

SAMSUNG BIOLOGICS

CRO Testing Services

| Expedite Your Success

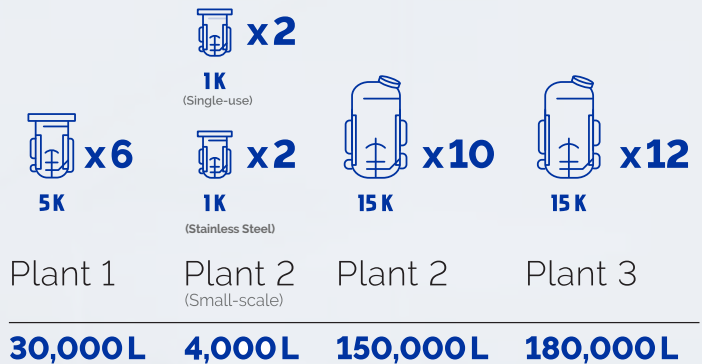
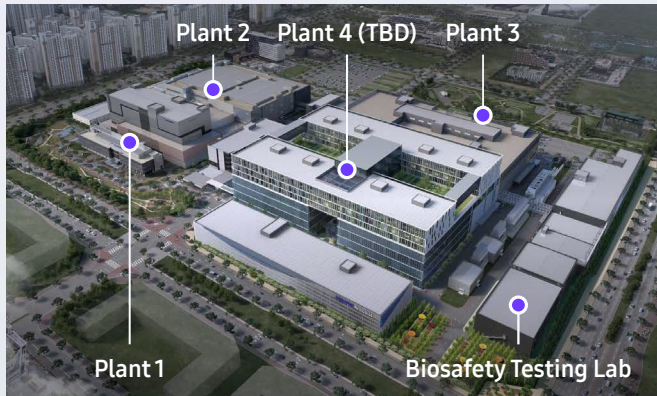


From Uncertainty to Confidence

Accurate and timely biologics testing is a critical step in the development and delivery of safe medicines to patients worldwide. Samsung Biologics provides precisely tailored testing solutions to help accelerate your drug development and commercialization journey.

We are here to provide you confidence even when your path ahead seems uncertain.

