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Customized Solutions for ATMPs R&D and Production
Cell and Gene Therapy Isolator

ZHEJIANG TAILIN BIOENGINEERING CO., LTD

CELL THERAPY PRODUCTS



Cell Collection



Cell Preparation



Cell Retransfusion

Risk Management in Cell Therapy Products Preparation

High risk operations including manual operations of sterile products or equipment, as well as products or key surfaces exposed to the environment. The extent of the risk depends on the level of segregation between personnel and the item and the degree of the control over the microbiological quality of the environment.

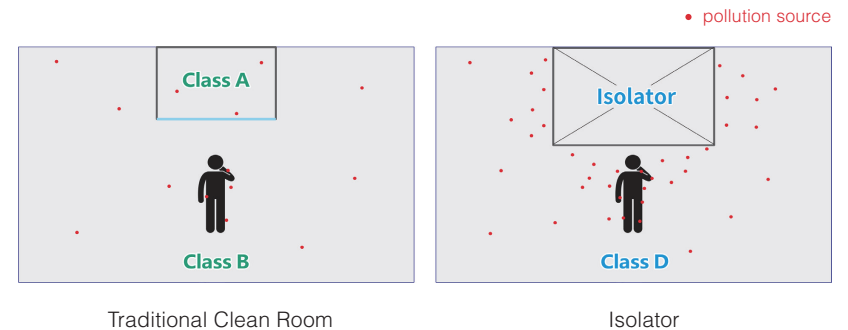
— ISO13408-1:2008

Contamination Prevention & Control in the Process of Cell Therapy Products Preparation

Cell therapy products has complex biological characteristics, and end products cannot perform terminal sterilization or sterile filtration, so the preparation process control of such products is particularly important.

It is extremely important to maintain sterile operating environment, isolation between personnel and products, avoid contamination and cross-contamination.

COMPARISON OF CONTAMINATION PREVENTION & CONTROL



B-Level Environment	D-Level Environment
Non-closed system, unable to isolate between people and products	Closed system, completely isolate between people and products
Unable to avoid contamination sources entering into the core operation area	Isolate contamination sources into the core operation area

EU Regulations Recommend Use Isolator for Cell Products Preparation

Guidelines on Good Manufacturing Practice Specific to Advanced Therapy Medicinal Products

Concurrent production of two different ATMPs/ batches in the same area is not acceptable.

However, closed and contained systems can be used to separate the activities.

The use of more than one closed isolator (or other closed systems) in the same room at the same time is acceptable, provided that appropriate mitigation measures are taken to avoid cross-contamination or confusion of materials, including separate ejection of the exhaust air from the isolators and regular checks on the integrity of the isolator.

COMPARED WITH TRADITIONAL CLEANROOM

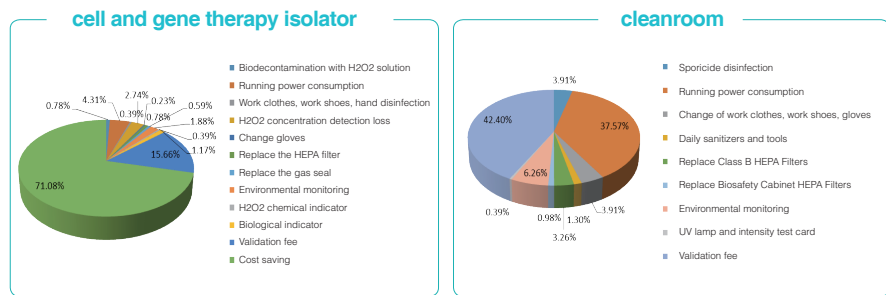
Tailin isolators have advantages in product safety and cost compared with traditional approach.

