LOTTE BIOLOGICS

Inquiries
Global : businessdevelopment@lotte.net
U.S. : businessdevelopmentandsales@lottebiologics.com

Possibilities Beyond Limits

LOTTE BIOLOGICS

Beyond Capacity Powered by Ownership

Turning the toughest timelines into first-to-market success

One client approached us with a highly compressed timeline after being unable to find a partner among other CDMOs. LOTTE Biologics took full ownership, working side by side with the client and aligning global teams across time zones. Together, we delivered all milestones and completed DS tech transfer in just 8.5 months—helping the client achieve a first-to-market position, with regulatory acceptance including from the FDA.

Proven Commercial Excellence

- 20+ years of GMP manufacturing experience
- 62+ regulatory approvals worldwide

Agile Mindset. Deep Innovator Legacy

- 8.5 months from sequence to DS Fill
- 45-day disposition timeline (30% faster than standard)

Dual Hub, One System

- One project, One partner
- Expedited internal tech transfer with one, unified quality management system

Best-in-Class Execution at Every Step

Many organizations offer end-to-end capabilities, but consistent execution across every stages is a challenge for the standard CDMO business model. We address this by partnering with leading specialists to deliver integrated, high-quality solutions across multiple modalities.
As a single point of contact, we help clients reduce complexity, avoid common pitfalls, and progress efficiently with greater confidence.

Modalities

Monoclonal Antibodies | Multi-specific Antibodies | Recombinant Proteins | Bioconjugation

Mammalian Production

Development & Tech Transfer

- RCB*, MCB, WCB
- Analytical & process development
- Process characterization
- Process validation

cGMP Manufacturing

- PPQ campaign
- Drug substance (DS) manufacturing
- Drug product (DP) manufacturing*

Quality & Regulatory

- Type V DMF
- QC release test
- Stability program ownership (DS/DP)
- Regulatory support

Bioconjugation

AXC Clinical and Commercial Manufacturing

- Linker and payload synthesis*
- cGMP linker and payload manufacturing*
- Bioconjugation process development
- Analytical development
- cGMP bioconjugate manufacturing
- Cryogenic storage

Quality & Regulatory

- QC release test
- Stability studies
- Regulatory support

*Via Strategic Partnerships

Mammalian Production Process

Cell Line Development*

Transfection* → Pool Generation & Isolation* → Clone Expansion & Ranking* → MCB, WCB Generation

Upstream Process

Vial Thaw → Cell Culture → Clarification or Harvest

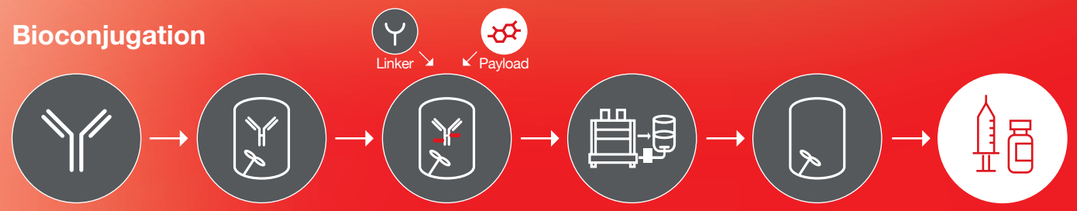
Stainless Steel Bioreactor
- Clinical : 1.1kL
- Commercial : 5kL, 15kL
- High-titer : 3kL

Continuous Centrifugation
Depth Filtration

Downstream Process

Aseptic Fill & Finish* ← Bulk Fill ← Purification ← Product Capture

Bioconjugation



Antibody

Antibody Reduction
- 100 - 1,000L single-use reactors
- TFF system

Conjugation / Quenching
- 100 - 1,000L single-use reactors
- Single use isolator

Purification
- Chrome 0.5 – 10L/min
- TFF system

Formulation / DS Fill
- Single-use TFF system
- Automated filling machine (bags or bottles)

Fill & Finish*

- 1-10L & 100-1,000L single-use mixers / - 6,700 L buffer prep and storage

*Via Strategic Partnerships

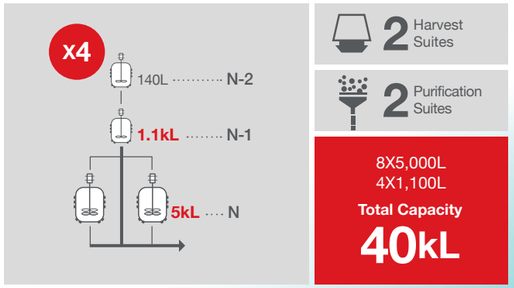
Dual Engines, Unified Expertise

From clinical to commercial, we provide a fully integrated scaling pathway—expanding through 5kL, and reaching 15kL manufacturing in Songdo.
This aligned network enables our clients to scale seamlessly, minimizing revalidation, avoiding process disruptions, and accelerating time to market.

