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Enabling a Healthier World

**Lonza**

Cell & Gene

# Cocoon<sup>®</sup> Platform

The Next Step  
in Cell Therapy  
Manufacturing



[Lonza.com/cocoon](https://lonza.com/cocoon)

# Why We're Different

The Cocoon® Platform is a highly scalable, cost-effective solution that reduces your overall manufacturing costs related to labor and facility.

## Benefits of the Cocoon® Platform

Rooted in flexibility, the Cocoon® Platform is a functionally closed, highly customizable and scalable integrated cell manufacturing platform with minimal touchpoints. It drives down costs, provides greater access to patients and delivers a higher quality product.

### Integrated automation

Integrate multiple steps for a complete cell processing solution. In the Cocoon® Platform, you can perform protocols including isolation, cell selection, activation, transduction/transfection, expansion and harvest in an automated system. A versatile system, the Cocoon® Platform allows for manufacturing at a centralized location or at the point of care.

This process automation reduces the chance of operator error and batch failures, and it ensures easy tech transfer across multiple sites.

### Functionally closed system

Experience enclosed manufacturing designed to minimize touchpoints and cleanroom space requirements.

The result? Reduced risk of human error and cleanroom requirements for improved product quality and process efficiency.

### Superior scalability

Save space and drive down costs by scaling your manufacturing process across every phase of production. The Cocoon® Platform can transition from a single benchtop unit into the Cocoon® Tree® for an easily scalable solution.

From R&D and Process Development to clinical trials and commercial-scale production, the Cocoon® Platform services your entire development pipeline.







REF PNB40F0001  
SN SNB1923C01  
2020-06-05

S1 S2 S3 S4 S5

**COCOON™**  
ACTES Cassette

50°C  
-20°C  
STERILE EO

Octave Biotech Inc.  
A Lonzo Company  
369 Dalton Avenue  
Kingston, ON K7M 4Z1 Canada

**LONZO**



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## A flexible cell therapy platform



Enjoy the freedom to choose how and where you manufacture your cell therapies.

Expand at your pace. The Cocoon® Tree® arrays cocoons vertically in an efficient, compact system. When ready to scale up, you simply add trees as you need them.

Easily transfer programs from one Cocoon® Platform to the next. The Cocoon® Platform allows for better asset management as you can manufacture various therapies in the same system.

Choose from centralized or decentralized manufacturing at the point of care—or a combination of both.

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## Single-use cassette



The Cocoon® Platform works with a single-use cassette tailored to your product.

Protocols are performed within the functionally closed cassette, based on your pre-set programming.

Each cassette:

- Is functionally closed, disposable and adaptable
- Is process-specific for adherent/suspension cells
- Has an integrated cold chamber for internalizing process reagents and consumables
- Is appropriate for lentiviral and gamma-retroviral transduction processes as well as non-viral transfection with Lonza's 4D-Nucleofector™ LV Unit
- Aseptic processing and sampling through weldable tubing or SPIROS™ medical-grade connections for maintaining a closed environment

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## Environmental unit



The temperature-controlled environmental unit provides high-quality, reliable results during cell processing and cultivation.

It features:

- Dual-zone temperature control (37°C and 4°C)
- Built-in precision pump with sensors for in-process monitoring
- CO<sub>2</sub> and Dissolved Oxygen Process Control
- Integrated magnet for cell enrichment

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## User-friendly software



We designed the Cocoon® Platform interface and software to make work easier. Our state-of-the-art software is user-friendly and editable for simple on-site customization.

Easy-to-use interface elements include a touchscreen and drag and drop process setup. Flexible programming and in-process monitoring deliver superior analytics.

Cocoon® Platform Software:

- Monitors and controls temperatures and gases
- Displays protocol design/controls flow pathways
- Monitors pH and DO in real time; automatically performs in-process adjustments to maintain optimal culture conditions
- Provides electronic batch records (21 CFR Part 11 compliant)
- Enables product traceability

# Functionally Closed, Automated Manufacturing Process Steps

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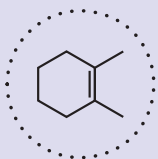
## Unit operation options

### Starting material and reagents

Suspension or adherent cells  
Fresh or frozen leukopak

Preload reagents:

