
BioCentriq™

# A Global Cell Therapy CDMO

*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

# BioCentriq's History and Milestones

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

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BioCentriq opens its Newark, NJ GMP manufacturing facility

**2020**

**2021**

GMP Manufacturing commences

AVENGE BIO

GC

GC acquires BioCentriq for $73M

**2022**

**2023**

Continued successful manufacture and release of GMP drug product

**LEAP™ Platform**

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# Experienced and Dedicated Leadership Team

130+ years of combined leadership experience in therapeutic discovery, development and commercialization

**James Park**

*Interim CEO*

SAMSUNG BIOLOGICS

Bristol Myers Squibb™

**Jackie Panter**

*Chief Quality & Compliance Officer*

MINARIS REGENERATIVE MEDICINE

LEGEND BIOTECH

**David Smith, Ph.D.**

*VP, Development*

Oribiotech MINARIS REGENERATIVE MEDICINE

**Mark Broadley**

*VP, Operations*

ZIMMER BIOMET

charles river

Cognate BioServices, Inc.

**Alex Klarer**

*VP, Business Strategy & Innovation*

MINARIS REGENERATIVE MEDICINE

Genentech

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# Our Team is Committed to Cell Therapy

80+ full-time employees and growing

Seasoned personnel with direct experience in the following:

- Process Development
- Analytical Development
- GMP Manufacturing
- MS&T
- Program Management
- Quality Control
- Quality Assurance
- Regulatory and Compliance
- Supply Chain Management


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# 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

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# A Global CDMO with State-of-the-Art Facilities

Reaching patients world-wide through a global footprint including 14 GMP manufacturing suites

## North America

### Princeton Corporate Plaza

South Brunswick, NJ

2 GMP Manufacturing Suites, Pilot Plant, AMD, PD and QC Labs, Plus Supporting Infrastructure

### Life Science & Engineering Center

Newark, NJ

2 GMP Manufacturing Suites, Pilot Plant, AMD, PD and QC Labs, Plus Supporting Infrastructure

## APAC

### Cell Center

Seoul, S. Korea

10 GMP Manufacturing Suites, Pilot Plant, AMD, PD and QC Labs, Plus Supporting Infrastructure

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# North America GMP Infrastructure

| | Newark (NJ) | South Brunswick (NJ) | South Brunswick (NJ) "Suite G" *Expansion Opportunity* |
|---|---|---|---|
| **Airport proximity** | EWR, JFK, LGA | EWR, JFK, LGA, WOU | EWR, JFK, LGA |
| **Total Facility Size** | ~ 17,382 sq. ft. | ~8,517 sq. ft. | ~12,272 sq. ft. |
| **Cleanrooms** | 2 | 2 | 0 |
| **Manufacturing Development** | Yes | Yes | TBD |
| **GMP Manufacturing** | Yes | Yes | TBD |
| **Cryostorage Facility** | Yes | Yes | TBD |
| **Backup Power** | Yes | Yes | TBD |



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# 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