Syracuse, New York, United States

Our Syracuse Bio Campus, originally built as an internal commercial manufacturing site for a leading global biopharma, brings firsthand experience in making critical outsourcing decisions. Notably, we operate eight 5kL stainless steel bioreactors—representing a strategic “sweet spot” between clinical and commercial scale that is rarely available in the U.S.
Built on this perspective and capability, we partner closely with our clients to stay aligned on what matters most—accelerating timelines, strengthening regulatory confidence, and ensuring a reliable, scalable supply chain.

Bioreactor Configuration



2 Harvest Suites

2 Purification Suites

8X5,000L
4X1,100L
Total Capacity
40kL

Regulatory Approvals
62+
As of 2025

Songdo, Incheon, South Korea

Our Songdo Bio Campus is a large-scale manufacturing site with eight 15kL bioreactors, purpose-built for commercial production. Programs can be seamlessly transferred from our Syracuse Bio Campus when larger-scale capacity is needed, ensuring a smooth and efficient scale-up.
Located in the Songdo bio cluster, the campus enables close collaboration with key vendors and partners, while the 15kL scale deliver clear cost of goods sold (COGS) advantages for high-volume manufacturing. As a newly built, state-of-the-art facility, it also features advanced digitalization for real-time monitoring, process simulation, and seamless scale-up/down.

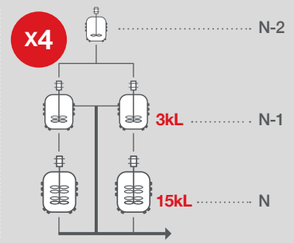
Gravity Flow Design

- 5F — **Fifth Floor** — Media / Buffer Prep.Room
- 4F — **Fourth Floor** — Quality Control Area, MSAT Area
- 3F — **Third Floor** — Bioreactor Hall, Media Hall Room
- 2F — **Second Floor** — Bioreactor Tech Core, Buffer Hall Room
- 1F — **First Floor** — Purification Area / Cold Room

Bioreactor Configuration

TiterFlex Quad™
Bioreactor System

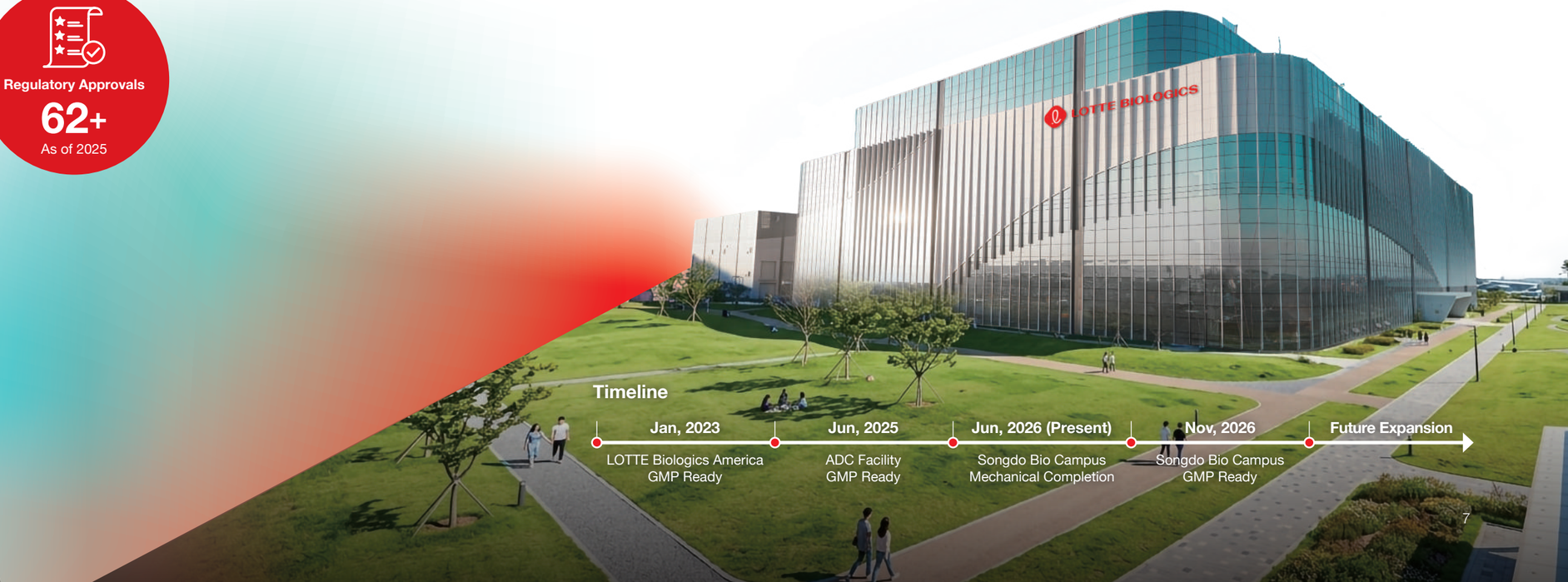
- For high titer products, **3kL bioreactors are utilized as production bioreactors**
- Production on a 2-day cadence is possible for most products currently under development



