksshops own our 28,000m² building



13,000L

13,000L cell culture capacity
200 - 2,000L single-use bioreactors
Four segregated cell culture suites



70+

In the past ten years, the team has cumulatively developed over 70 antibody products.



Fully integrated service

Drug substance and drug product provide one-stop production and efficient quality control.



15 million vials and prefilled syringes

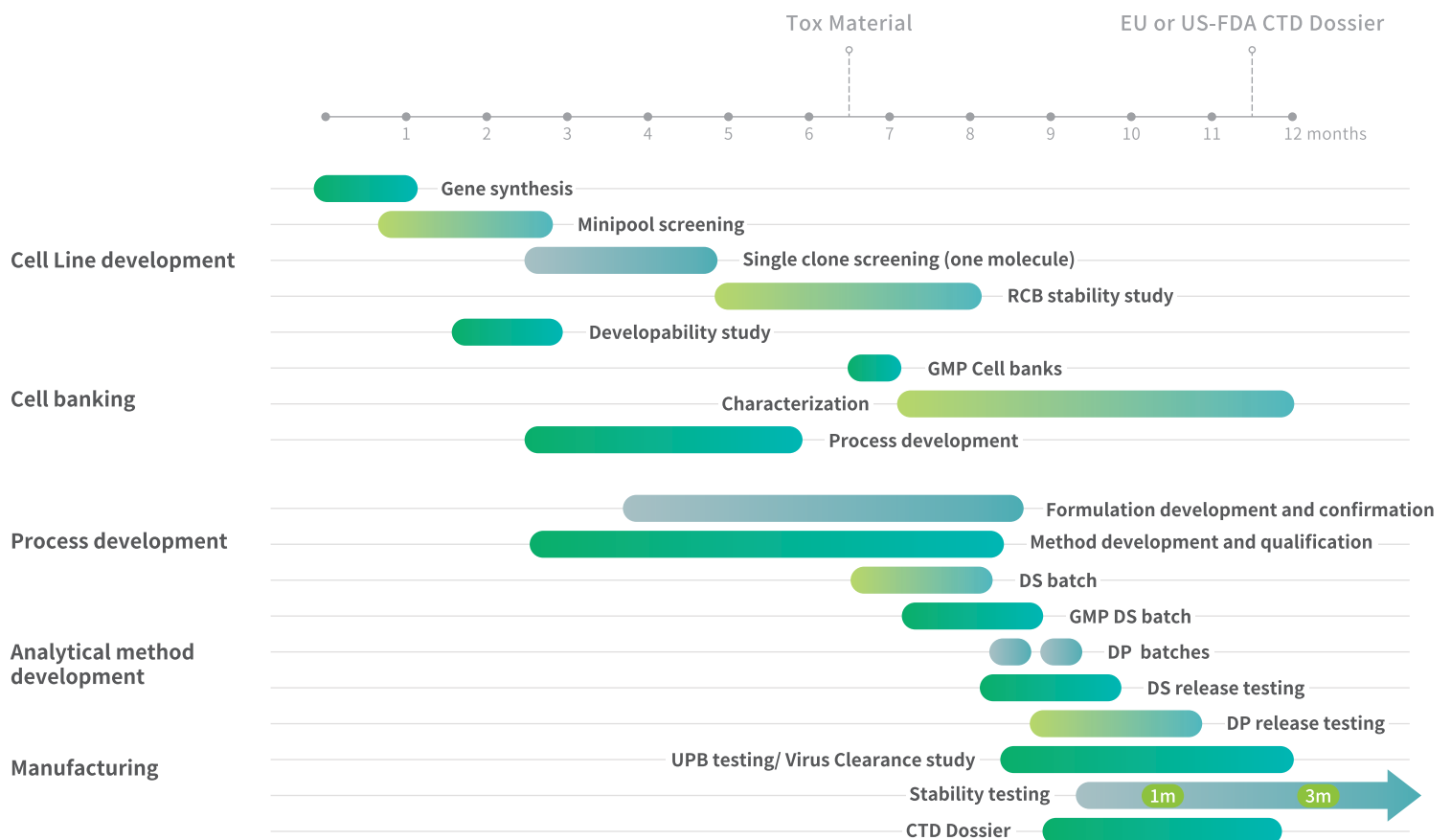
Aseptic fill & finish for clinical and commercial drug product. Annual capacity 15 million vials and prefilled syringes.