- Media
- Cytokines
- Growth factors
- Virus
- Buffer
- Antibodies
- Activation reagents
- Other (as required)



### Magnetic cell selection

Capable of enrichment or  
depletion

Options to use micrometer to  
nanometer scale beads



### Activation

Suitable for use with various  
activation substrates or cells





## Transduction or transfection

Processes available for lentiviral and retroviral viruses

Option for direct, sterile connection with Lonza's 4D-Nucleofector™ LV electroporation system

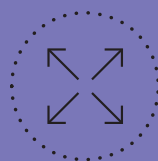


## Cell culture and expansion

Suitable for culture of T cells, NK cells, dendritic cells, HSPC, and MSC

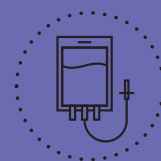
Working volume of 460 mL with media recirculation

Active perfusion

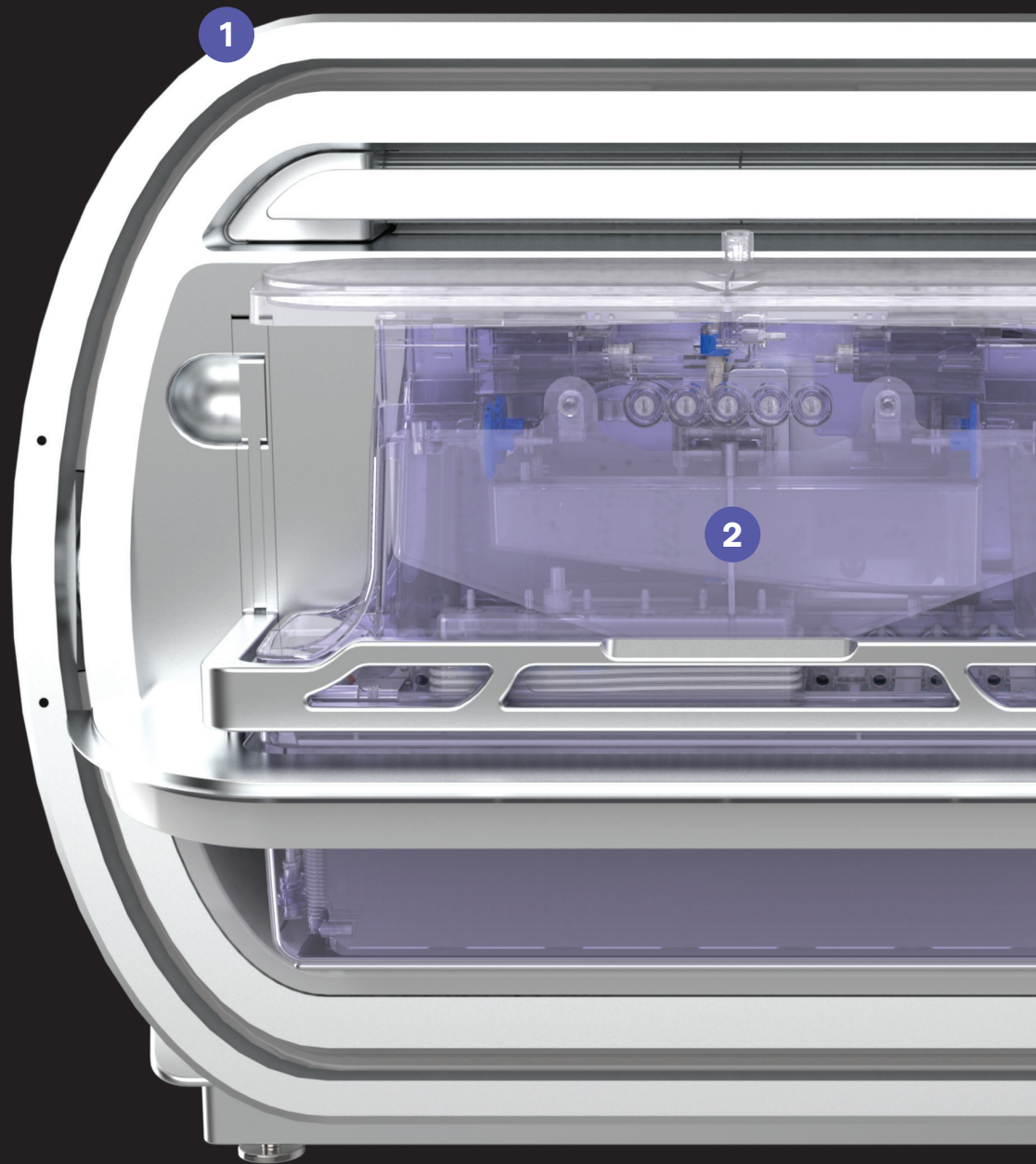


## Final formulation

Harvest in relevant buffer solutions for infusion-ready formulation







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### Environmental unit

- Dual-zone temperature control (37°C and 4°C)
- Built-in pump and sensors for in-process monitoring
- CO<sub>2</sub> and Dissolved Oxygen Process Control
- Integrated magnet for cell enrichment

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### Single-use cassette

- Functionally closed, disposable, and flexible
- Process-specific: adherent/suspension cells
- Integrated cold chamber for internalizing process reagents and consumables
- Appropriate for lenti- and gamma-retroviral transduction processes, as well as non-viral gene transfer using Lonza's transfection system, the 4D-Nucleofector™ LV Unit





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## Software

- Monitors and controls temperature and gases
- Protocol design/control flow pathways
- Monitors pH and DO in real time; automatically performs in-process adjustments to maintain optimal culture conditions
- Provides electronic batch records (21 CFR Part 11 compliant)
- Enables product traceability

# Our Commitment to Regulatory and Quality Excellence

Regulatory and Compliance Status
Cocoon® Platform is not regulated as a medical device but falls under manufacturing equipment classification
Qualified for GMP clinical/commercial manufacturing
ISO 9001/ISO 13485 Quality Management System Certifications
CE Mark certification in Europe
U.S. Type V Master File
21 CFR Part 11/Annex 11
IEC 61010 Safety and electrical emissions
IEC 62304 for software development
Certified for compliance in all major countries

Quality