Cell Therapy Products Preparation under different environment

Isolator V.S Biological Safety Cabin (BSC)& Clean Room

	Isolator	Biological safety cabin & Clean Room
Comprehensiveness	Closed-system, Personnel do not need to enter key operation area	Personnel need to enter key operation area
Space/Equipment Requirement	D-level, relatively low investment on air conditioning environment maintenance	B-level, high investment on air conditioning environment maintenance
Background Environment	D-level Room	Strict requirements on HVAC, filtration, air shower and buffer
Installation Start Time	3 to 4 weeks	> 6 months
Biological Decontamination	Vaporized Hydrogen Peroxide (VHP)	Formaldehyde steamed + UV + Disinfecting manual wiping
Biological Decontamination Time	2 Hours	2 Days(Steamed every 15 days)
Operation Cost	Low	High
Human Comfort	Comfortable	Uncomfortable
Flexibility	More Restriction on people's activity space, but cellular operation is flexible	Less Restriction on people's activity space, but high risk of contamination
Cell Operation Support Equipment	Integrated Design; Reduce the risk of cross-contamination	Each Equipment, such as biological safety cabin and CO2 incubator requires separate verification

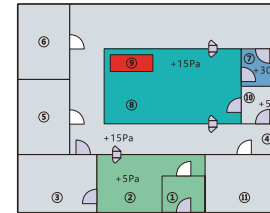
Annual Operating Cost Comparison



LAYOUT COMPARISON TRADITIONAL CLEANROOMS

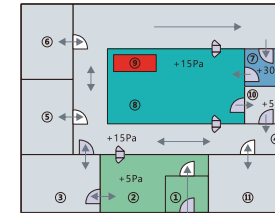
Example with BSC protection facilities

Environmental Layout



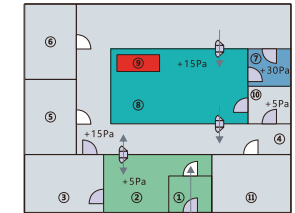
- ① Entrance
- ② Monitoring Room
- ③ First Changing Room
- ④ Buffer Between Laboratories
- ⑤ Preparation Room
- ⑥ Material Storage Room

People Flow



- ⑦ Second Changing Room
- ⑧ Cell Preparation Room
- ⑨ Safety Cabin
- ⑩ Second Changing Room
- ⑪ Sample Storage Room

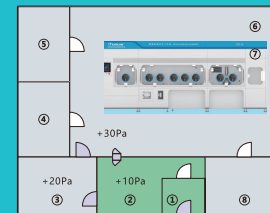
Material Flow



- Key Processing Zone A-level
- Direct Support Area B-level
- Indirect Support Area D-level
- Unclassified Area
- Stationary Direct Support Area C-level
- Airlock
- Non-gas gate
- Indirect Support Area D Draw Material Airlock

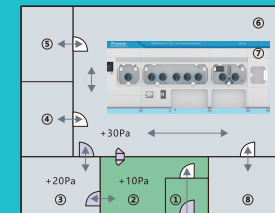
Tailin cell and gene isolator

Environmental Layout



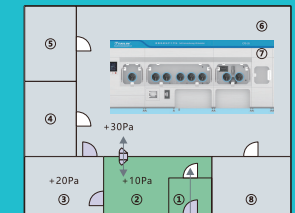
- ① Entrance
- ② Monitoring Room
- ③ First Changing Room
- ④ Preparation Room
- ⑤ Material Storage Room
- ⑥ Cell Preparation Room

People Flow



- ⑦ Isolator
- ⑧ Sample Storage Room

Material Flow



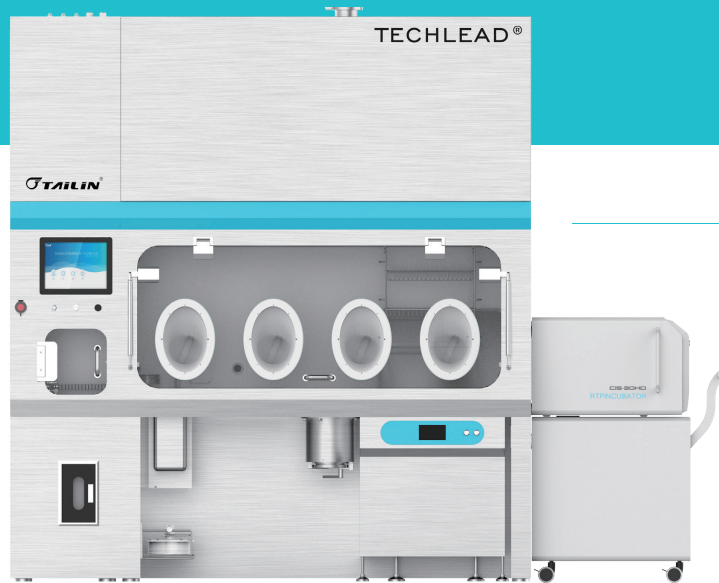
- Indirect Support Area D-level
- Unclassified Area
- Stationary Direct support area C-level
- Airlock
- Non-gas gate
- Raw Material Airlock

