CPO

From IMPs to Commercial Pharmaceuticals
Contract Packaging Organization

PRESTIGE BIOLOGICS

Full range of reliable CPO (Contract Packaging Organozations) services from packaging, pharmaceutical storage and distribution

Prestige Biologics has adopted the full-single-use-system in the industry first in Korea. And established production facilities incorporating our proprietary ALITA Smart BioFactory technology. Through innovative engineering, we provide upgraded CDEMO services in the CDMO sector. We offer optimal solutions for our customers, including facility design tailored to their needs and efficient production of clinical samples and commercial products, enabling them to respond flexibly to the rapidly changing pharmaceutical environment. With a customer-centric approach, we ensure quality stability and guarantee on-time delivery of customer projects through rigorous development.
Contract Packaging Organizations (CPO) services are crucial processes that ensure the stability, safety, and efficacy of biopharmaceuticals. Prestige Biologics provides comprehensive packaging services from investigational medicinal products (IMPs) to commercial pharmaceuticals.

Certificates

EU GMP

Certificate of GMP Compliance of a Manufacturer awarded by EMA (No. ES/017/22)

KGMP

Certificate of GMP Compliance of a Manufacturer awarded by MFDS (No. 2646)

SGS WHO GDP

Certificate of WHO GDP Compliance awarded by SGS (KR21/81826538)

ISO ISO 9001 : 2015

Certificate of ISO 9001:2015, KS Q ISO 9001:2015 awarded by DNV (10000461781 -MSC-RvA-KOR)

CPO Sevices

We provide customized secondary packaging solutions for Investigational medical products.

- Double-blind labelling
- Labeling of vial or pre-filled syringe
- Single label of Booklet label
- Support for cold chain distribution

Plant 1. PIONEER
6,400 L

Plant 2. FRONTIER
28,000 L

CPO Process

Prestige Biologics's CPO service provides secondary packaging services tailored to the customers' requirements and follows packaging processes that comply with EU and international GMP standards. We offer labeling and re-labelling services for IMPs such as vials and pre-filled syringes to meet the requirements for double-blind testing. Additionally, we establish specific GMP Standard Operating Procedures (SOPs) for individual projects based on the Time Out of Refrigeration (TOR) criteria for the investigational medicinal products (IMPs), ensuring compliance across processes.

Preparation
- Establishment of Master Batch Record and QC test Standard Operating Procedures (SOPs)
- QC test for Secondary packaging materials

Labelling
- Double-blind labeling
- De-labeling
- Re-labeling
- Operator GMP training according to SOPs

Inspection
- Visual inspection after packaging
- Verification of IP code, vial labels, and carton labels for consistency

Storage
- Cold storage validated at 2~8℃

Distribution
- Temperature controlled transportation at 2~8℃
- Local distribution within 24 hours

Secondary packaging pre-and post-GMP operator campaign	Performing to ensure Time Out of Refrigeration (TOR)	Cumulative total of over 31 secondary packaging bathes completed

We are continuously expanding our investments in reliable collaborative partners to meet the needs of temperature-sensitive IMPs and bio-cold chain. This includes domestic and international transportation services as well as cold chain storage services.

Storage Service with Robotic System

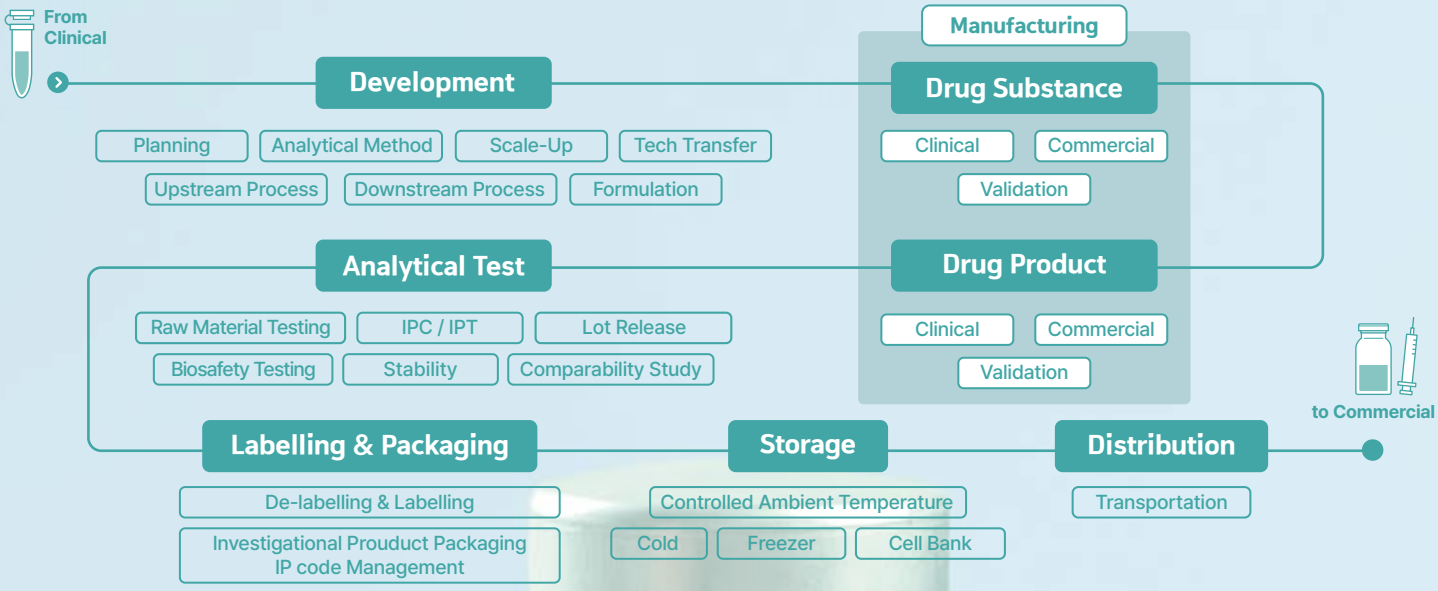
Prestige Biologics' Campus 2 is equipped with a large-scale robotic automated storage system featuring Rail Guided Vehicles (RGV). The automated warehouse system is divided into 3 temperature-controlled areas: ambient, cold, and frozen, all compliant with GMP standards. The ambient storage area accommodates a total of 3,600 pallets, the refrigerated storage area holds 144 pallets, and the frozen storage area has a capacity of 144 pallets. We operate an internationally recognized automated warehouse system.

* Ambient (15℃ to 25℃): 3600 Pallets, * Cold (2℃ to 8℃): 144 Pallets, * Frozen (-25℃ to -15℃): 144 Pallets

Plant 3. VOYAGER
88,000 L

Plant 4. ADVANTURE
32,000 L

The Right CDEMO Partner for You



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