OUR SERVICES

Fully integrated CDMO service

From gene to IND/BLA
Clinical to Commercial Fill & Finish

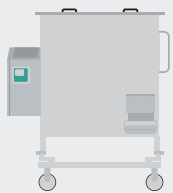
FAST INTEGRATED SERVICES



OUR LABORATORIES



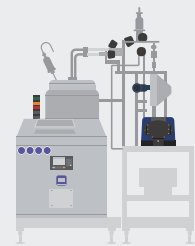
OUR ADVANTAGES



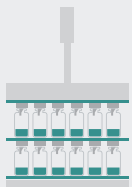
Competitive pricing



Flexible business cooperation modes



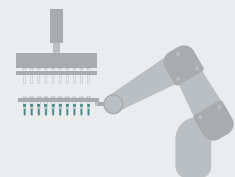
Rigorous information protection system



Compliance with NMPA, FDA, EMA, and ICH guidelines



Experienced team, more than 200 staff



Full-service CDMO for biologics with focus on antibody products (mAbs, bsAbs, Fc, n-body, and biosimilars)

High Drug Substance capacity

13,000L cell culture, multiple lines
200L, 250L, 500L, 2,000L



15 million sterile units/year

Three aseptic filling lines
Fully single-use components
Liquid, lyophilized, prefilled syringes, and
cartridges. 0.5mL to 50mL



International compliance to NMPA, FDA, and EU GMPs

NMPA Manufacturing license
Passed QP audit
40+ client audits
Passed third-party US FDA audit



