CDMO Services
by Celltrion

World proven Mab Development and Manufacturing Capabilities can be Yours

Unlock global market entry for your valuable products with Celltrion as your trusted partner. **Benefit from our expertise in R&D, manufacturing, clinical studies, and securing regulatory approvals from FDA and EMA.** With world-class facilities and dedicated professionals, we empower your journey to success.

Key Services

- Optimization of cell culture and purification process
- Analytical method and product quality verification
- Clinical/non-clinical material production
- Support of clinical trial documents
- Commercial production
- Support of regulatory approval documents

Early Stage Development

- Cell line development
- Upstream process development
- Downstream process development
- Formulation development
- Analytical method development
- Non-GMP DS & DP production & stability study

Clinical Manufacturing

- DS manufacturing for clinical phase I, II, III
- Process optimization
- Process characterization
- Analytical method validation
- In-process/Release testing
- DS stability study

Commercial Manufacturing

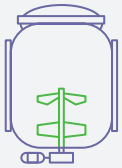
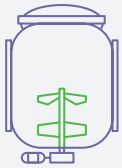
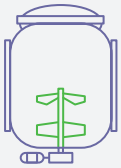
- Process fit analysis
- Process control strategy/Scales-down model study
- Analytical tech transfer
- In-process/Release testing
- Engineering run
- Process performance qualification
- DS stability study

Clinical/Regulatory Support

- Clinical design
- Clinical filing consulting
- Clinical data analysis
- CMC preparation & IND filing support
- CTD preparation & BLA filing support

Multiple Scales, Multiple Capacities, to reach out Multiple Satisfactions

Our multiple scales and capacities, ranging from **1,000L to 15,000L**, cater to your specific needs. Plant 3 spanning **1,500L** to **5,500L~7,500L**, goes above and beyond to exceed market expectations.

Plant 1	Plant 2	Plant 3	Single Use Plant
			
12,500L X 8	**15,000L** X 6	**7,500L** X 8 ('25 operational)	**1,000L** X 2
100,000L	**90,000L**	**60,000L**	**2,000L**

One-stop process

Our site offers **full package of production solutions**, not only **clinical material** and **commercial production** but also **customer tailored services** from **clinical design** to **regulatory approval support**. With our seamless one-stop approach, you can save both time and cost while ensuring the highest levels of quality and client satisfaction.

Delivering on-time Excellence

With streamlined processes and efficient logistics, we prioritize **punctuality** and **reliability**, allowing you to meet your target without delay.

Seamless Communication and Unparalleled Transparency

Providing you with **real-time updates**, **progress reports**, and **clear insights** into the status of your projects. Count on us to keep you informed every step of the way.

Swift Troubleshooting and Responsive Support

With a **proactive** and **solution-oriented approach**, we swiftly **troubleshoot issues**, **minimizing downtime** and **ensuring smooth operation.**

Analytical Testing Capability

Testing Scope

- Raw material
- Environmental monitoring
- In-process control
- Release
- Method Validation

Stability testing

- Compliance with ICH guideline
- Real-time (long-term) and accelerated conditions
- Validated stability chamber from -90°C to 42°C
- Real-time monitoring and alarm system

In-process & release testing

- Compendia assays
- UV absorbance
- SoloVPE®
- Water content
- CCIT
- HPLC/UPLC/Bio-LC/GC
- CE-SDS
- icIEF
- Real-time PCR
- Cell-based potency
- ELISA
- Biacore
- SDS-page
- Sterility
- Endotoxin
- Bioburden
- Microbial identification

Biosafety testing

- Mycoplasma testing
- In vitro adventitious virus assay

Know-how & Rich experience

With unparalleled know-how and rich experience in the industry, we ensure that our customers receive the best possible service.

9 products

7 for in-house, **2** for customer
Exceptional **CMC capabilities** through growing portfolios

+20 years

2,100+ cGMP DS batches
> **98.5%** batch success rate

+90 countries

400+ accumulated regulatory approvals;
FDA, EMA, Health Canada, PMDA, ANVISA

54 inspections

54 successful inspections;
FDA: 7, EMA: 5, PMDA: 2
Others: 40

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