Both **ATF/TFF**

Real time monitoring **Raman**

8X15,000L
8X3,000L
Total Capacity
120kL



Timeline

- **Jan, 2023** — LOTTE Biologics America GMP Ready
- **Jun, 2025** — ADC Facility GMP Ready
- **Jun, 2026 (Present)** — Songdo Bio Campus Mechanical Completion
- **Nov, 2026** — Songdo Bio Campus GMP Ready
- **Future Expansion**

Ideas to IND

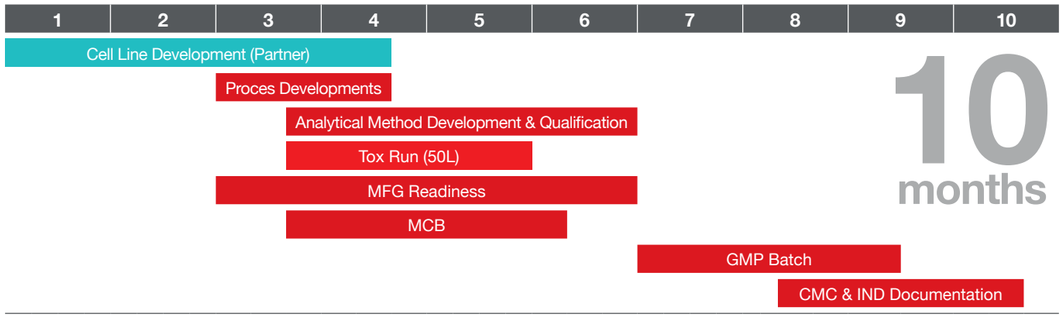
Turning Science into Clinical Reality

Clinical Production Service

Drug development is a long and unpredictable journey. What you need is not just a service provider, but a committed ally with an innovator's mindset.
At LOTTE Biologics, we combine proven scientific expertise, global dual-site integration, and a culture of partnership to de-risk your path and accelerate progress — delivering reliability, flexibility, and breakthrough impact for you and your patients.

Timeline

From CLD to IND in just 10 months, our seasoned experts deliver solutions you can count on – accelerating your journey with confidence.



Quality You Can Trust

Flexible Capacity You can Count on

Commercial Production Service

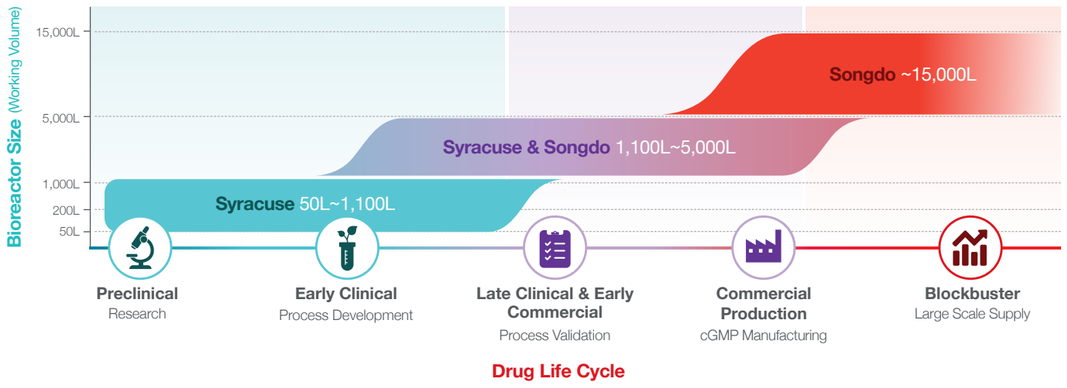
In an era of macroeconomic uncertainty, locking into large-scale capacity too early can expose biotech companies to unnecessary risk.
LOTTE Biologics offers a proven 5kL scale trusted by global innovators, and up to 15kL for fast commercial scale-up. By combining scale-out and scale-up in one integrated system, we give our partners the middle ground where science meets practicality — maximizing flexibility and ensuring programs move forward with speed and confidence, backed by robust quality systems and regulatory readiness across the globe.