Certificate of Compliance provided for the Cocoon® Instrument, Cassette, and Software containing: <ul style="list-style-type: none"> <li>• Sterility Assurance Statement</li> <li>• Summary of Quality Control Testing, and</li> <li>• Compliance to our Quality Management Systems/cGMP</li> </ul>
Installation Quality/Operational Quality (IQ/OQ) on-site
Biannual preventative maintenance schedule ensures superior operation
Best-in-class support
Shipping and packaging validation
Cassette shelf-life validation





Quality and regulatory compliance are fundamental in our culture. The Cocoon® Platform is manufactured in a cGMP environment with manufacturing practices that are certified to **ISO 13485:2016, ISO 9001:2015** and relevant country-specific GMP regulatory guidelines and standards. The Cocoon® Platform (Cocoon® Cassette, Cocoon® Instrument and Cocoon® Software) are designed, manufactured and tested under these quality management systems. Our facility is staffed with a team of highly experienced quality and operational experts to ensure compliance. To assess and facilitate compliance, we regularly evaluate our own quality systems and conduct reviews to identify issues that may affect our clients' product and service quality.



The Cocoon® Cassette is lot-traceable. Cassettes are sterilized using a cycle validated to deliver a minimum sterilization assurance level (SAL) of  $10^{-6}$ . The Distribution Simulation and Accelerated Aging Packaging Tests executed for Cocoon® Cassette and accessories qualify the Cassette and accessories to maintain a single sterile barrier for six months. Materials used in the manufacture of the Cocoon® Cassette in direct contact with the product flow path are required to meet strict biocompatibility criteria. Leachable/Extractable (LE/EX) studies have been performed as per ISO 10993-18 and the resulting data assessed for risk to patient according to the principles found in ISO 10993-17 and ISO/TS 21726.



The Cocoon® Instrument has been tested for compliance with **CE (Conformité Européenne)**, US FCC, Canada and other country-specific safety and EMC standards and guidelines. Cocoon® Instrument assessment for environmental compliance is as per RoHS directive and REACH directive. Additionally, the Cocoon® Platform displays the WEEE directive marking.



**Installation and Operation Qualification (IQ/OQ)** of the Cocoon® Platform ensures that the equipment is properly integrated into your lab and performing to its expected capabilities. On-site service and maintenance at regular intervals following installation allow for continued, optimal operation of the automated bioreactor.



