BioCentriq™

An Entrepreneurial CDMO for Cell Therapy

Patient-Focused. Experienced. Collaborative.

BioCentriq®

Vision

To be an industry-leading cell therapy CDMO improving access to and affordability of life-changing therapies

Mission

To accelerate delivery of innovative cell therapies by translating, optimizing, and scaling processes for GMP manufacture

Our Story

New Jersey Innovation Institute

NJIT funds construction of GMP facility

2016

2019-2020

Established strategic partnerships with industry leading organizations

NIMBL PALL McKinsey & Company TERUMO KYTOPEN

BioCentriq™

BioCentriq opens its Newark, NJ GMP manufacturing facility

2020

2021

GMP Manufacturing commences

GC

GC acquires BioCentriq for $73M. Provides full backing of BioCentriq ventures

2022

2023

Continued successful manufacture and release of GMP drug product

LEAP™ Platform

LEAP CAR-T

LEAP NK

Series A

$29.2M Raised

2024

BioCentriq®

BioCentriq Value Proposition

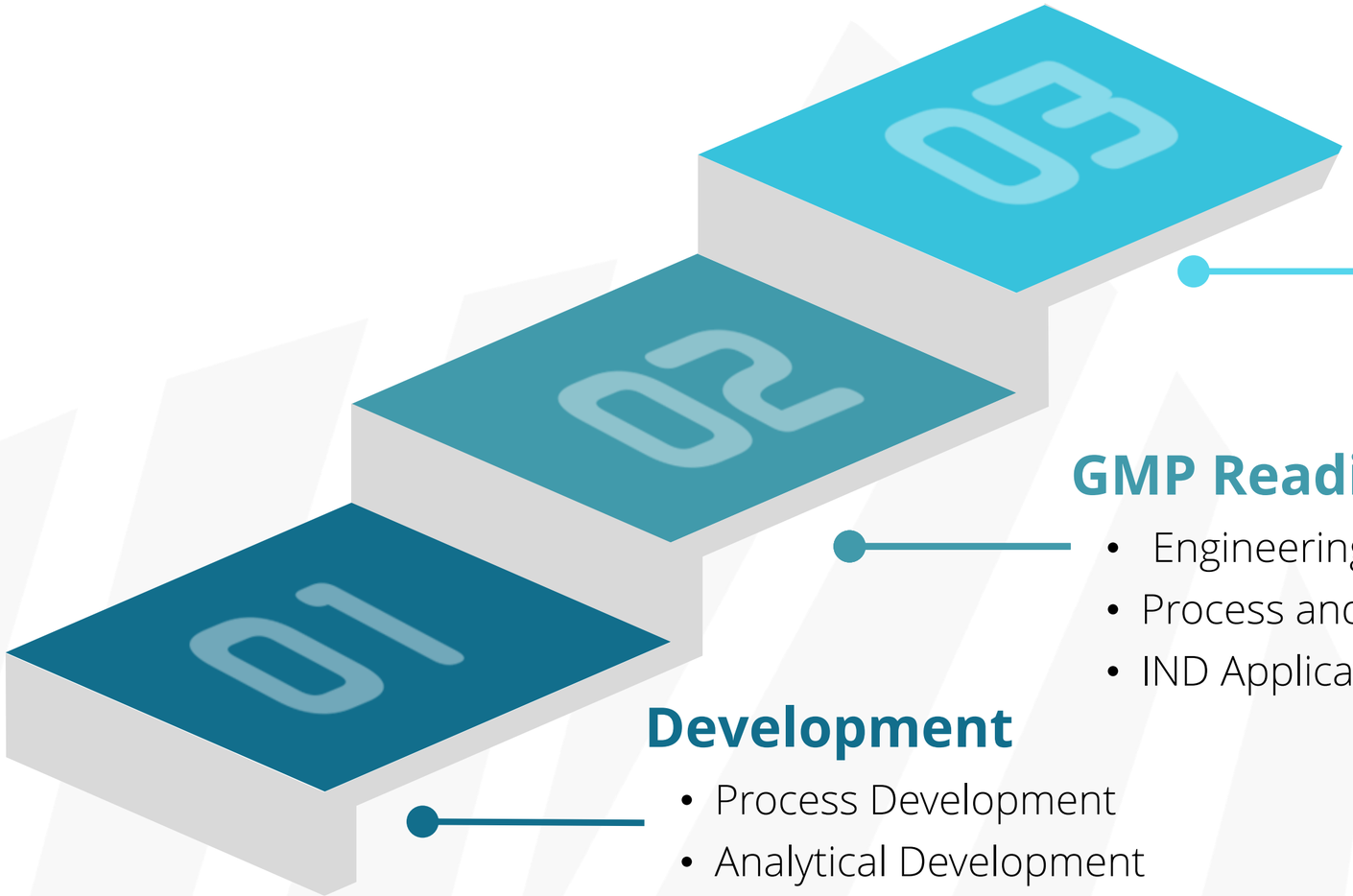
Patient-centricity is our commitment. Delivering excellence is our service promise.