Our Manufacturing Capabilities and Operational Excellence



2,760+ Highly Trained Workforce

364 KL Total Capacity (256 KL to be added by 2022-2023)

>98% Batch Success Rate

Nov. 2016 IPO

52.5 Bn US\$ Market Capital (Aug. 2020)

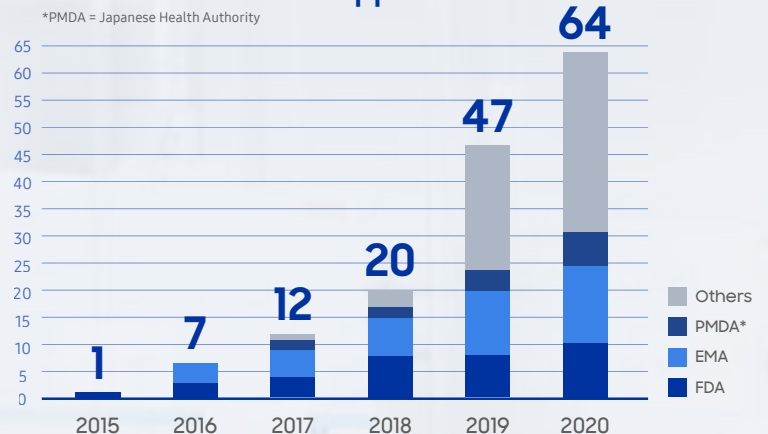
24+ Inspections

64+ Approvals

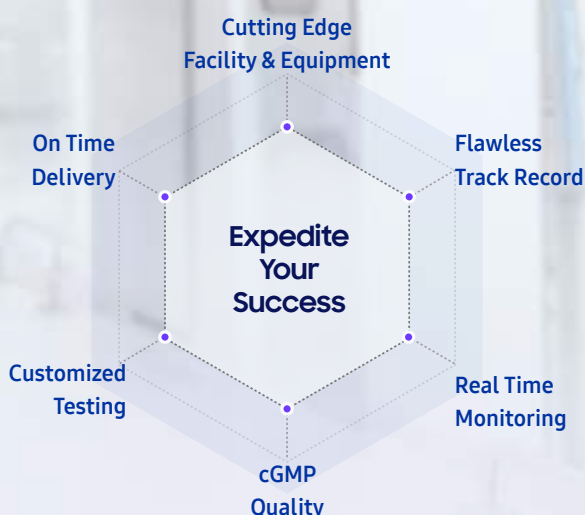


Accumulated No. of Approvals

*PMDA = Japanese Health Authority



Comprehensive CRO Testing Services



cGMP Quality and Control

- 60+ CMO Inspections & Approvals
- 600+ Successful Batch Releases
- FDA & MFDS Inspection (zero observations)

On Time Delivery

- 24/7 Equipment Monitoring System
- 24/7 Dedicated Sample Management System
- Online Testing Status Tracking System

Fully Tailored for Client Needs

- Flexible Turnaround Time
- Selectable Scope of Testing

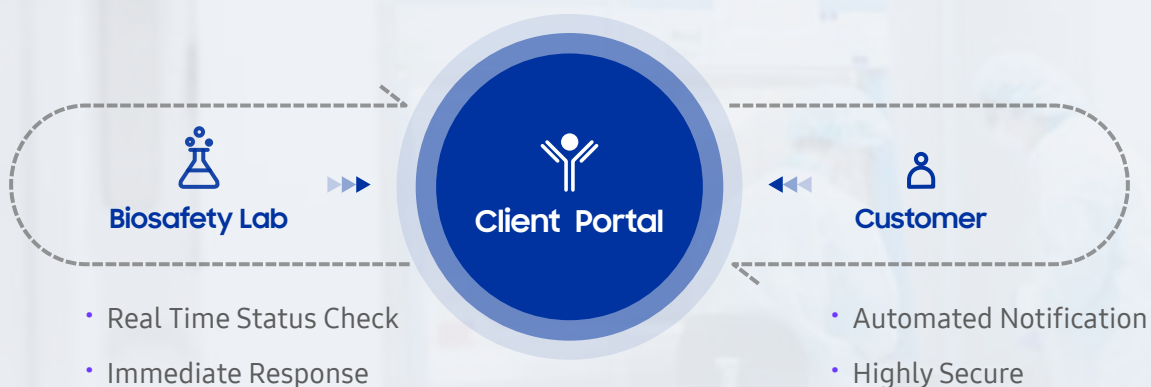
CRO Testing Capabilities

Service	Test	Feature
Biosafety Tests	Mycoplasma Detection	Culture , qPCR
	In-vitro Adventitious Virus Assay	Culture with 3 or 4 cell lines and viruses
	Viral Contaminants Detection	qPCR (Minute Virus of Mice)
Microbial Tests	Bioburden	Membrane Filtration, Direct Inoculation, Pour Plate
	Endotoxin	Chromogenic, Turbidimetric, Gel-clot
	Sterility	Membrane Filtration at Isolator
	Microbial Stability Study	Antimicrobial Effectiveness Test, Microbial Challenge Test
Batch Release Tests	General Characteristics	Appearance, pH, Osmolality, Particulate Matter
	Chemical Test	A280, Peptide Mapping, HPLC, N-Glycan Profiling
	Biological Test	Cell-Based Assay, ADCC, Antibody Proliferation
	Biochemical Test	SDS-PAGE, iCIEF, Host Cell DNA by qPCR, CE, Host Cell Protein ELISA

*Upcoming Services in 2022 | Viral Clearance, Cell Banking & Storage, Cell Line Characterization

Biosafety Testing Timeline Service

Expedited release and cost savings to enhance client satisfaction



Contact Us

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