The Cocoon® Software manages the Cocoon® Platform user access, and it controls and monitors the Cocoon® Instrument and production orders. The validated Cocoon® Software is compliant with FDA's **Part 11 (21 CFR Part 11)** and the European Union's **Annex 11** to enable computerized systems use during regulated manufacturing activities. We follow **IEC 62304** for software development.



A **Certificate of Compliance**, provided with the Cocoon® Cassette, summarizes the compliance details pertaining to the manufacturing of the Cocoon® Cassette: current Good Manufacturing Practices (cGMP), Sterilization, Leachable/Extractable, integrity testing, bacterial endotoxin and Quality Control/release testing before batch release.



The Cocoon® Platform is classified as Equipment under EMC/Safety regulations. The Cocoon® Platform has a **U.S. Type V Master File** on file with the US FDA, which can be referenced in regulatory filings. Product Dossiers are available to assist customers with non-US regulatory submissions.



Clients have the ability to demonstrate an aseptic manufacturing process and sampling through **weldable tubing or SPIROS™ medical-grade connectors** for maintaining a closed environment.



A **Certificate of Compliance** is provided with the Cocoon® Instrument. It summarizes compliance details pertaining to the manufacturing of the Cocoon® Instrument such as current Good Manufacturing Practices (cGMP), conformance to Electrical testing and Safety Testing, validated software version and Quality Control Testing before batch release.



All Cocoon® Instruments come with best-in-class support and an optional service contract for biannual maintenance to ensure the Cocoon® Platform continually functions at peak performance.

# Go Beyond: An Integrated Cell Manufacturing System

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## Support and service

- Flexibility in reagents
  - Quality and regulatory support
  - Process Development and analytical services
  - Convenient single-use cassettes
  - Remote and on-site support and service
  - Networking capability with integrated electronic batch records and remote alarms
  - Integrated process analytics
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## Customizable options

- Options for cell therapy manufacturing through Lonza CDMO
- Access and direct integration to Lonza's 4D-Nucleofector™ LV
- Viral manufacturing
- Future integration into track and trace software through flexible API, including Lonza's MODA software package







# The Next Breakthrough... We'll Get There Together.

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## What drives us?

A passion for your product. We'll empower you to use the Cocoon® Platform exactly the way you want.

### Why work with us?

We understand the need to work fast with a focus on the future. We offer:

- A partnership. We work as an extension of your team, so you can meet your specific project needs
- Access to world-class experts with 20+ years of cell and gene therapy manufacturing expertise
- Dedicated cell-and-gene-therapy regulatory consultants and Quality Control and Assurance Specialists
- State-of-the-art facilities across three continents—North America, Europe and Asia
- Flexibility to address the needs of small or large companies
- A selection of training programs along with customized training specific to your process
- Transparent service contracts with no surprises
- Comprehensive IQ/OQ services to ensure you meet and maintain GMP regulations

### Flexible solutions for your process

Use the Cocoon® Platform exactly the way you want. Choose a ready-to-go, off-the-shelf solution for immediate clinical use. A completely customized solution tailored to your process.

We'll work side-by-side with you, every step of the way, to create your ideal cell therapy system.



# Technical specifications

## Model:

Cocoon® Platform Gen 2 (#100-002-001-000)

## Dimensions:

Width	856mm (33.7")
Depth	529mm (20.8")
Height	512mm (20.2")

## Weight:

60 kg (132 lbs)

## Input voltage:

100-240 VAC 50/60 Hz

## Power consumption:

Nominal	450 W
Maximum	600 W

## Pump flow rate:

0.7 to 70 mL/min

## Atmospheric control:

Gas mix unit for CO<sub>2</sub>, user selectable range from 1% to 5%

## Dual temperature control:

Culture zone – 35°C to 39°C  
Refrigeration zone – 2°C to 8°C

## Types of starting material:

Fresh or cryopreserved cells; Total PBMC, selected / enriched cells – T cells, monocytes, NK cells

## Available cell processing steps:

Cell washing, magnetic selection, cell activation, viral transduction, transfection, cell expansion, cell culture and medium exchange, formulation of final cell product



# Create Your Ideal Cell Therapy System.

From clinical trials  
through commercial-  
scale manufacturing,  
we'll get you to the  
next level. On budget.

[Lonza.com/cocoon](http://Lonza.com/cocoon)

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