- Global CDMO specializing in cell banking and autologous and allogeneic cell therapies
- State-of-the-art facilities with flexible, phase-appropriate quality management systems
- Proven track record developing, manufacturing, and releasing GMP drug product
- Industry-leading executive, technical, and business development teams
- Committed to accelerating project timelines and reducing cost
- Strong strategic partnerships to facilitate and foster innovation

BioCentriq®

Providing Services throughout the Product Lifecycle

Reliable approach to translating processes from the bench to the clinic



GMP Manufacturing

- Phase I, II and III
- FDA Compliant Production
- Drug Product Release and Storage

GMP Readiness & CMC Support

- Engineering & Comparability
- Process and Method Qualification
- IND Application/ CMC

Development

- Process Development
- Analytical Development
- Feasibility & Pilot Runs

BioCentriq®

Proven Track Record across Services

Extensive expertise in multiple therapeutic applications and cell types

Successful manufacture and release of GMP drug product

Successful creation of GMP Master Cell Banks and Working Cell Banks

Integration of the latest enabling technologies

Kytopen FlowFect, Terumo Quantum Flex,

Experience across multiple cell types and unit operations

T Cells, NK Cells, MSC, HSC, Dendritic Cells, iPSC, Epithelial Cells, Extracellular Vesicles

BioCentriq's North American Footprint

New Jersey

GMP Manufacturing

- Four Grade-B/ISO-7 GMP suites designed for cell therapy manufacturing
- Multiproduct facility with separate air-handlers, 24x7 monitored EMS & BMS
- Purpose built for advanced Person in Plant

Technology Transfer (MSAT) & Process Development

- Outfitted with a range of the latest process and analytical technologies
- LEAP Advanced Therapy Platform

Quality Control Labs: Dedicated analytical testing labs with in-house methods

Storage and Warehousing:

- Temperature-controlled storage for ambient, refrigerated, and frozen materials
- Fully validated chain of custody (COC) processes ensuring material integrity

Training Laboratories: Dedicated space at the Newark location with six BSCs, mock gowning area, and classroom facilities.

BioCentriq®

Asia Pacific Footprint

Seoul

GMP Manufacturing

- 224,000 sq. ft. facility footprint
- 14 Grade-B/ISO-7 GMP suites designed for cell therapy manufacturing
- Clinical through Commercial. 17-year track record
- 18,000 commercial lots per year. Total 72,400 lots completed
- Technology Transfer (MSAT) & Process Development