Integrated Solutions for ATMPs R&D and Production

Cell and Gene Therapy Isolator

Tailin cell and gene therapy isolator meets the stringent aseptic requirements of cell therapy products and reduces installation and operational costs by providing a continuous clean environment, featuring integrated design, and simplified installation and operation procedures.

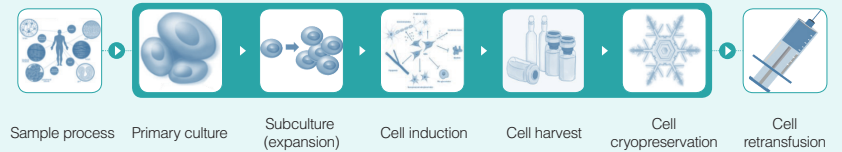
Tailin cell and gene therapy isolator system is designed based on stringent GMP aseptic production requirements and meets the requirements of various regulatory agencies (FDA, EMA, NMPA) regulations and industry guidelines (ISO, PDA, USP and Chinese Pharmacopoeia).



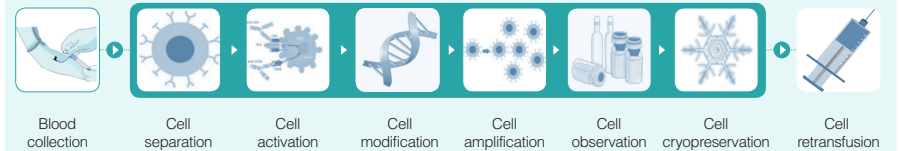
APPLICATIONS:

Provide a series of full set of equipment solutions for the **Preparation** and **Quality Control** for cell therapy prod-

Provide aseptic manufacturing solutions for stem cell therapy drug preparation



Provide aseptic manufacturing solutions for immunotherapy drug preparation



Advantages

Aseptic

Class A clean environment
Comply with GMP

Sterilization

Integrated VHPS®
decontamination system

Data Monitoring

Real-time recording of system
control & environmental
monitoring data
Record and storage of operation
video
Data traceability of the whole
process of production operation

Modular Design

Flexible and customizable
according to customer
requirements

Extensive Options

Crucial equipment available
for selection

Space Saving

Compact design
No need for large building
space layout

Cost Saving

Install in Class D
Reduce the costs of construction
and operating



MODULAR DESIGN

Highly Integrated
Intelligent
Modular

Tailin cell & gene therapy equipments are fully GMP compliant



Rapid sterilization transfer chamber

- VHPS sterilization
- 30L volume
- Complete sterilization and aeration within 30min
- Used for tissue samples, reagents, consumables and other items fast delivery



Integrated low-speed centrifuge

- Embedded design VHPS sterilization
- Max. rotation speed: 5000r/m
- Max.relative centrifugal force:3000Xg
- Max. volume: 50ml*16(800ml) or 250ml*4(1000ml)
- Data stored in the isolator PC



Micro-observation system

By equipping different cell imaging systems, imaging observation of various types of cells is possible, which in turn enables quality monitoring of cell culture/production.



