

Cocoon[®] Platform

The Next Step
in Cell Therapy
Manufacturing



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

The Cocoon Platform integrates multiple steps for a complete cell processing solution, including isolation, cell selection, activation, transduction / transfection, expansion, and harvest. This automation reduces the chance of operator error and batch failures, ensuring easy tech transfer across multiple sites.

FUNCTIONALLY CLOSED SYSTEM

The platform is designed to minimize touchpoints and cleanroom space requirements, reducing the risk of human error and improving product quality and process efficiency.

SUPERIOR SCALABILITY

The Cocoon Platform can transition from a single benchtop unit to the Cocoon Tree® for an easily scalable solution, saving space and driving down costs across every phase of production, from R&D and Process Development to clinical trials and commercial-scale production.



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.

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 a non-viral transfection.
- Aseptic processing and sampling through weldable tubing or SPIROS™ medical-grade connections for maintaining a closed environment

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
- CO₂ and Dissolved Oxygen Process Control

User-friendly software



Integrated magnet for cell enrichment. 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

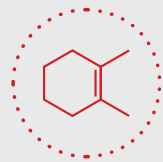
Unit operation options

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
electroporation systems

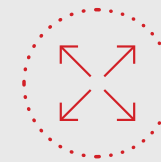


Cell culture and expansion

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

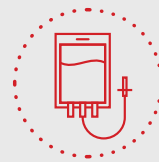
Working volume of 460 mL
with media recirculation

Active perfusion



Final formulation

Harvest in relevant buffer
solutions for infusion-ready
formulation





1

ENVIRONMENTAL UNIT

- Dual-zone temperature control (37°C and 4°C)
- Built-in pump and sensors for in-process monitoring
- CO₂ and Dissolved Oxygen Process Control
- Integrated magnet for cell enrichment

2

SINGLE-USE CASSETTE

- Functionally closed, disposable, and flexible
- Process-specific: adherent/suspension cells
- Integrated cold chamber for internalizing process reagents and consumables
- Appropriate for lentiviral and gamma-retroviral transduction processes as well as a non-viral transfection

3

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



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 Cassette is lot-traceable. Cassettes are sterilized using a cycle validated to deliver a minimum sterilization assurance level (SAL) of 10⁻⁶. Packaging and aging validations support 2-year shelf life for Cocoon Cassettes and Accessories. 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.



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.

REGULATORY AND COMPLIANCE STATUS
Cocoon is Advanced Manufacturing Technology Designated (FDA) with the FDA
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



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 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.



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.

QUALITY
Certificate of Compliance provided for the Cocoon Instrument, Cassette, and Software containing:
• Sterility Assurance Statement • Summary of Quality Control Testing, and • Compliance to our Quality Management Systems/cGMP
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



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 SPIROST™ 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 Integrated Cell Manufacturing System

Fleet management - Cocoon Silk

- Real-Time Global Monitoring
- Centralized Batch Data and Analytics
- GMP Traceability
- User Access Management
- AI Assistant for Training & Troubleshooting
- Secure Cloud Connectivity

Built-in flexibility

- Reagent agnostic
- Off-the-Shelf applications available, or customize every process step
- Cassettes available for both adherent and non-adherent cell types
- Cassette accessories configurable to specific process inputs and outputs
- API available for integration into 3rd party systems

Support and service

- Quality and regulatory support
- Process and analytical development services
- Global field service for preventative maintenance emergency repair
- Global field applications for remote and on-site run support
- Manufacturing Services available via Octane CDMO



The Future of Personalized Medicine is Here

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 regulation

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:	Pump flow rate:
Cocoon® Platform Gen 2 (#100-002-001-000)	0.7 to 70 mL/min
Dimensions:	Atmospheric control:
Width 856mm (33.7") Depth 529mm (20.8") Height 512mm (20.2")	Gas mix unit for CO ₂ , user selectable range from 1% to 5%
Weight:	Dual temperature control:
60 kg (132 lbs)	Culture zone – 35°C to 39°C Refrigeration zone – 2°C to 8°C
Input voltage:	Types of starting material:
100-240 VAC 50/60 Hz	Fresh or cryopreserved cells; Total PBMC, selected / enriched cells – T cells, monocytes, NK cells
Power consumption:	Available cell processing steps:
Nominal 450 W Maximum 600 W	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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