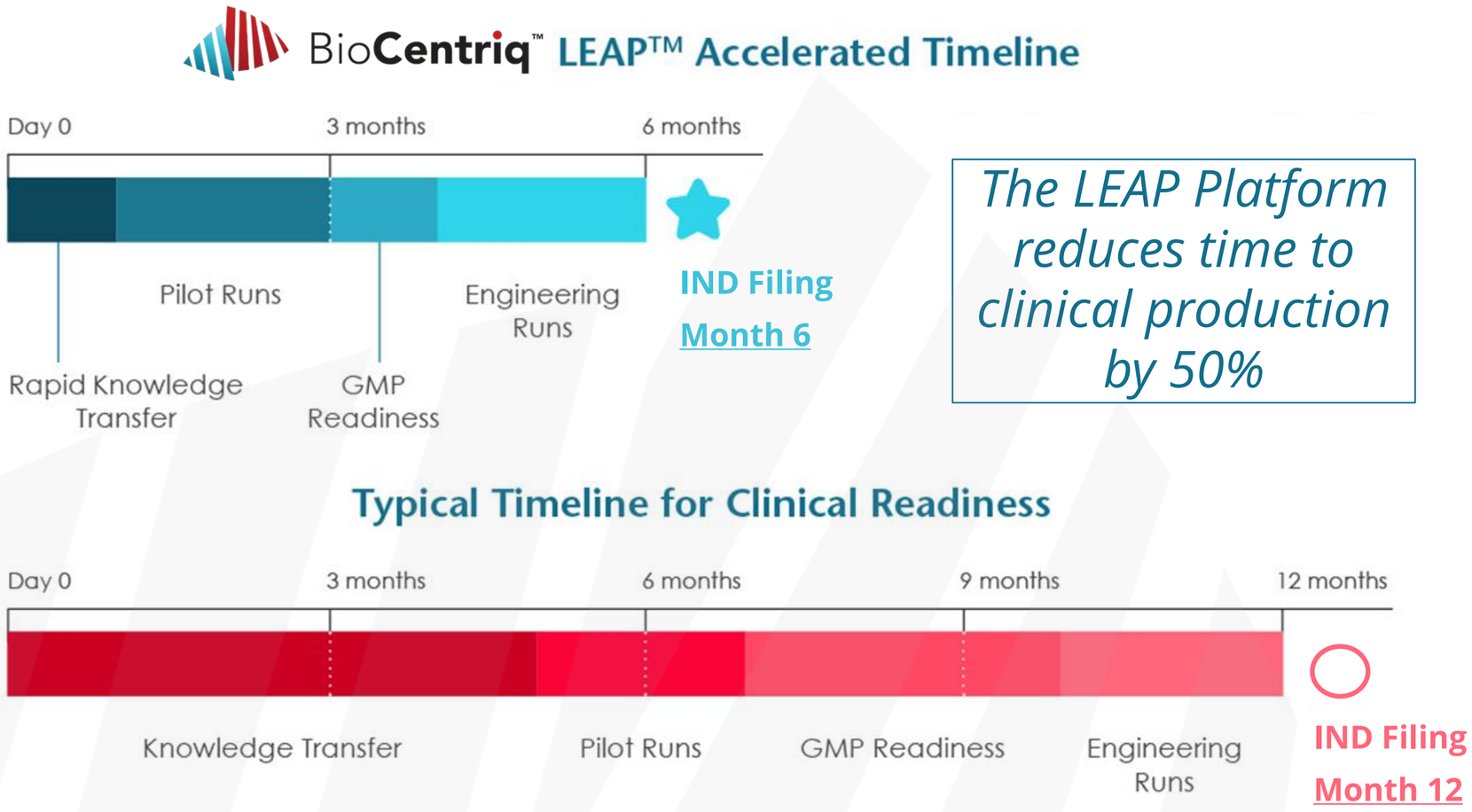
Global Logistics

- Established vaccine distribution network includes 45 countries and 286 cities across the globe

Capacity Update

- Accepting new projects with 1–2-months lead time

The LEAP Platform Accelerates the Path to the Clinic



The LEAP Platform reduces time to clinical production by 50%

- Reduces process development and scale-up timelines
- De-risks clinical trials
- Leverages experienced, industry-leading, tech transfer and manufacturing teams
- Utilizes pre-existing protocols, methods, reports and batch records

