A Global **CDMO** Dedicated to Your Success

Integrated CDMO Manufacturing Execution
for Clinical and Commercial Supply

◆ Korea, EU-GMP Certified

PRESTIGE BIOLOGICS

Built for Biologics Manufacturing

Prestige Biologics is a biologics-focused CDMO purpose-built to support seamless technology transfer and reliable commercial manufacturing, delivering consistent quality, predictable timelines, and stable operational performance.

Manufacturing Philosophy

- An integrated approach to process design, equipment, and operations
- Manufacturing optimized for reliable tech transfer and reproducible execution

Single-Use System

- 154,000 L total manufacturing capacity
- Single-use–based manufacturing enabling
  · Low cross-contamination risk
  · Fast batch changeover
  · Consistent product quality

Right-on-Time Deliverables

- Reliable supply aligned with development and commercial timelines
- Predictable project execution as a core CDMO operating principle

Track record

Biosimilars

12

First-in-Class

2

Over 190 batches

Well Trained Workforce

300+

87%

R&D / Quality Workforce

Certification

GMP

EMA

MFDS

WHO(SGS)-GDP

ANVISA

Flexible & Scalable Manufacturing Infrastructure

Plant 1 Early-Stage Manufacturing Projects

- 3 × 2,000 L bioreactor–based early GMP manufacturing
- PD lab and 200 L pilot unit operation
- Rapid transition from process development to GMP manufacturing

Plant 2 Clinical to Commercial Manufacturing

- 14 × 2,000L Bioreactor (3 DS Suites)
- Fully integrated operations across Upstream · Downstream · DP · QC · Warehouse
- Clinical & Commercial DP with Packaging

Plant 3 Next-Generation & Platform-Ready Facility

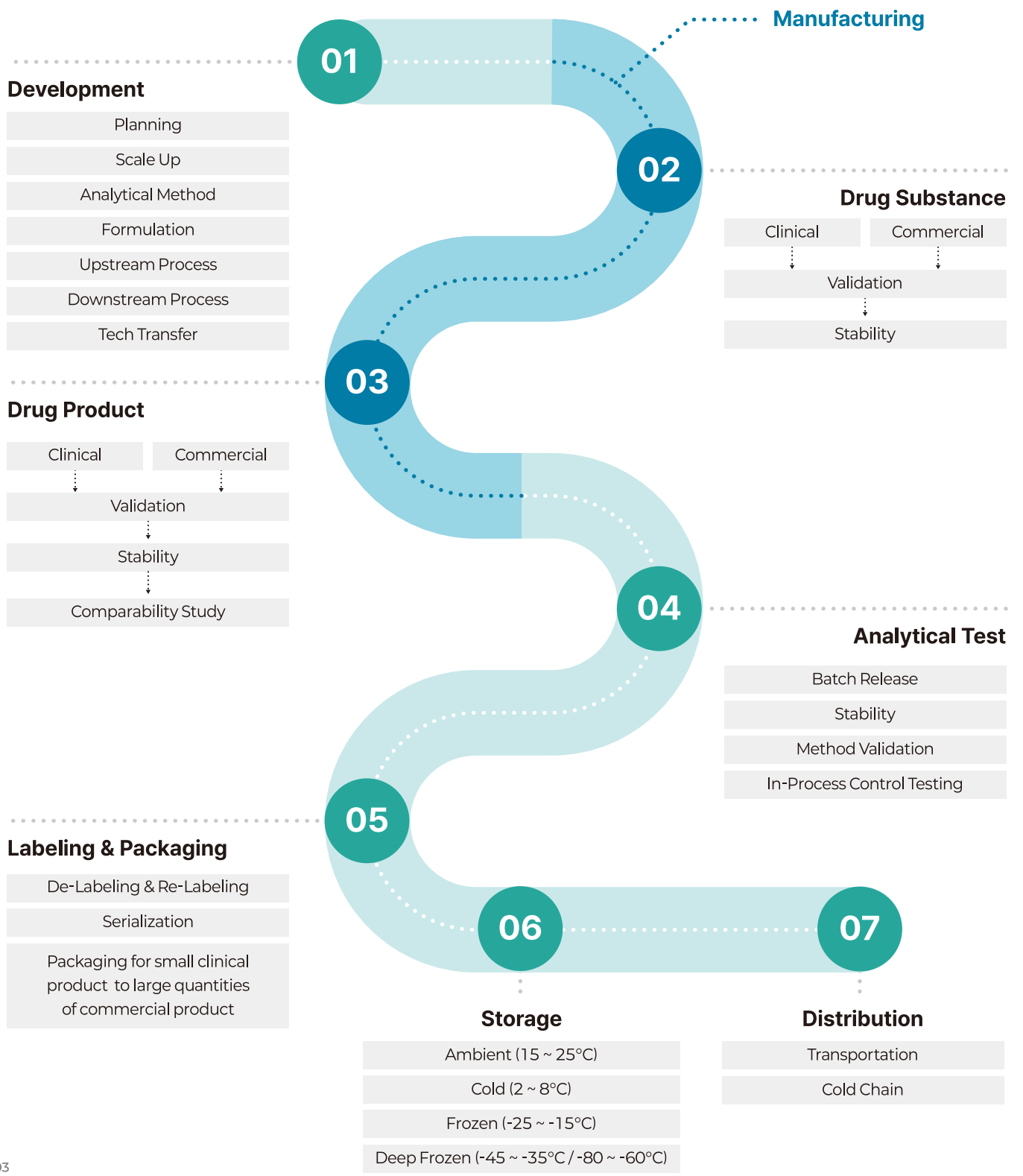
- 44 × 2,000L Bioreactor (10 DS Suites)
- Modular, hyper-flexible manufacturing lines
- Rapid quality testing through QC lab integration

Plant 4 Large-Scale Hybrid Manufacturing

- 16 × 2,000L Bioreactor (2 DS Suites)
- Upstream: Single-use–based, flexible, low cross-contamination
- Downstream: Stainless steel–based, robust and reproducible

From Early Development to Commercial Supply

Prestige Biologics provides integrated CDMO services covering defined manufacturing execution scope, ensuring consistent execution from early development through commercial supply.



