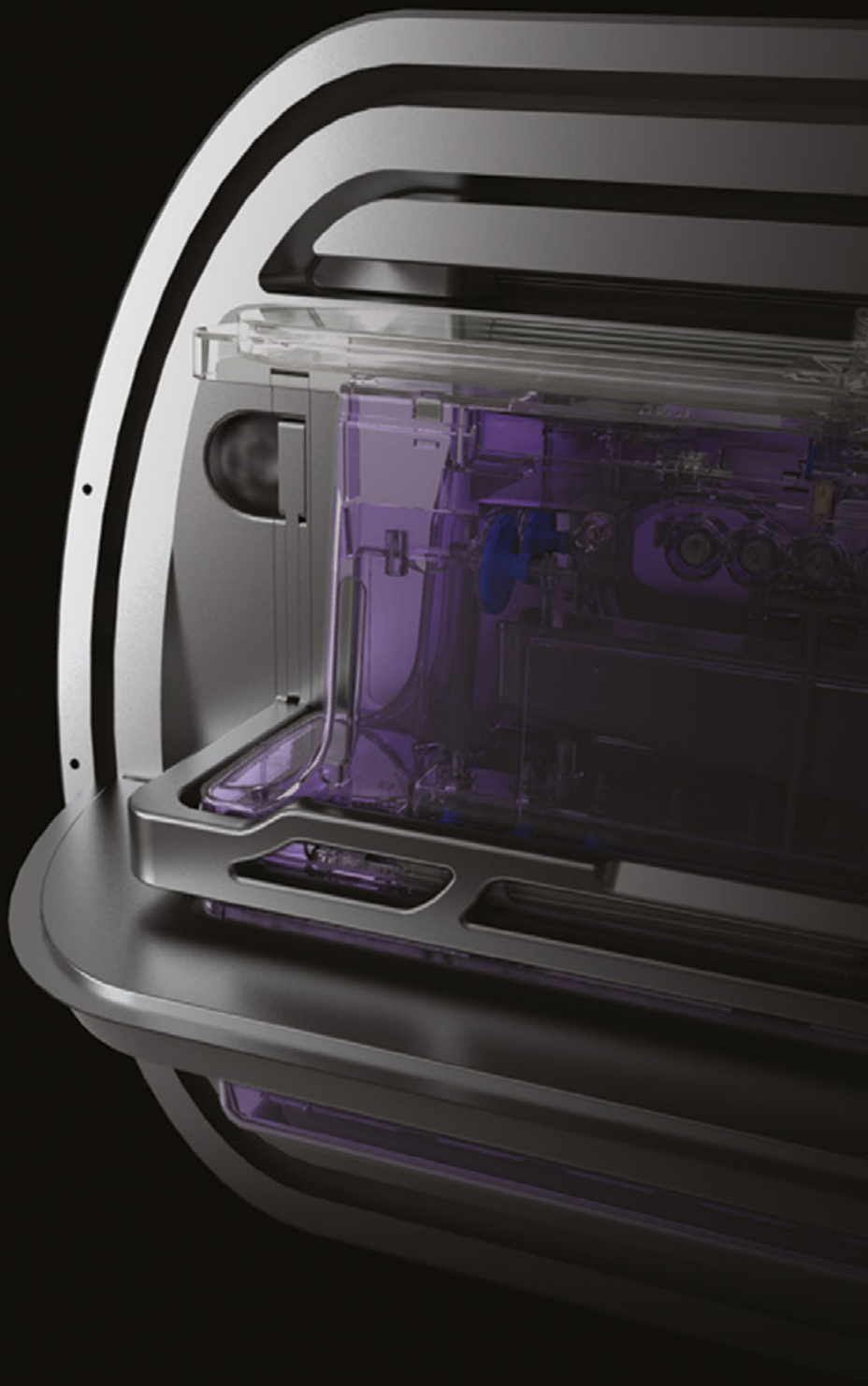
Enabling a Healthier World

Lonza
Cell & Gene

Cocoon® Platform

The Next Step in Patient-Specific Cell Therapy Manufacturing



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 end-to-end cell manufacturing platform with minimal touchpoints. It drives down costs, provides greater access to patients and delivers a higher quality product.