Friendly Software



Embedded cell incubator

Volume: 30L~100L
Leakage rate <0.5%V/h
VHP in-situ sterilization

Temperature display and control accurate to 0.1 C ,
Temperature uniformity better than ± 0.3 C Highly Integrated Intelligent Modular
CO₂ concentration control: Vaisala infrared probe precise control, concentration accurate to 0.1%, uniformity better than 0.2%
Humidity control: bottom water tray humidification, humidity control in the chamber more than 95%, suitable for cell culture



Honeycomb cell culture system

Cell culture Incubation System

In order to meet the requirements of cell culture production of different scales, two cell culture solutions can be provided.
Embedded cell incubator & Honeycomb culture incubator

HONEYCOMB CELL CULTURE SYSTEM



docking incubator

flexible docking between incubator and cell therapy workstation through incubator transfer vehicle

1. Closed-system

A-level environment, avoid the risk of contamination

2. Energy conservation

Satisfy GMP sterilized preparation requirements, dispense with B+A

3. Small space

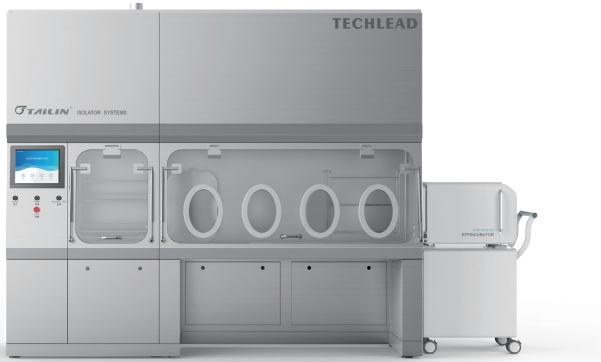
Multiple batches of cells can be prepared in a small space

4. Real-time trace

Track and Record the complete operation process

5. Customization

Customize the integrated equipment according to the preparation process



APPLICATIONS:

Hospitals
 Cell research institutions
 Cell therapy companies



CIS-30SAD

Provide aseptic culture environment

Closed-system, 0.22um filtration is adopted for the gas entering the incubator

Support multi-level authority management

Meet the requirements for setting up three levels of authority, electronic records, electronic signatures, audit trails, etc.

Air tightness self-check

Keep the incubator closed

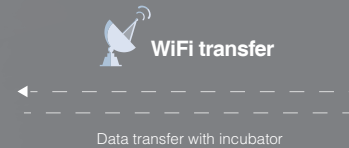
Electronic interlock + positive pressure design

Guarantee the aseptic environment inside



High-throughput cell culture management

1. It can realize the management of multiple batches of cell culture at the same time, and the incubators are independent of each other without interfering with each other.
2. Through the CIS-30SAD, the rapid aseptic connection of the cell incubator with the cell operation isolator and the honeycomb culture incubator can be realized to prevent cross-contamination.
3. With its own sterilization chamber, it can quickly sterilize the docking incubator



COMPARISON: Honeycomb cell culture system



Technical Parameter

	Item	Parameter
Volume	incubator volume	30L
Temperature	setting range	RT+3~55°C
	resolution	0.1°C
	display error	±0.1°C(@37°C)
	control error	±0.3°C(@37°C)
	control fluctuation	±0.3°C(@37°C)
	control uniformity	±0.3°C(@37°C)
	insulation	≤8°C
Humidity	Relative Humidity (RH)	≥90%RH
CO ₂ Concentration	control range	0%~20%
	display resolution	0.1%
	display error	±0.2°C(@5%)
	control error	±0.5°C(@5%)
O ₂ Concentration	control range	1%~21% or 21%~90%
	control error	±0.2
	sensor absolute accuracy	±0.5(1%~21%) ±2.0(21%~90%)
Power	power supply	24V
	power consumption	160W
Air tightness	hourly leak rate	W1%
Noise	noise at work	W65dB(A)
Data	data processing	real-time data recording, storage, transmission
Alarm	alarm function	a. Temperature high/low alarm b. CO ₂ concentration high/low alarm c. Water pan shortage alarm d. Humidity sensor failure, CO ₂ concentration sensor failure, fan failure alarm, etc.