BioCentriq®

Project Turnaround Times to Get into GMP

Detailed Gap Assessment Provided at Project Kick-Off

Project Initiation Lead time: ***1 month***
Industry Average: ***2-3 months***

PD/Pilot Run(s) Lead time: ***2 months***
Industry Average: ***4-5 months***

GMP Facility Lead Time: ***4 months***
Industry Average: ***6-8 months***

GMP Rooms available in the next 12 months: ***1.5 Rooms***

LEAP Platform Gets You to IND Submission Sooner

- Pre-designed workflow mimics client process
- Advance-draft batch records
- Fully trained manufacturing personnel
  - Technical SMEs (MS&T) works hand in hand with Operations personnel.
    - Observe pilot runs
    - Hands-on unit ops training in development space
- Fully equipped GMP suites with qualified equipment
  - Multi-functional automated equipment
  - Proven experience using with multiple cell types
- Analytical method suitability
- Environmental monitoring
- Advanced-draft CMC package outline

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LEAP CAR-T Platform

Wash/T Cell Isolation	T Cell Activation	Transgene Insertion	Cell Expansion	Final Fill & Formulation

• Manual
  • Kits
  • Beads
• Prodigy & Plus
• Lovo
• Rotea
	• Lentivirus
	• Retrovirus
	• MaxCyte
	• Nucleofector
	• Neon/Xenon
	• Kytopen
		• GRex
		• Quantum Flex
		• Xuri
		• Prodigy
			• Finia
			• CRF
			• Manual	

In Process & Release Analytics: Cell counts, flow cytometry, ELISA, PCR

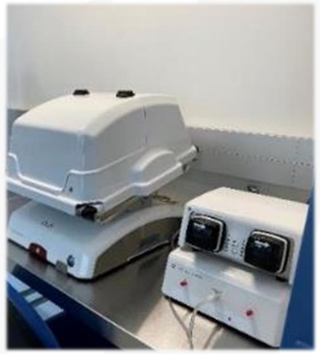
Environmental Monitoring

Process Capabilities

Upstream: Thaw, Selection, Washing, Gene Modification (Viral or Nonviral)

Culture: Adherent, Suspension (15mL-200L)

Downstream: Washing, Buffer Exchange, Formulation and Fill, Cryopreservation



Cytiva Xuri

Miltenyi CliniMACS Prodigy

Terumo Quantum Flex

MaxCyte GTx

ThermoFisher Rotea

Terumo FINIA

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Analytical Capabilities

Dose: Cell count & viability, ddPCR

Identity: PCR, gene expression, SDS-PAGE, flow cytometry

Potency Testing: Proliferation, cytotoxicity, ELISA, enzyme activity, viral vector titer

Purity Testing: Identification, metabolites, endotoxin, residual host cell DNA, residual host protein

Outsource Testing: Sterility, NGS, bioburden, STR, mycoplasma, etc.

NC-200 Cell Counter

Vi-CELL BLU Cell Counter

BD CytoFLEX Flow Cytometer

Bio-Rad QX200 ddPCR System

Varioskan LUX Plate Reader

Nova FLEX2 Analyzer

BioCentriq®

Commitment to Quality: Our Foundation for Success

BioCentriq has been successfully producing GMP drug product for use in human clinical trials since 2022

Quality Operations

Manage Client QA Relationship
Manage Floor Support (BR, RM, etc.)
Qualifications
Validations

Quality Control

Environmental Monitoring
Microbiology Testing
Analytical Testing
Stability
Data Integrity

Quality Systems

Training
Documentation
QRM
Deviation, CAPA, CCs,

Compliance

Inspection Management
Management Review
Quality Planning
Site Quality Manual
Site Master File

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Global CDMO specializing in cell banking and autologous and allogeneic cell therapies.

State-of-the-art facilities with flexible, phase-appropriate quality management systems in US and Korea

Proven track record developing, manufacturing, and releasing GMP drug product

Industry-leading executive, technical, and business development teams with specialized expertise in cell therapy

Committed to accelerating project timelines and reducing cost

Strong strategic partnerships to facilitate and foster innovation in cell therapy manufacturing

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