End-to-end 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.

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.

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 mixture of both.

Customizable cassette

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

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

Each cassette:

- Is 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

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_2 and Dissolved Oxygen Process Control
- Bar code scanner for login and traceability for Chain of Custody and Chain of Identity

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/DO and automatically in real-time using biofeedback; can automatically adjust the process
- Delivers information logging/electronic batch records (21CFR Part 11 compliant)
- Provides full sample and product traceability

Closed, Automated Manufacturing Process Steps

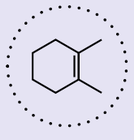
Unit operation options

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

Positive or negative selection

Options to use micro bead or nano bead systems

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

Expansion

Suitable for T cells, dendritic cells, NK cells

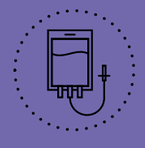
iPSC, HSC, MSC

Working volume of 460 mL with media recirculation

Active perfusion

Final formulation

Fill and finish capabilities



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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_2 and Dissolved Oxygen Process Control
- Barcode scanner for login and traceability for Chain of Custody and Chain of Identity

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Customizable cassette

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

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Software

- Monitors and controls temperature and gases
- Protocol design/control flow pathways
- Monitor pH/DO and can automatically adjust process real-time using biofeedback
- Information logging/electronic batch records—21CFR Part 11 compliant
- Full sample and product traceability

Our Commitment to Regulatory and Quality Excellence

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
Type V DMF (Drug Master File)
21 CFR Part 11/Annex 11
61010 Safety and electrical emissions
IEC 62304 for software development
Certified for compliance in all major countries

Release and installation
Provide Certificate of Compliance for the Cocoon® Platform and Cassettes • Assurance of sterility • Validation of cassette integrity • End-of-line functionality validation testing for the Cocoon® Platform and software
Installation Quality/Operational Quality (IQ/OQ) on site
Biannual preventative maintenance schedule ensures superior operation
Best-in-class support
Aseptic processing and sampling through weldable tubing or SPIROS medical-grade connections for maintaining a closed environment
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® 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.

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.

The Cocoon® Platform is classified as Equipment under EMC/Safety regulations. The Cocoon® Platform has a **Drug Device Master File Type V** on file with the US FDA, which can be referenced in regulatory filings.

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.

The Cocoon® Cassette is lot-traceable. Cassettes are sterilized using Ethylene Oxide (EO) Gas in a validated sterilization process. The validation demonstrates that the sterilization process delivers a minimum 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. A **Leachable/Extractable (LE/EX)** study, component biocompatibility assessment and toxicological risk assessment of the Cassette and accessories have been assessed for acute and subacute/subchronic toxicity and genotoxicity from exposures based on the intended use of the Cassette. This risk assessment indicates that the likelihood of adverse effects to the leachable compounds detected is low.

Installation and Operation Qualification (IQ/OQ) of the Cocoon® Platform is executed when the Cocoon® Instrument is installed in the manufacturing facility as per approved protocols. Cocoon® Instrument service is executed as per the maintenance schedule to verify performance following service operations.

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.

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.

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 End-to-End Cell Manufacturing System

Support and service

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

Customizable options

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

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

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 supplied by ground outlet

Power consumption:

Nominal	450 W
Maximum	600 W

Frequency:

50–60 Hz

Pump speed:

2–400 mL/min

Atmosphere control:

Gas mix unit for CO_2, compressed air and N_2;
min. pressure: 1.0 bar, max. pressure: 2.5 bar

Temperature control:

+4°C to +38°C

Types of starting material:

Leukapheresis, bone marrow, cryopreserved PSCs

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.

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