Strong track record

IND/CTA approvals for the United States,
Australia, and China



OUR FACILITY

DRUG SUBSTANCE

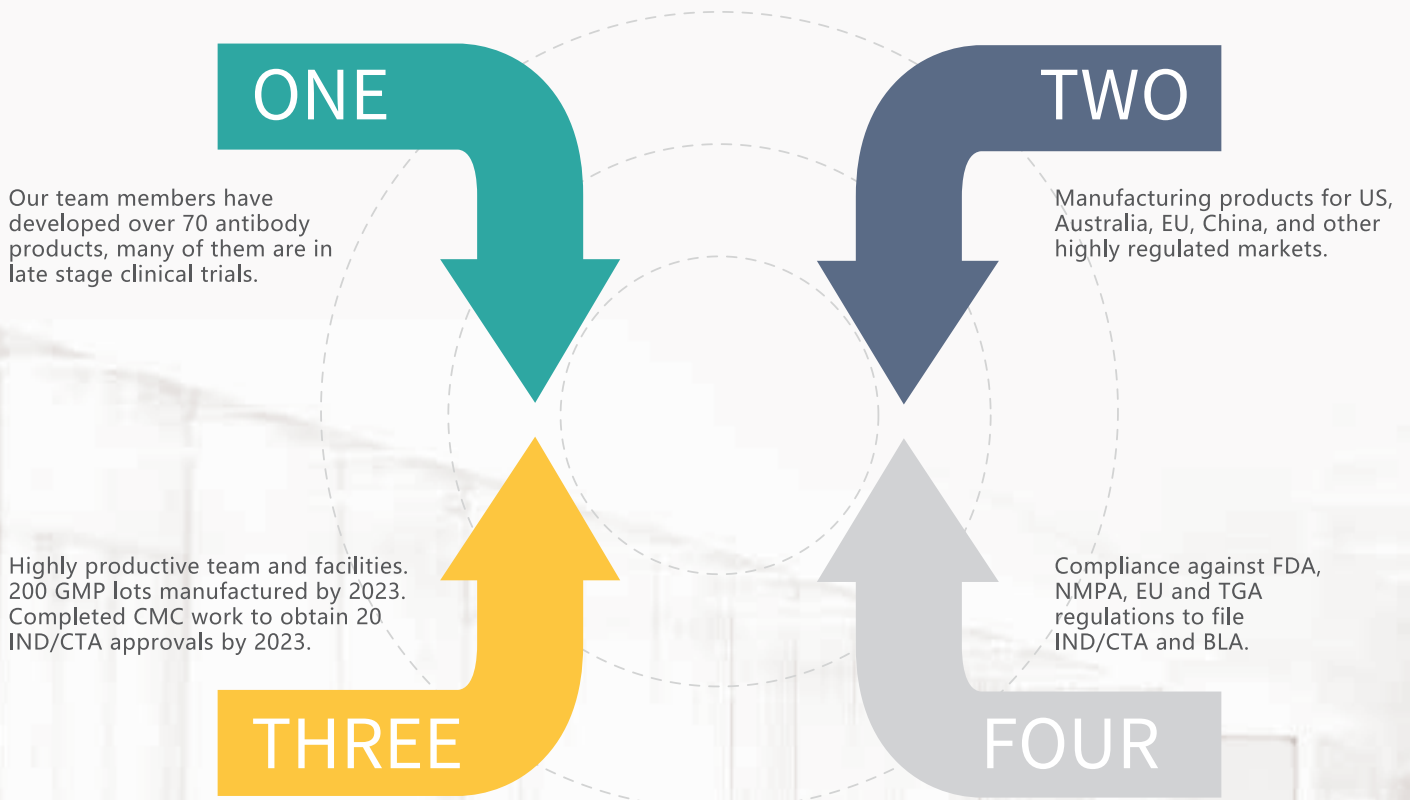


OUR FACILITY

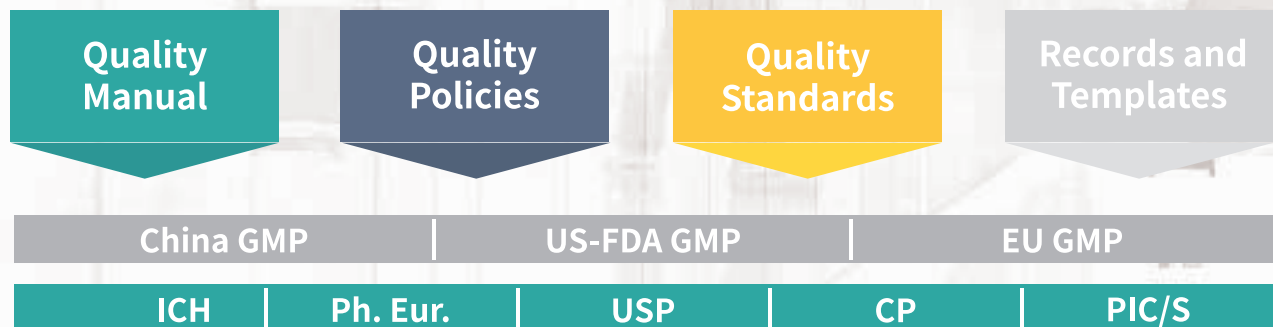
COMMERCIAL DRUG PRODUCT LINES



OUR PEOPLE HAVE DEEP EXPERIENCE ROBUST QUALITY MANAGEMENT SYSTEM



Adhere to international standards: FDA, EMA, NMPA, and ICH guidelines and GMP regulations



All services are controlled by our well-established quality system, project management execution, and focus on achieving customer satisfaction.

QUALITY MANAGEMENT SYSTEM



Quality Management System

Bioworkshops are committed to manufacturing safe, high-quality products. Our Quality Management System is designed to achieve compliance with NMPA, FDA, and EU Good Manufacturing Practice applicable for biological medicinal substances and products for human use.



Project management — Keep effective communication

An experienced Project Manager is assigned to every client project. They will drive the lifecycle of the project for fast delivery.



Regulatory Affairs

Focus on biologics CMC document preparation and drug applications in China, United States, and Europe. We design and execute registration strategies for each project according to our clients' specific goals.



Data Security

The backbone of our IT systems is solid network infrastructure with segregated office and production networks to ensure data security and efficient operation.

