BioSpherix MEDICAL

www.biospherixmedical.com
1 (315) 625-8025
"Beyond the needs of people,
to meet the needs of cells"

XVIVO SYSTEM

GMP COMPLIANT CELL PRODUCTION MINI-FACILITY

- **SAVES MONEY**
- **SAVES TIME**
- **SAVES SPACE**
- **REDUCES RISK**
- **PRODUCES BETTER CELL PRODUCT**

COMPLETELY CLOSED-SYSTEM PRODUCTION LINE
Cells are produced in a series of modular interconnected chambers. All instruments and processing tools are integrated inside according to process steps. Cells and supplies enter on one end. Waste is expelled aseptically along the way. Cell product emerges at the opposite end. One advantage over traditional brick-and-mortar, walk-in clean rooms is that the process can be developed anywhere. Then when it is time for cGMP certification, surround it with, or move it to, Class 100,000 (ISO 8, Class D) clean zone.

GMP PRODUCTION FOR PHASE 1 CLINICAL TRIALS
Cell manufacturing process can be debugged, optimized, and characterized during translational research phase. Once validated, cell production mini-facility can be converted to GMP by simply surrounding it in minimally classified space. Surrounding by Class D (ISO 8) cleanspace, isolators meet regulations. Modular clean rooms can be constructed around isolators for ISO 8. Any production line can be fitted. Any room can be fitted.

Economical and practical alternative to expensive clean rooms!

The XVIVO is a new cell production system based on isolation technology. Isolation barriers are proving valuable for food and pharmaceutical manufacturing and now we offer the first one for therapeutic cells.

It saves money in many ways. Capital costs are less. Operating costs are a lot less. You investment is rock-solid because modular design is flexible. Accommodate different processes. Move it to different locations. Adapt it to any existing space. Scale up indefinitely. Scale out indefinitely.

Implementation is fast. Prefabricated modules can be assembled and installed quickly. Qualifications and validations are straight forward and assured. GMP compliance can be achieved faster than ever before. Time-to-clinic is measured in months, instead of years.

Flexibility and low cost also reduces risk considerably, compared to massive inflexible cleanroom facilities. Now one can invest in cell therapy with confidence.

Complete isolation between the cells in an aseptic environment and the contaminated world outside maximizes quality. Unprecedented new features, achievable in traditional brick-and-mortar clean rooms, may even produce a better product!

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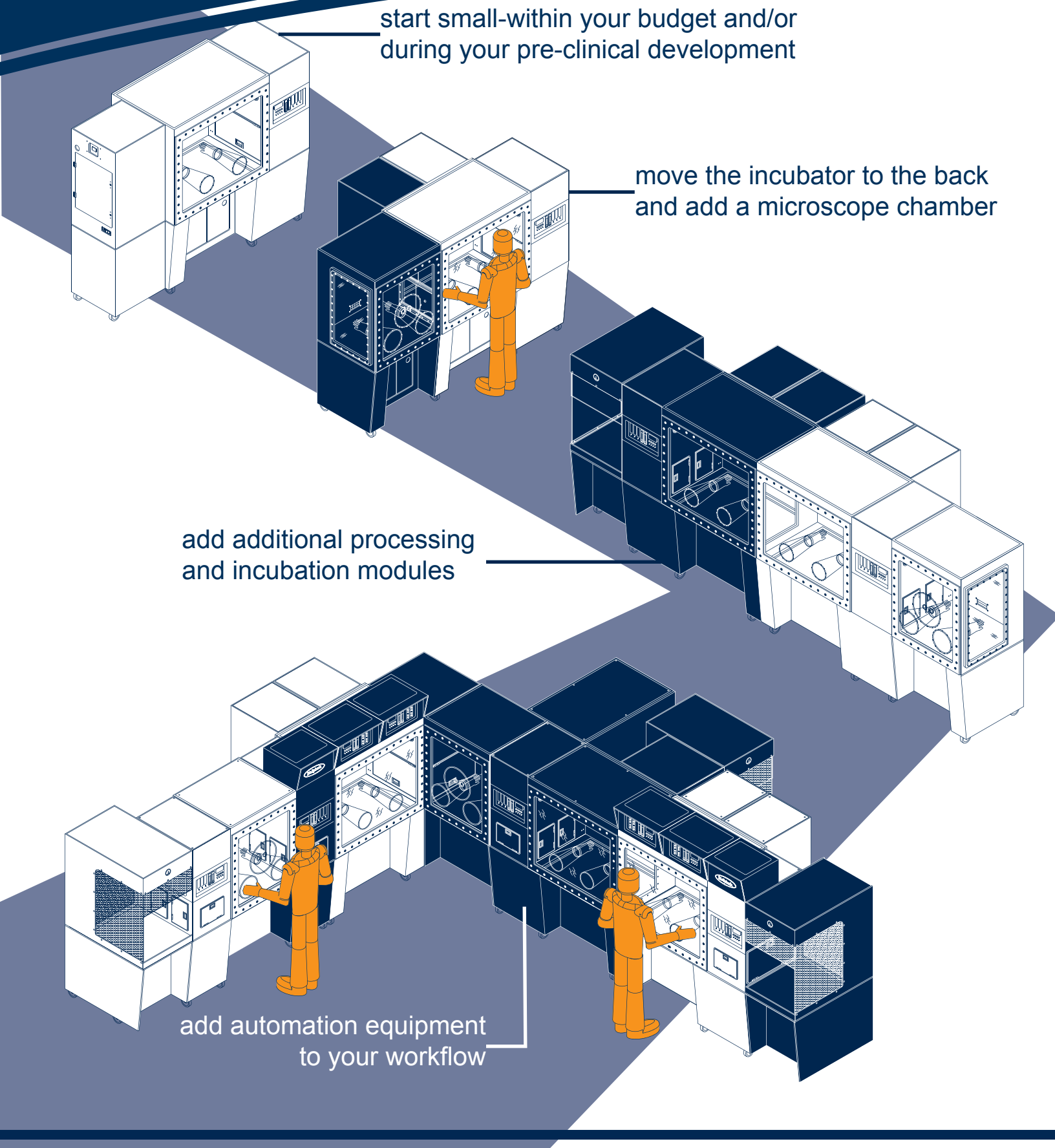
Self-Contained GMP Compliant

MODULAR

Cell Processing and production Facilities



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XVIVO GMP SYSTEM

CYTOCENTRIC PLATFORM...

