Your Trusted Biologics
CDMO Partner

BINEX.

www.bi-nex.com



Proven Quality. Trusted CDMO. Excellence, Delivered by Binex.

1. Global Compliance & Proven Quality

- Quality systems fully aligned with FDA, EMA, and global regulatory standards.
- Committed to our global partners' commercial manufacturing.
- 48+ successful regulatory inspections passed with consistently strong outcomes.

2. Scalable & Flexible Manufacturing

- Seamless support from early clinical development through full-scale commercial supply.
- Flexible manufacturing capacity tailored to your specific program requirements.

3. Integrated End-to-End Solutions

- One-stop manufacturing and full documentation support for IND, IMPD, and CTD Module 3.
- Fully integrated services delivered through our trusted partner network, with Binex managing every step.
- Centralized project management with a single point of contact.

4. Accountable & Agile

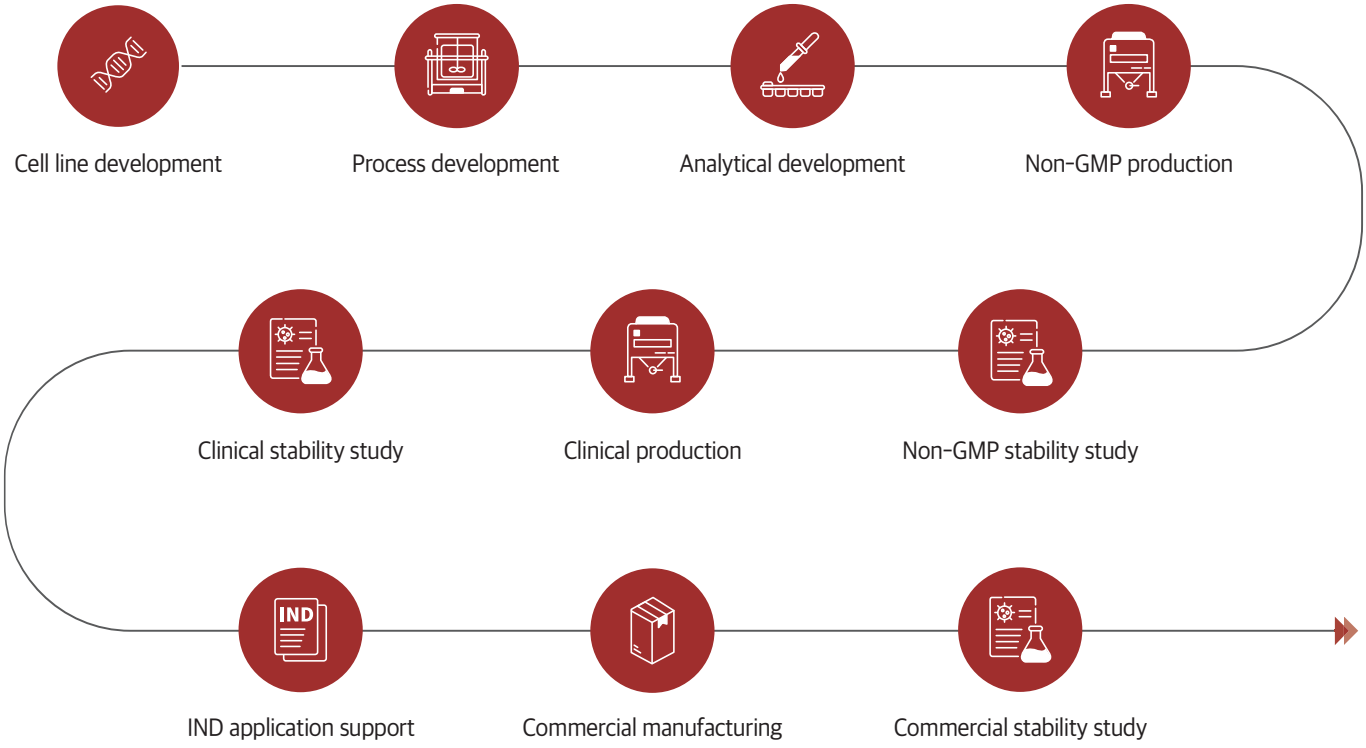
- Dedicated project teams with clearly defined escalation paths.
- Guaranteed 24-hour response time to keep your project on track.



