CELL & GENE THERAPY ISOLATORS

OUR SOLUTIONS FOR ALL CGMP MANUFACTURING PROCEDURES IN ADVANCED CELL THERAPIES

Segregated environments for cell processing and expansion, tissue engineering, gene therapy

COMECER®

CELL & GENE THERAPY ISOLATORS

Designed according to the highest pharmaceutical standard, our isolators for cell cultures and related activities represent the best option to move forward into this field assuring the best product quality with reduced costs of implementation in your existing laboratory.

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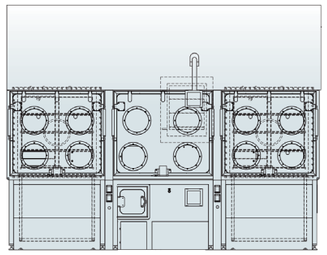
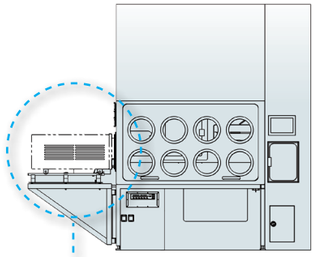
Different approaches

Based on the stage of development or number of patients different approaches can reflect into different configurations.

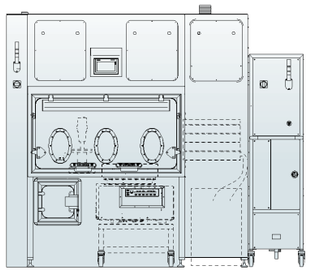
Customized solution can be also developed according to customer and process needs



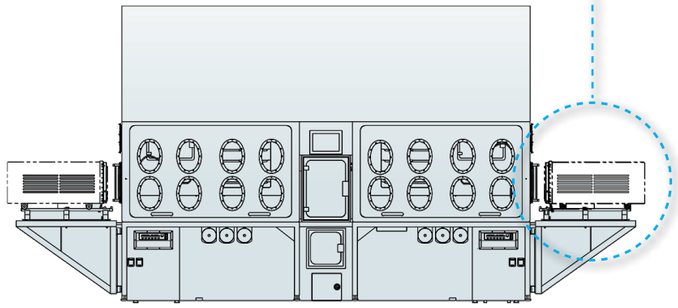
Modular Workstation with Fixed Incubators



Single Chamber with Flexycult Incubators



Compact Workstation with Fixed Incubators



Double Chamber with Flexycult (ready for scale up)

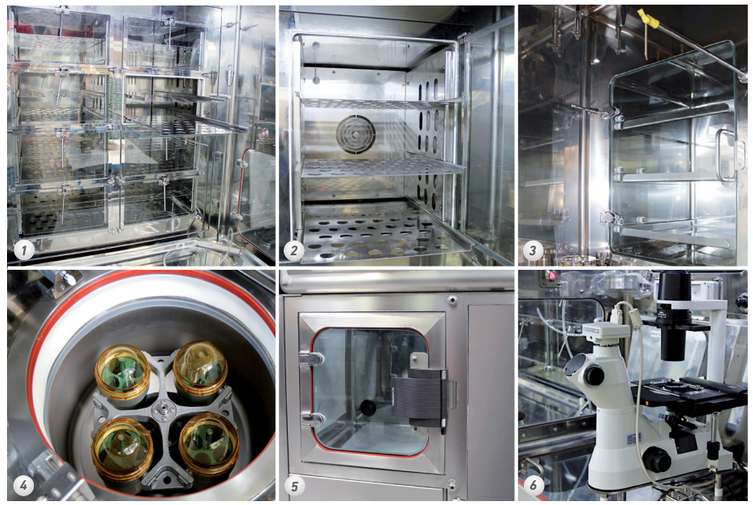
FLEXYCULT™

Modular Incubation System for Advanced Theraphy Labs

Play video
www.comecer.com/FlexyCult

Laboratory devices integration

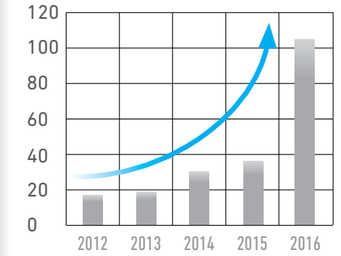
In addition to the traditional accessories of isolators (such as Integrated VPHP generator, Environmental Monitoring for Viable and Non-Viable, laminar airflow sensor, ...)



1. A CO_2 Incubator can be integrated into the isolator, and the entire volume is accessible through sealed doors. Interior can be customized according to different culture devices to be stored inside
2. Storage area: a storage volume has been foreseen for media and other process material.
3. A Refrigerator of variable capacity according to the needs is accessible from the interior of the isolator chamber through a single door. The internal volume is then equipped with sliding trays.
4. Centrifuge: refrigerated centrifuge with air tight bucket of anodized aluminum suitable for H_2O_2 decontamination has been integrated. Centrifuge control panel has been moved outside the clean area
5. A Transfer Hatch with rapid decon cycle is the way in and way out for the process.
6. Integrated microscope.