Technology Transfer

We provide optimal and seamless internal tech transfer within 3-4 months, led by experienced experts who work closely with you to ensure your product is delivered on time.

Kick Off/ Gap Assessment → Verification Run or Small-Scale Run → Engineering Run → Clinical GMP → PPQ → Regulatory Approval

From Preclinical to Commercial Production



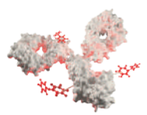
From Cell Culture to Conjugation

All at One U.S. Site

Flexible and High-quality Bioconjugation Manufacturing with Proven Biologics Expertise

Our bioconjugation manufacturing facility is designed and purpose built to support potent bioconjugates, up to OEL 5, through deep-rooted know-how in commercial biologics manufacturing, ensuring the highest standards in quality, consistency, and operational excellence. We fully leverage single-use systems to offer flexibility, rapid-changeover, and reduce contamination risk. The Syracuse Bio Campus is one of the few bioconjugation sites on the East Coast, providing strategic proximity for our partners and reducing time-to-clinic/market.

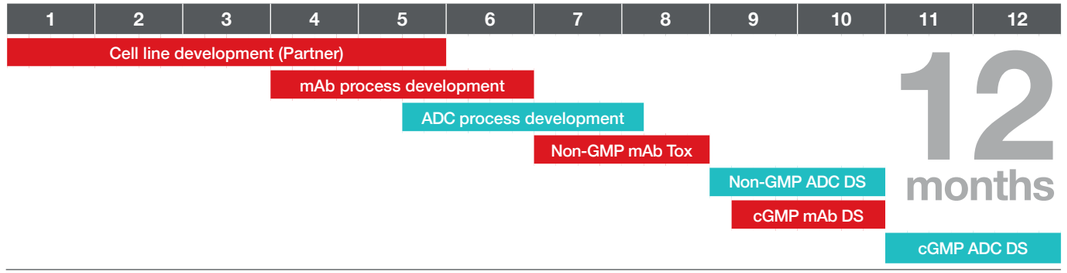
ADC Platform



SoluFlex Link™

- Enhanced solubility
- Improved PK and efficacy

Parallel Development Process for Antibody and Conjugation



Subject to Change

Bioconjugation Capabilities

Scope

- Conjugation of complex molecules including ADC, AOC, AXC

Capacity

- 100L-1,000L single-use reactors

Additional Capacity

- Redundancy built in for non-potent bioconjugates

Advantages of Using a State-of-the-art Single-use ADC Reactors

1. Scalability
2. High purity & maximized production yield
3. Minimize product loss and contamination

Warehouse & Cold Chain Storage

- 24/7 Real-time temperature monitoring & access control
- 59,400L Capacity in cryogenic storage
- Drug substance storage capabilities

- -20, -60, -80 °C Freezers
- 2-8 °C Cold rooms
- Five -40 °C walk-in freezers
- Freeze/Thawing equipment

High-Potency API Safety

- Industry-standard containment (OEL target 10 ng/m³) ensures safe handling of potent compounds

Quality & Compliance

- In-house QC, extended characterization, and regulatory expertise for global compliance

Scalable cGMP Manufacturing

- Flexible production of up to 1kL for clinical and commercial AXC drug substance

The Connected Experience: Zero-Distance Collaboration

We are advancing toward a fully integrated digital ecosystem where virtual and physical manufacturing environments are seamlessly connected. Data flows continuously across development, scale-up, and commercial manufacturing-enabling real time insight, proactive decision-making, and enhanced process robustness.