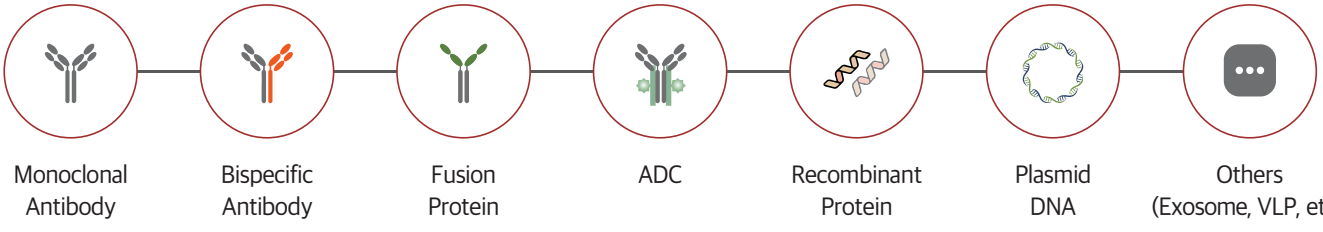
End-to-End CDMO Services

We provide full-lifecycle CDMO services spanning cell line development through commercial manufacturing, supporting a broad range of modalities with scalable capacity and deep in-house analytical and regulatory expertise.
Every program is led by a dedicated project team with clear accountability and rapid turnaround, backed by flexible, scalable manufacturing and fully integrated solutions from early clinical development all the way to commercial scale.

Workflow



Diverse Modalities



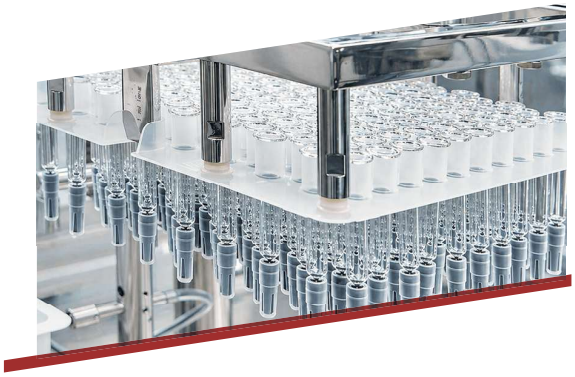
Capacity

▪ Drug Substance

Classification	Suite	Scale
Mammalian	1	200 L / 1,000 L
	2	500 L
	3	1,000 L
	4	1,000 L
	5	1,000 L / 1,000 L
	6	5,000 L
	7	5,000 L / 5,000 L
Microbial	8	180 L
	9	500 L

▪ Drug Product

System	Capacity
Liquid Vial	10,000 vials/batch
Lyophilized Vial	5,000 vials/batch
Pre-filled Syringe	6,000 syringes/batch



Advanced Analytical Center

- Protein Identification
- Glycosylation Analysis
- PTM (Post Translational Modification) Analysis
- Advanced Structure Analysis
- Purity & Homogeneity Analysis



Track Record & Quality.



145+
Clients

101+
IND/BLA Approvals

1,316+
GMP Batches

48+
Inspections & Audits

98%
On-time Delivery

3 months~
Tech Transfer

FDA U.S. FOOD & DRUG ADMINISTRATION

EMA EUROPEAN MEDICINES AGENCY

PMDA

Ministry of Food and Drug Safety

swissmedic

Health Canada

MEDSAFE New Zealand Medicines and Medical Devices Safety Authority

Australian Government Department of Health, Disability and Ageing

DIRECCION NACIONAL DE VIGILANCIA SANITARIA PARAGUAY

FDA Taiwan Food and Drug Administration 衛生福利部食品藥物管理署

Medicines & Healthcare products Regulatory Agency

REPUBLIC OF TÜRKİYE MINISTRY OF HEALTH

ANVISA Agência Nacional de Vigilância Sanitária

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