



LOTTE BIOLOGICS

NEW TODAY BETTER TOMORROW

Biologics CDMO Service

ABOUT LOTTE BIOLOGICS

LOTTE BIOLOGICS was established in 2022 and is headquartered in Seoul, South Korea. LOTTE BIOLOGICS will be entering the biologics CDMO business after acquiring Bristol Myers Squibb Syracuse biologics manufacturing site in 2022. This newly established organization aims to become a global top 10 CDMO in the biopharma industry.

With initial operations in 1948, LOTTE has grown to become the fifth-largest conglomerate corporation in South Korea. LOTTE has various business units, including petro/fine chemicals, food, retail, hotels, electronics, construction, and IT. LOTTE has 30+ global locations across the US, Europe, and Asia.



VISION

To Deliver Therapies that Enable a Healthier World

MISSION

To be the most trusted partner in the industry with high standards of quality and innovative technologies that reliably deliver benefits for patients worldwide.

CORE VALUES



Inspired by Science



Embracing Diversity



Fostering Talent



Connecting Lives

CEO Message

We are delighted to enter the biopharmaceutical manufacturing industry as a CDMO. The Syracuse plant, which has been a key player in manufacturing critical drugs during its long history, will continue to build on its legacy by serving as a foundation for LOTTE Biologics manufacturing operations.

The purchase of the fully operational Syracuse plant will allow LOTTE Biologics to immediately provide services as a CDMO. While we will continue to manufacture the site's current products, we will also introduce new products, consider expansions into new technologies, and broaden the scope of our CDMO services to meet the needs of prospective customers.

LOTTE Biologics, Chief Executive Officer

Richard W. Lee

RICHARD LEE



LEADERSHIP TEAM

Executive Committee

Michael C. Hausladen, Ph.D.

General Manager of LOTTE Biologics USA

The State of University of New York at Buffalo, B.S., M.S. and Ph.D. in Chemical Engineering

Former Activities and Functions

- Bristol Myers Squibb, Senior Director of Cell Therapy Facility
- Bristol Myers Squibb, Director of Drug Substance Technology, External Manufacturing

Richard Schicho, Ph.D.

Corporate Advisor of LOTTE Biologics

Johns Hopkins University, Ph.D. in Chemical Engineering
Duke University, B.S. in Chemistry

Former Activities and Functions

- Takeda Pharmaceutical, Director of Manufacturing Science and Technology
- Bristol Myers Squibb, Associate Director of Manufacturing Technology

Jong Soo Ha

Vice President and Chief Financial Officer of LOTTE Biologics

Sogang University, MBA
Dong-A University, B.A. in business administration

Former Activities and Functions

- LOTTE Global Logistics, Head of SCM Business Division

Board of Directors

Hun Ki Lee

**Executive Chairman of LOTTE Biologics
Chief Strategic Officer of LOTTE Corporation**

Seoul National University, B.A. in Chemical Engineering

Former Activities and Functions

- LOTTE Rental, CEO
- LOTTE Chemical Titan, CEO
- LOTTE Chemical Corporation, R&D, Business Strategy

Hyun Joon Paek, Ph.D.

Board Member of LOTTE Biologics

Kyoto University, Master's in Polymer Chemistry
Brown University, Ph.D. in Biomedical Science
Waseda University Business School, MBA

Former Activities and Functions

- Abrax Japan, Chief Operating Officer
- Axil Capital Advisors, Principal
- Metcela, Vice President, Corporate Development
- Tissue Genesis, LLC, Director of R&D



The site acquisition agreement has been executed between Bristol Myers Squibb and LOTTE, and is awaiting regulatory approvals. The Syracuse site is currently under BMS ownership and control until the deal closing in the second half of 2022.

MANUFACTURING FACILITY OVERVIEW

LOTTE BIOLOGICS will offer biologics drug substance manufacturing services with 35,000L of production bioreactor capacity utilizing stainless steel bioreactors, analytical QC testing laboratories, and warehouse.

Site Overview

(The site remains under BMS ownership and control until the deal closing by the second half of 2022)

- Comprehensive end-to-end biologic drug substance capabilities, including an on-site cell bank facility and cryogenic storage of drug substance
- Designed to support concurrent manufacturing of multiple products with minimal product change over time
- Robust manufacturing support services on-site including End-to-End MS&T* capabilities, procurement, quality assurance & control, environmental, health and safety, engineering, and enabling functions such as HR and finance
- Regulatory compliance track records with approval by 62+ Health Authorities worldwide including FDA, EMA, PMDA and MFDS