Customer Project Execution Framework

Prestige Biologics executes customer manufacturing projects in a structured and predictable manner, ensuring consistent manufacturing execution from project kick-off to the start of GMP batch manufacturing.

Project Kick-off

- Project scope, timeline, and responsibilities alignment
- Development stage and manufacturing strategy definition
- Early identification of key project risks

Technical Assessment & Gap Analysis

- Review of manufacturing process, analytical methods, and facility fit
- GMP applicability and risk assessment
- Definition of additional development or mitigation requirements

Tech Transfer

- Manufacturing and analytical method transfer
- Facility fit and feasibility evaluation
- Technology transfer governance and oversight

Material Readiness & Scale-up

- Finalization and GMP qualification of raw and ancillary materials
- Scale-up strategy definition
- Draft preparation of Manufacturing Batch Records

Engineering Batch

- Pre-GMP engineering batch manufacturing and testing
- Verification of process reproducibility and analytical methods
- Final adjustments prior to GMP manufacturing

GMP Manufacturing & Batch Release

- GMP DS and DP manufacturing
- QC testing and QA review
- Batch release and supply execution

Project Timeline

2 – 4 weeks

3 – 4 weeks

2 – 3 months

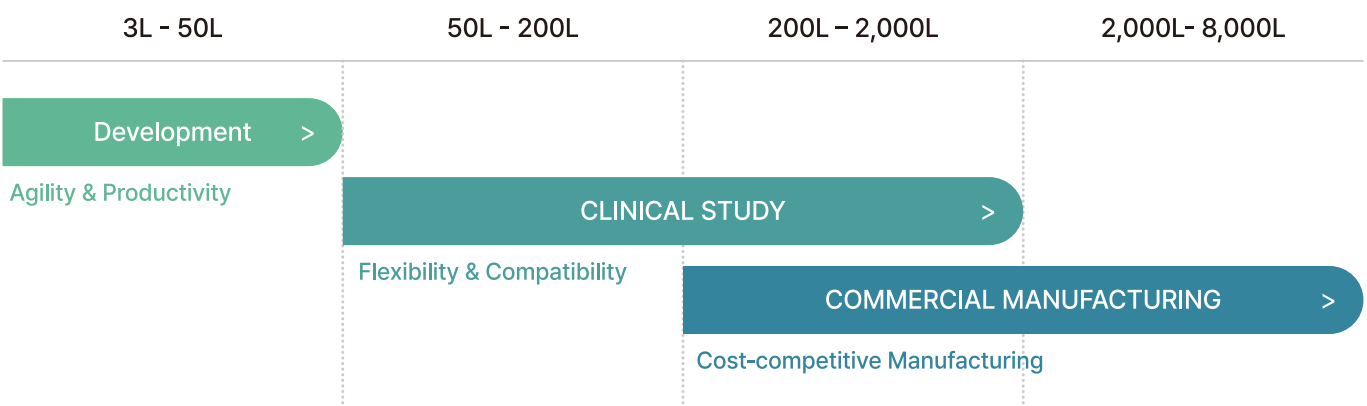
1 - 2 months

4–6 months from project kick-off to the first GMP batch start

CDMO Manufacturing & Additional Services

Manufacturing Service (DS · DP)

We provide flexible DS and DP manufacturing services tailored to development, clinical, and commercial stages, enabling seamless transitions across all phases.



QC Analysis

- GMP batch release support
- Analytical testing: HPLC, UPLC, CE-SDS, icIEF, ELISA, qPCR, etc.
- Method transfer, verification & validation (phase-appropriate)
- Stability testing support (ICH compliant)
- GMP-compliant data for regulatory submission

Clinical Trial Packaging

- Dedicated clinical packaging operations, fully separated from GMP manufacturing
- End-to-end execution of clinical packaging and labeling based on sponsor-provided specifications
- Flexible support for protocol amendments, labeling changes, and multi-country clinical trials
- GMP and GDP compliant packaging

Storage

- Validated storage conditions (ambient, cold, frozen, and deep frozen)
- Automated inbound and outbound system (ambient)
- EMS-based real-time monitoring
- Integrated management of cell bank, DS, DP, and clinical

Why Customers Choose Prestige Biologics

ONE

End-to-End DS and DP Manufacturing at a Single Site

Our facility and equipment are configured to support technology-transferred manufacturing across DS and DP within a single site, enabling consistent process execution from drug substance through drug product.

TWO

Structured Project Management Focused on Reliable Delivery

Each manufacturing project is managed through a clear, stage-based project management approach. Key technical and operational risks are identified early to support predictable timelines and consistent quality.

Three

Robust GMP Systems Supporting Reliable Commercial Manufacturing

GMP manufacturing is performed under established quality systems and clearly defined responsibilities across manufacturing, quality, and project teams. This ensures regulatory compliance, operational control, and consistent manufacturing performance.

PRESTIGE BIOLOGICS

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Brochures

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