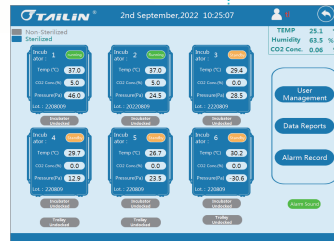
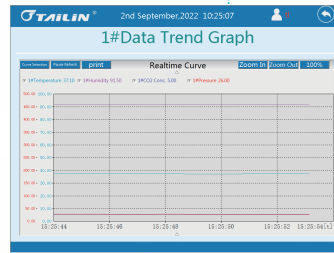
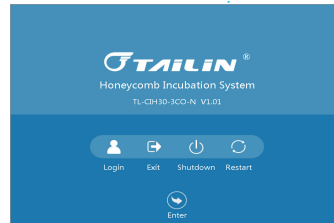
Tailin



Product A

Incubator Brand	Tailin	Product A
Interface Shape	Square	Circle
Cultivate Spatial Utilization	92.7%	63.6%
Door Seal Form	Inflatable Seal (Electronic interlock)	Tape Seal (Mechanical interlock)
Docking Sterilization	VHP automatic sterilization	Use sporicide to wipe surface
Cultivation Process Observation	Able to observe	Unable to observe

SOFTWARE CONTROL SYSTEM

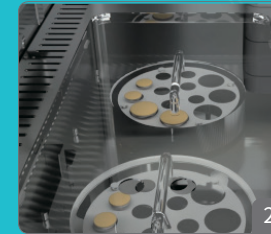
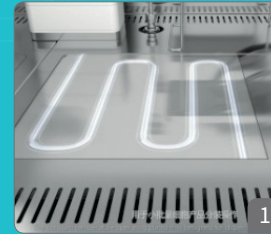


Operation interface:

- ✓ Operation management system
- ✓ Electronic records/electronic signatures
- ✓ Video traceability management system
- ✓ Device automatic/manual operation
- ✓ Product batch number information can be input by scanning
- ✓ Bio-decontamination parameters
- ✓ Trend curve
- ✓ Operation video recording
- ✓ Real-time record storage of environmental parameters

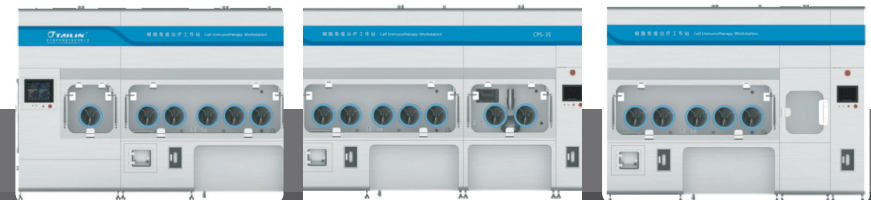
OPTIONAL MODULE

Integrated modular configuration



	1	2	3	4	5	6
module	Cooling operation	Refrigerators	Rewarming	Aspirator	Automatic transfer	Waste Channel
parameter	platform: 2-8 C	4 C, -20 C	Device: 30-60 C	Stepless speed regulation, foot control	deviceLiftable, swivel	RTP valve with collector

Customization: Flexible design to your needs



SERVICE



TECHNICAL SERVICE

- ✓ Fully technical communication before sales, and jointly determine technical solutions and URS documents with customers
- ✓ Provide FAT, SAT and document drafting
- ✓ Equipment on-site installation and commissioning
- ✓ DQ/IQ/OQ document drafting, validation and implementation
- ✓ Assist in the development of system cycles Support relevant confirmations based on microbiological, physical and chemical experiments
- ✓ Professional theory and practical skills training
- ✓ Provide systematic preventive maintenance
- ✓ Provide periodic revalidation
- ✓ On-site maintenance service

VALIDATION SERVICE

- ✓ Complete validation plan
- ✓ Comprehensive validation service
- ✓ System validation training
- ✓ Professional validation equipment and materials
- ✓ Experienced validation team
- ✓ Focus on validation of VHPS sterilization
- ✓ Professional computer software validation

SERVICE PROCESS

On-site Condition Confirmation

Such as room size, equipment layout, wall material, ventilation system interior items

Risk Evaluation

- ✓ Material confirmation: exposure to hydrogen peroxide
- ✓ Compatibility testing: intolerant materials
- ✓ Hydrogen peroxide sterilization risk assessment report

Bio-decontamination Solutions

Development of bio-decontamination solutions and approval by users

Installation

- ✓ Equipment in place, engineers on site
- ✓ Preparation of consumables
- ✓ On-site bio-decontamination
- ✓ Monitoring of process data
- ✓ Bis inoculation & culture

Maintenance Plan

Technical Consulting Service