*MS&T = Manufacturing Science and Technology



Manufacturing Capabilities



3

Inoculum Suites



7

5,000 Liter Stainless Steel Bioreactors



2

Purification Suites



59,400 Liter

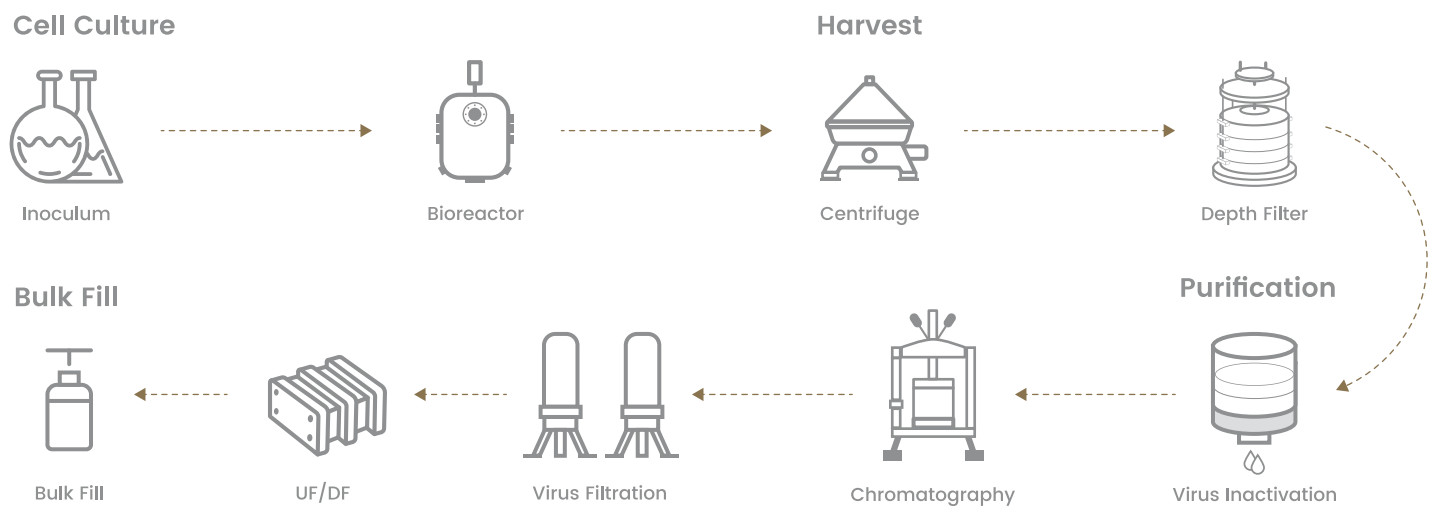
Capacity in Cryogenic Storage



cGMP Manufacturing

Upon obtaining all necessary regulatory approvals and completing the closing conditions, LOTTE BIOLOGICS will provide cGMP manufacturing services for clinical and commercial supply of Biologics Drug Substance. The state-of-art Syracuse facility will support three independent inoculation suites and two purification suites to accommodate multi-product operations. In addition, highly talented and experienced workforces will deliver quality products on-time.

Manufacturing Process



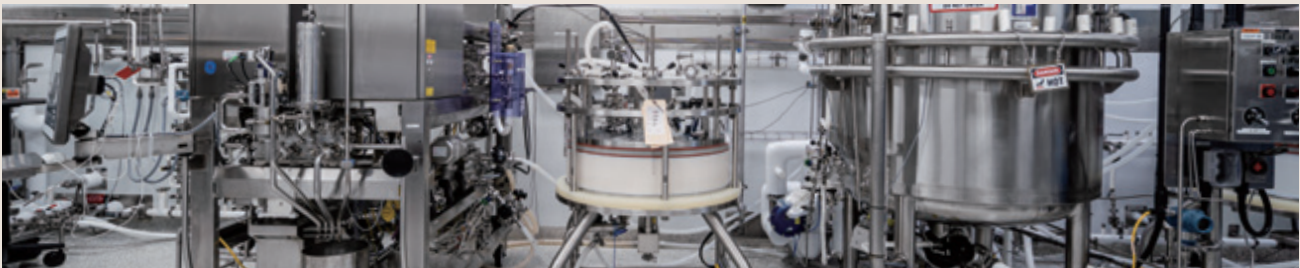
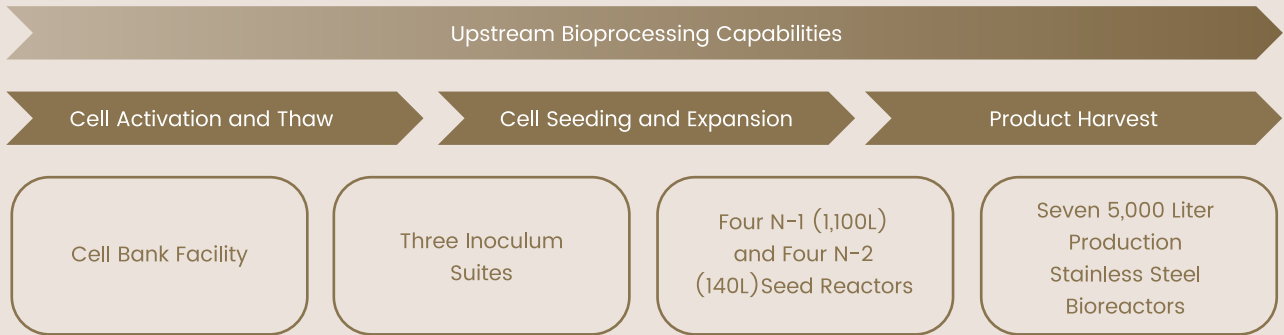
Cell Banking and Inoculum

