AURIGENE
PHARMACEUTICAL SERVICES



Integrated Drug Substance & Drug Product

One Partner. One Quality System. Zero Hand-Off Risks

25 Years

6 Commercialized

900+ Scientists

125+ Clients

6 Bi-Specifics in journey to clinic

3 R&D Centers

20KL Installed DS Capacity

10g/L Peak titer via process intensification

10L-2KL Single-use Scale Progression

~10 Weeks Stable Pool

12–14 Weeks Downstream Cycle

100 % PPQ Success in 4 Yrs

Expression Platforms

CHO-S, DG44, CHO-ZN (GS-/-) & transposase systems with Cell-Celector monoclonality.

Upstream

AMBR screen-ing g50L g 200L SUB; fed-batch, processintensifi-cation.

Downstream

Affinity, IEX, HIC, Mixed-mode, TFF & dedicated viral clearance.

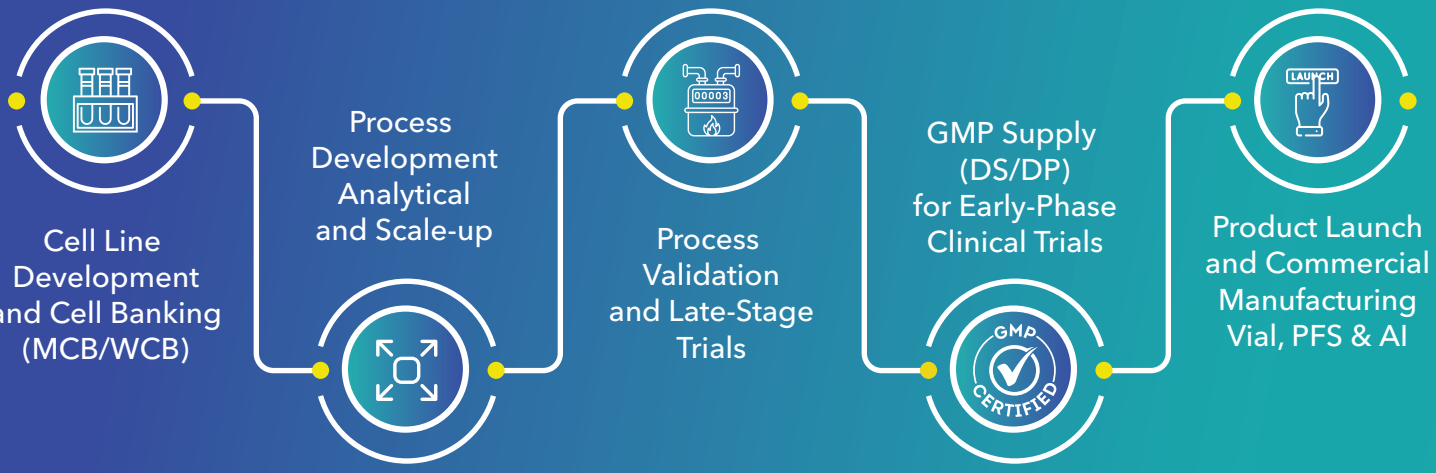
Capacity Expansion

Expanding to 30KL by FY2027. Stainless-steel or single-use flexibility – a high degree of flexibility to run either stainless-steel or single-use bioreactor systems, backed by rich technology-transfer experience.

DS Manufacturing Footprint

4 × 1,000L	10 × 1,000L	3×1KL + 3×2KL	3 × 1KL
CCM4	CCM5	GV F2 · SUITE 1	GV F2 · SUITE 2

One Integrated Workflow



mAbs | Bispecifics | Biosimilars | Recombinant Proteins

Drug Product

Patient-Ready Presentations, Any Format

5.4 M	200 mg/mL	2	3 Formats	<1%	1-200
Vials / Year	High-concentration	Lines Rabs + Isolator	• Vial • PFS • Auto-injector	Aggregation Held Across Stability	mg/mL Dp Strength Range

Fill-finish Capacity – 5.4M Vials / Year

Fill-Finish Suite	FFM1 · RAB	FFM2 · Isolator (Single-Use)
Annual capacity	1.4M vials	4.0M vials
Lyo capacity	0.5M vials	1.0M vials
Vial sizes	2 – 50 mL	2 – 50 mL
Lines	Vial + PFS	Vial + PFS (expanding)

U.S. FOOD & DRUG ADMINISTRATION · EUROPEAN UNION GMP · ANVISA · Health Canada · Pmda · KOREA MFDS · CDSCO

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For more information

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