1

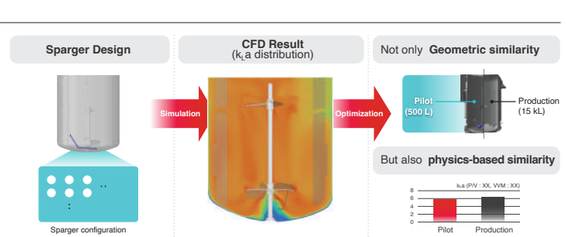
Real time transparent visibility for enhanced client confidence

Customer Service Platform

- Order Status
- Batch Record
- Quality Mgmt. Status
- Delivery Forecast
- Live Batch Tracking
- Analytic Data

2

Optimized scale-up and tech transfer



3

Global IT systems enabling standardized data management and technical transfer between sites

Digitalization Roadmap

Data Governance → **System Integration** → **Real-time Analysis** → **Digital Twin**

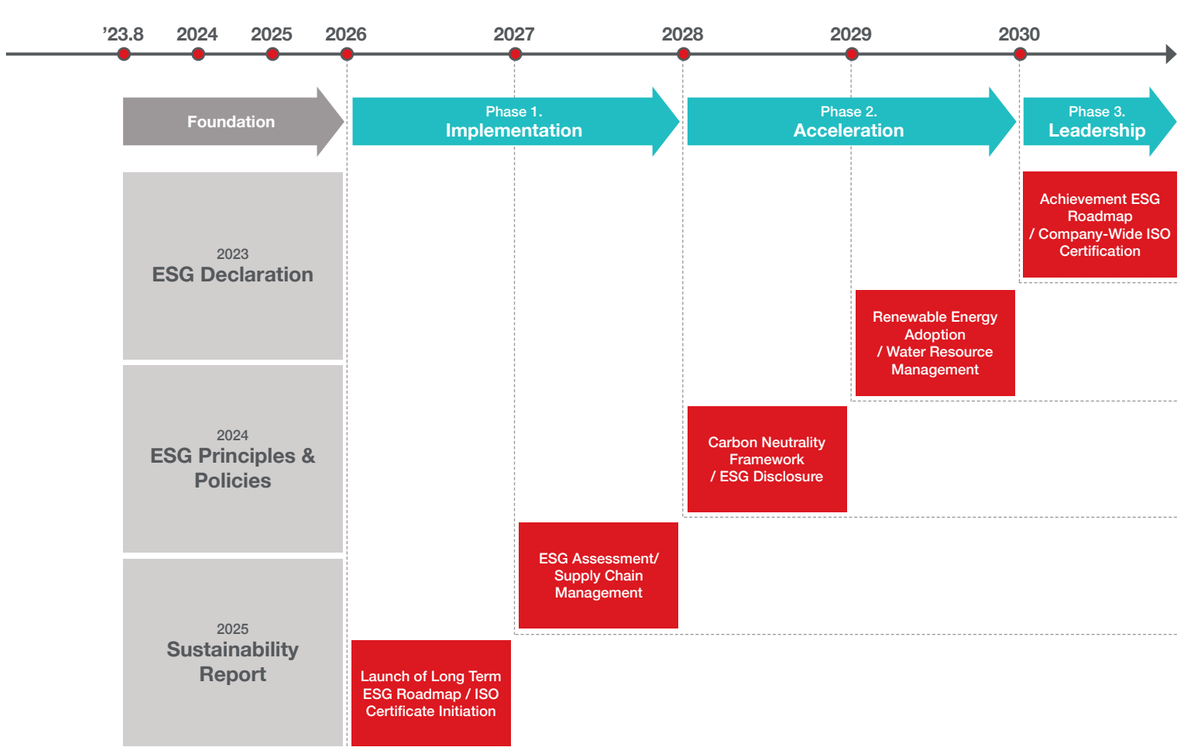
Enhancing control over process order and end-product quality through built-in data integrity.

Supporting rapid, automated, and data-driven decision making for manufacturing agility.

Creating a more visible and predictable pathway from tech transfer to commercial supply.

2030 Sustainability Management Roadmap

Since its 2023 ESG declaration, LOTTE Biologics has formalized policies on human rights, environment, safety, health, and ethics. For 2026-2030, it is implementing global standards through advancing carbon neutrality, expanding renewable energy and promoting biodiversity conservation



We are a CDMO that goes beyond service provider to work as one team with our partners, transforming ideas into expanding possibilities. Like light passing through a prism, our service, capabilities, and systems enable our partners' ideas to move forward with clarity and momentum.

"Possibilities Beyond Limits"

Songdo Bio Campus Plant 1

Mechanical Completion June 2026
GMP-Ready November 2026

Capacity

120,000L

Total Capacity in 2026

160,000L

(Songdo + Syracuse)