- Cell banking capabilities to support the following:
 - Cell line development along with, clinical and commercial cell banking
 - Liquid nitrogen storage of cell banks in vapor phase at -190°C and storage capacity of 7,300 vials
- Inoculum capabilities:
 - Three inoculation suites equipped with biosafety cabinet and incubators capable of separate products
 - Flexible design to accommodate single-use system and cleanable/reusable equipment



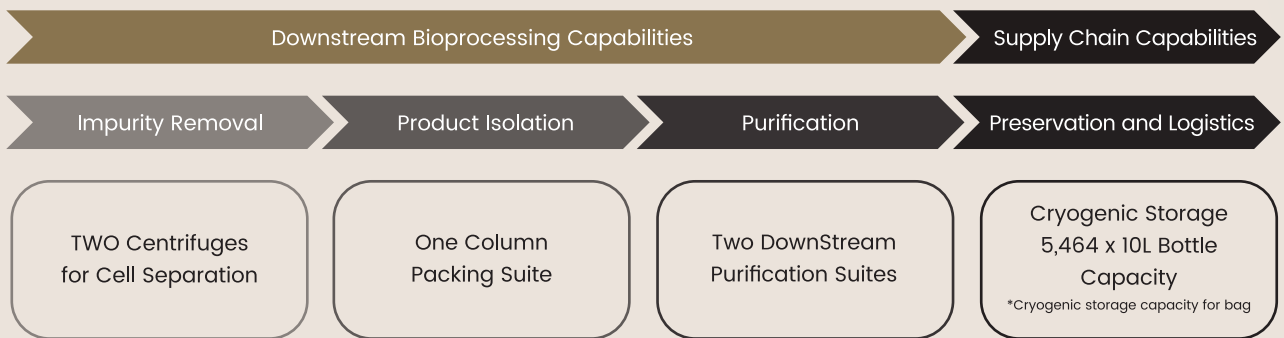
Upstream Process

- Upstream bioprocessing capabilities to support clinical and commercial-scale production
- Four trains consisting of 140L and 1,100L seed culture reactors with the ability to use the 1,100L as production bioreactor



Downstream Process

- Downstream bioprocessing and supply chain capabilities to support clinical and commercial-scale production
- Dedicated column packing and unpacking suite for supporting multi-product operations



Equipment Capabilities

Inoculation	Upstream	Downstream
<ul style="list-style-type: none">• Cell Bank Freezer• Biosafety Cabinet• Incubator Shaker	<ul style="list-style-type: none">• 140Lx4EA Stainless steel bioreactors• 1,100L x 4EA Stainless steel bioreactors• 5,000L x 7EA Stainless steel bioreactors	<ul style="list-style-type: none">• Centrifugation system (GEA)• 400–1,000mm Chromatography column• AKTA chromatography system (Cytiva)• Buffer (500–2,000L) and product vessels (100–2,000L)



Manufacturing Science and Technology

LOTTE BIOLOGICS will offer development service capabilities across the product life cycle management including product launches, scale-down/scale-up model development, continuous process verification and enable technology transfers (upon obtaining all necessary regulatory approvals and completing the closing conditions)

Manufacturing, Science and Technology team at the East Syracuse site is highly experienced in technology transfer and manufacturing process support of mammalian cell culture and purification processes.

- Product stewardship for the products manufactured at the site and new processes/product introductions to the facility through experience enabling rapid process validation activities
- 24/7 day-to-day technical strategic leadership, troubleshooting and scientific expertise
- Technical support and life-cycle management from development through commercial products
- Provide resolution of process deviations/investigations and implementation of Corrective Action/Preventative Action (CAPA)
- Design and support execution of laboratory-scale studies to manufacturing scale
- Facility fit and technology transfer execution with speed, enabling rapid product commercialization, and ensuring uninterrupted supply of product
- CMC strategy and authorship experience developing and transferring processes and methods in-house and to CMOs

List of Current Equipment for Process and Analytical Development at the East Syracuse Site