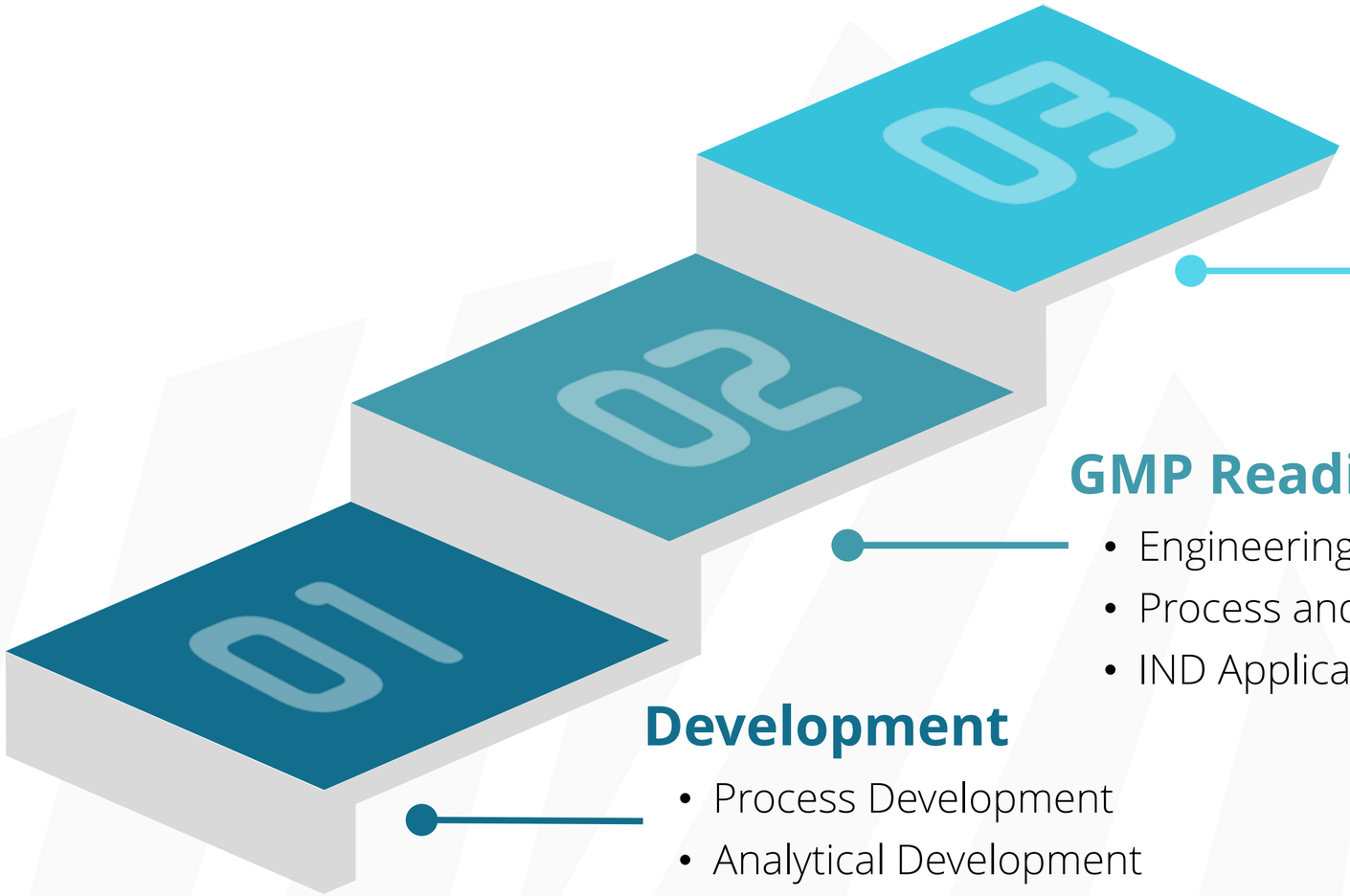
HaloLens, Kytopen FlowFect, Terumo Quantum Flex

Experience across multiple cell types and unit operations

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

# 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/EU Compliant Production
- Drug Product Release and Storage

## GMP Readiness & CMC Support

- Engineering Runs
- Process and Method Qualification
- IND Application

## Development

- Process Development
- Analytical Development
- Feasibility & Pilot Runs



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# Experienced Development and MS&T Teams

Work collaboratively with our partners to refine and optimize phase-appropriate GMP processes

- Identify and resolve process or analytical development constraints
- Define the process and generate CMC data with QbD Principles
- Provide comparability and quality risk assessments throughout development
- Current with FDA guidance to ensure efficient and compliant technology transfer, IND approval, and clinical production
- Engage early with MS&T and Manufacturing to ensure GMP readiness and reduce technology transfer timelines

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# Thought Leadership in CAR-T Manufacturing

- Through collaboration and innovation, BioCentriq is dedicated to evaluating emerging process technology and platforms to create the next generation of manufacturing solutions.
- BioCentriq team members are actively involved in efforts to progress CAR-T manufacturing methods with the goal of increasing process robustness and product quality.

Molecular Therapy
**Methods & Clinical Development**
Original Article

Clinically relevant T cell expansion media activate distinct metabolic programs uncoupled from cellular function

**Efficient, Large-Scale Transfection of T-cells USING FLOWFECT® TECHNOLOGY**

BioCentriq Release Study Results

Advancing the robust manufacture of t-cell therapies through the application of stirred tank bioreactors

Cytotherapy, Volume 21, Issue 5, Supplement, May 2019, Page S36

Improving the quality cell yield of T-cell immunotherapies through selective pressures imparted by culture media supplements