State of the art and challenges

EMA ATMP recommendations



The number of ATMP procedures recognized by EMA in the last 5 years is showing continuous growing. This represents a confirmation of the growing interest around ATMP

Pre-Market

1. *Persevering through lengthy developmental timelines*
2. *Navigating the regulatory environment*

Post-Market

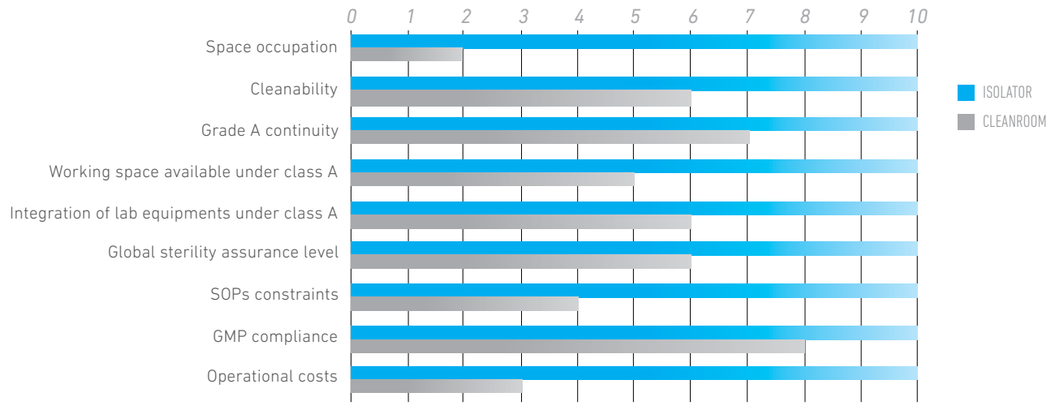
1. *Securing reasonable reimbursement*
2. *Encouraging adoption*

Manufacturing

1. *Scaling up production*
2. *Addressing distribution logistics*
3. *Managing cost of goods sold at scale*

Similar to any new drug, the development of ATMP represents a challenge in several aspects of the process to reach the commercialization. From the manufacturing stand point Isolation Technology offers currently the best solution as far as reliability, low cost of implementation and sterility assurance of the product.

Isolator vs cleanroom comparative chart *(Performance comparison)*



Technical data

Material	Compact Workstation with Fixed Incubators	Modular Workstation with Fixed Incubators	Modular Workstation with Fixed Incubators	Double Chamber with Flexycult (ready for scale up)
Shell structure	AISI 316 L	AISI 316 L	AISI 316 L	AISI 316 L
Stainless steel finish	external: Scotch-Brite internal: Mirror-Brite	external: Scotch-Brite internal: Mirror-Brite	external: Scotch-Brite internal: Mirror-Brite	external: Scotch-Brite internal: Mirror-Brite
Air classification				
Main chamber	class A (after decontamination)	class A (after decontamination)	class A (after decontamination)	class A (after decontamination)
Pre-chamber	class A (after decontamination)	class A (after decontamination)	class A (after decontamination)	class A (after decontamination)
Working internal pressure				
Main chamber	50-100 Pa	50-100 Pa	50-100 Pa	50-100 Pa
Pre-chamber	25-50 Pa	25-50 Pa	25-50 Pa	25-50 Pa
Filters				
Main chamber	H14 inlet and outlet	H14 inlet and outlet	H14 inlet and outlet	H14 inlet and outlet
Pre-chamber	H14 inlet and outlet	H14 inlet and outlet	H14 inlet and outlet	H14 inlet and outlet
Make up air flow rate	280 m^3/h	366 m^3/h	349 m^3/h	697 m^3/h
Overall dimensions *(w x d x h)*	2100 x 930 x 2200 mm	3600 x 1800 x 2800 mm	2250 x 1542 x 3000 mm	4156 x 1542 x 3000 mm
Internal dimensions *(w x d x h)*	1557 x 595 x 700 mm	3440 x 903 x 600 mm	1720 x 800 x 600 mm	4100 x 941 x 550 mm
Net weight	1200 kg	2500 kg	1500 kg	3000 kg
Utility requirements				
Compressed air	6 bar, 25 nL/min	6 bar, 25 nL/min	6 bar, 25 nL/min	6 bar, 25 nL/min
Power supply				
Isolator	230V (1Ph+N+PE) 50/60Hz 32A TN-S	230V (1Ph+N+PE) 50/60Hz 32A TN-S	230V (1Ph+N+PE) 50/60Hz 32A TN-S	230V (1Ph+N+PE) 50/60Hz 32A TN-S
VPHP generator	230V (1Ph+N+PE) 50/60Hz 25A TN-S	230V (1Ph+N+PE) 50/60Hz 25A TN-S	230V (1Ph+N+PE) 50/60Hz 25A TN-S	230V (1Ph+N+PE) 50/60Hz 25A TN-S
Installed power	5 kW	19.5 kW	12 kW	17 kW

https://www.comecer.com

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