- 5-20L Lab-scale bioreactors
- 50-140L stainless steel and single use mixers (Media preparation)
- Wave Cell Bag Mixers
- Incubator shakers
- AKTA purifiers and TFF systems
- BioProfile FLEX Analyzers (Nova BioProfile), Vi-Cell cell viability analyzers
- HPLCs (Waters-Empower System), TOC analyzers, automated ELISA systems, BIACORE, UV/Vis spectrophotometers
- Densitometers, CARY, SoloVPE, Gly-Q analyzer, plate readers, iCE3, Tecans, mass spectrometers
- Milli Q Water system, Particle sizer, Nanodrop
- Plate washers, Quant Studio 7 PCR system, viscometer
- -40, -70, -86°C Freezer / Walk-in cold room (2-8°C)
- Biosafety Cabinets
- Cryogenic freezers and nitrogen dewars



Quality Control

LOTTE BIOLOGICS will offer a fully GMP-approved quality control testing laboratory with analytical services, including in-process, finished product, and stability testing (upon obtaining all necessary regulatory approvals and completing the closing conditions)

Analytical Service Capabilities

- Incoming raw materials testing
- In-process testing (pH, purity, protein concentration, bioactivity, etc. as appropriate)
- Drug substance release testing
- UV Absorbance
- HPLC/UPLC, GC (Gas Chromatography)
- Microbiological testing (Endotoxin, Bioburden)
- Microbial identification
- TOC (Total Organic Carbon)
- SDS-PAGE, Immuno-blotting (Western blots)
- Impurity Analysis (ICP-MS)
- Cell-based potency
- Stability testing
- ELISA (Enzyme-Linked Immunosorbent Assay)
- MODA-EM® Paperless QC Microbiology



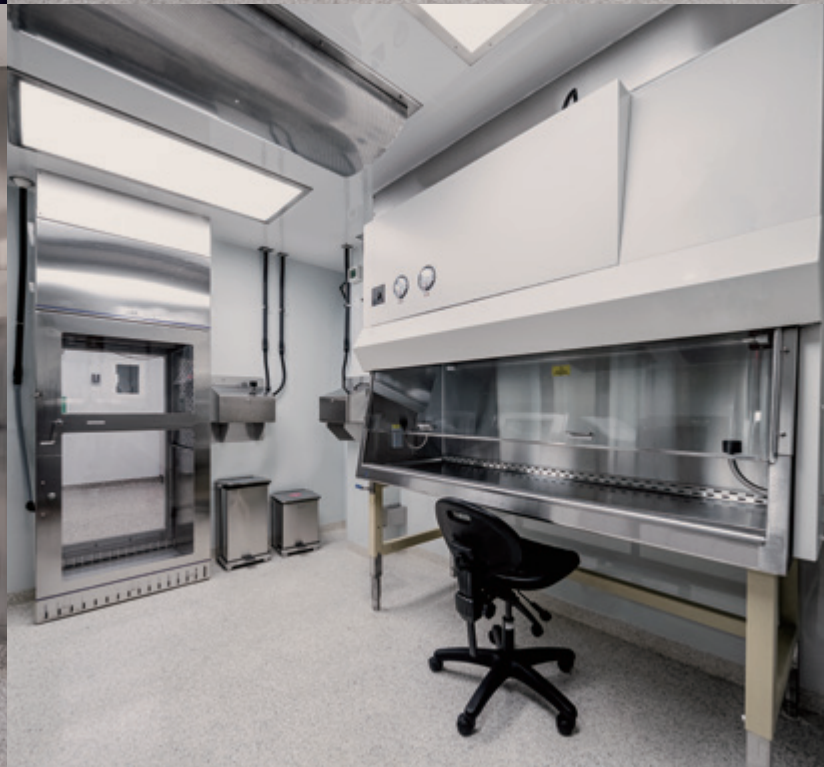


Quality and Regulatory Compliance

Quality and regulatory compliance is our top priority at LOTTE BIOLOGICS
LOTTE BIOLOGICS is committed to provide the highest quality products to our customers



LOTTE BIOLOGICS





**NEW TODAY
BETTER TOMORROW**

LOTTE BIOLOGICS Manufacturing Capabilities ¹

Inoculation



Three
Inoculation Suites

Cell Culture



35,000L
Stainless Steel Bioreactors
(5kLx7EA)

Purification



Two
Purification Suites

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The Syracuse site is currently under BMS ownership and control until the deal closing in the second half of 2022.

Food



Retail



Chemical / Construction / Manufacturing



Tourism / Service / Finance



**Major
LOTTE
Companies**
(85 Subsidiaries Total)

LOTTE BIOLOGICS

Headquarters

LOTTE World Tower, 300 Olympic-ro,
Songpa-gu, Seoul, Korea 05551
Tel. +82-2-3213-8250
Email: businessdevelopment@lotte.net



www.lottebiologics.com