Cell & Gene Therapy Insights 2020; 6(2), 287–294

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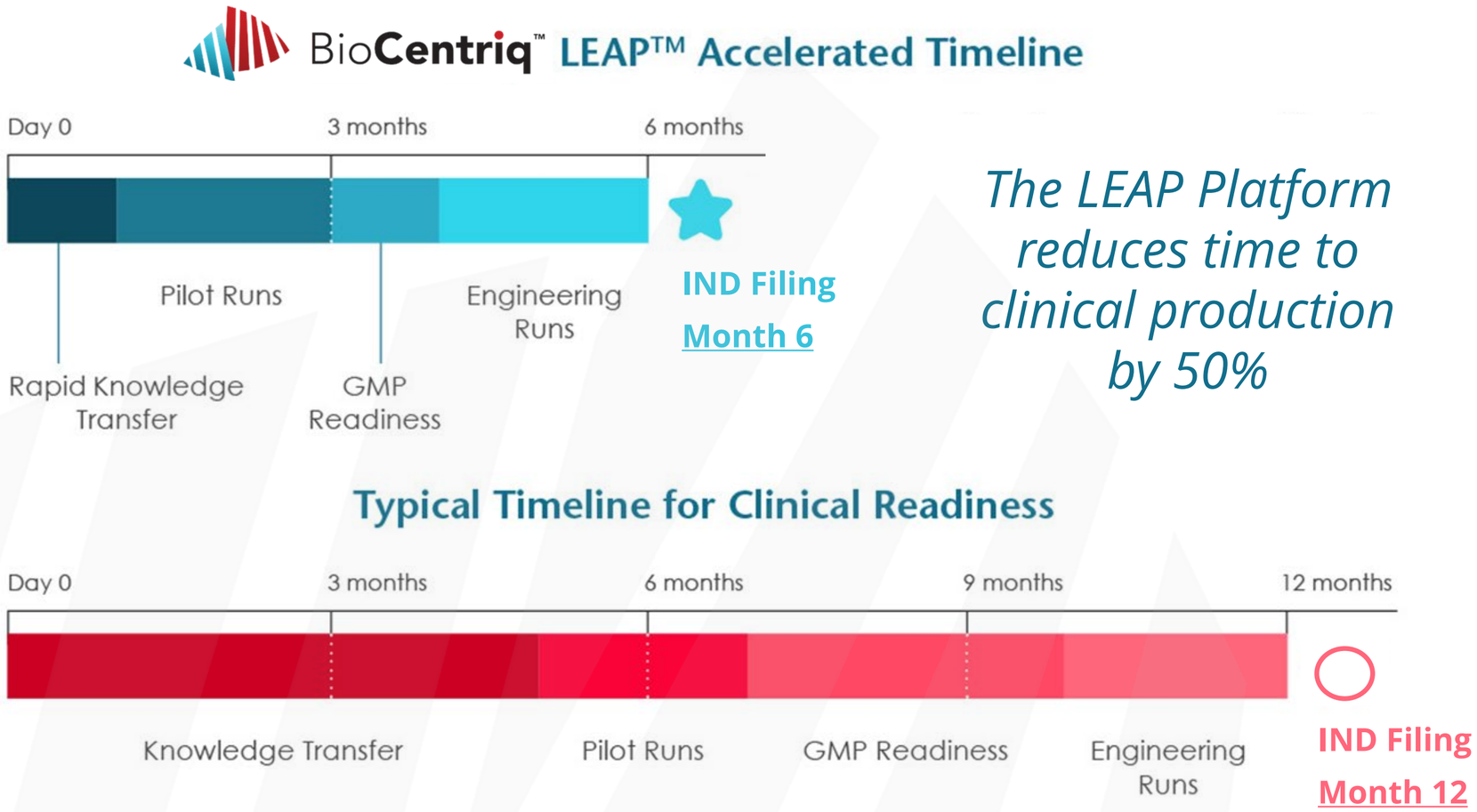
# The LEAP Platform Accelerates the Path to the Clinic




*The LEAP Platform reduces time to clinical production by 50%*

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

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# Small- to Large-Scale Development Expertise



## Suspension Cell Systems

CAR-T / TCR / TIL
NK Cell
iPSC
HEK293T
K562

## Adherent Cell Systems

MSC
HEK293
Monocytes/Dendritic Cells
Macrophages

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# 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**

**Pall**
**Allegro STR-50, 200**

**Cytiva**
**AKTA Pilot 600**

**Terumo**
**Quantum Flex**

**Repligen**
**KrosFlo KMPi**

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# Analytical Capabilities

**Dose:** Cell count & viability, ddPCR

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

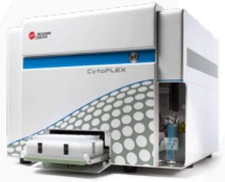
**Potency Testing:** Proliferation, cytotoxicity, ELISA, enzyme activity, viral vector titer

**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**

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# Roadmap to GMP Manufacturing

## Technology Transfer

- Knowledge Transfer
- Process Development
- Pilot Runs/Training
- Engineering Runs
- APS Runs
- Analytical Method Transfer
- Analytical Method Feasibility
- Method Qualification
- Client IND Review

→ GMP Manufacturing

- Gap & Risk Assessment
- Quality Target Product Profile (QTPP)
- Critical Quality Attributes (CQA)
- Critical Process Parameters (CPP)
- Critical Material Attributes (CMA)
- Process & Testing Unit Operation (PUO, TUO)

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# 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

BioCentriq produces safe and effective GMP drug product ensuring all activities are conducted in a controlled and transparent manner with the appropriate supporting documentation

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# Why BioCentriq?

We have the experience, capabilities, and commitment you need

- Proven track record developing, manufacturing, and releasing GMP drug product
- Robust, phase-appropriate quality systems
- Global footprint with state-of-the-art development and manufacturing facilities in the US and Korea
- Commitment to accelerating project timelines and reducing cost
- Experienced teams with specialized expertise in cell therapy
- Established strategic partnerships to facilitate and foster innovation



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