- is the only total quality approach to cell existence outside the body.
- fits every cell lab, cell manufacturer, and cell application.
- produces optimum cell potency.

CYTOCENTRIC ISOLATOR...

- implements 10x faster than a cleanroom.
- scales up and out efficiently for large scale production.
- is 10% of the cost of a cleanroom at equivalent production capacity.
- can be relocated, reconfigured & repurposed (in days).
- records every critical process parameter of every batch.
- can be validated in less than a week.
- is ideal for automation.
- produces validated clinical grade cells in any dirty lab.

Translational Research Capabilities at the St Vincent's Institute Isolator Facility

***Bleasdale, N[1]**, Anne Thorburn[2], Tom Kay[2], Lina Mariana[2], Tom Loudovaris[2]*

[1] *Australian Red Cross Blood Service, Melbourne, Australia*

[2] *St Vincent's Institute of Medical Research, Melbourne, Australia*

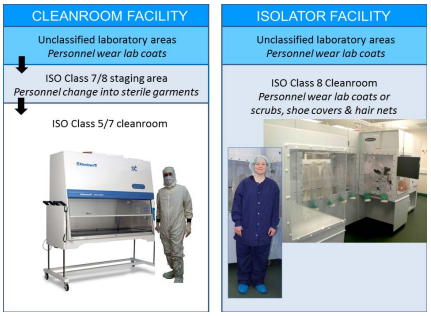
Since 2010, St Vincent's Institute has been part of a Commonwealth-funded project aimed at boosting Australia's capacity to develop and manufacture human cell and tissue-based therapies.

SVI, in partnership with Monash University, and with the support of the Victorian Consortium for Cell-based Therapies (VCCT), has established one of two biological isolator facilities in Melbourne.

The SVI Isolator Facility is housed on the St Vincent's Hospital campus and is available for processing of human cells and tissues for pre-clinical and clinical use.

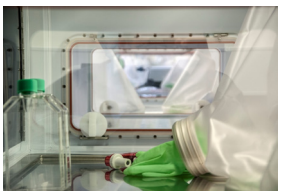
The **SVI Isolator Facility** houses a custom-built **BioSpherix Xvivo Isolator** that provides:

- a fully contained, controlled environment for manufacturing cell and tissue-based products intended for pre-clinical and clinical use.
- a flexible, cost-effective alternative to conventional cleanroom facilities.

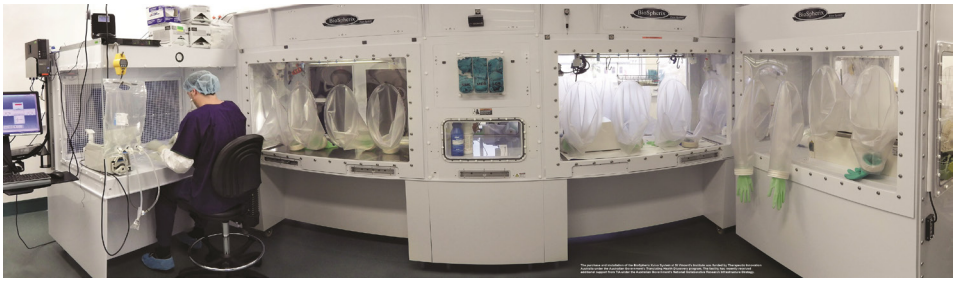


The isolator is certified to ISO Class 5 and is housed within an ISO Class 8 cleanroom*. These are the air cleanliness classifications required for isolator facilities engaged in the aseptic manufacture of human therapeutic products.

* *ISO 14644-1:2015 Cleanrooms and associated controlled environments, Part 1 Classification of air cleanliness by particle concentration.*

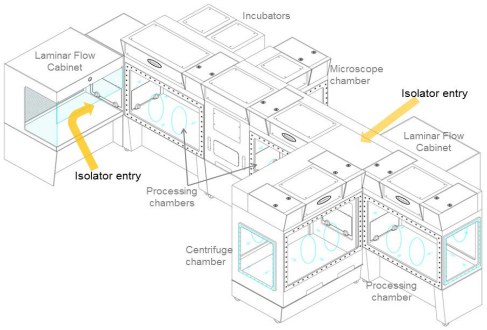


This facility was established with funding from Therapeutic Innovation Australia (TIA) under the Australian Government's Translating Health Discovery program, and from St Vincent's Institute. Additional soft infrastructure support was provided by TIA under the National Collaborative Research Infrastructure Strategy (NCRIS) program.



Features of the BioSpherix Xvivo Isolator:

- Laminar flow hoods
  These provide a staging area for materials entering the isolator
- Heated processing chamber/s
  Ambient → 45ºC
- Chilled processing chamber
  4ºC → ambient
- Independently controlled incubators
- Refrigerated centrifuge
- Microscope
- Adjustable temperature and gas controls
- Particle monitoring and control

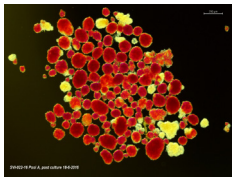


Benefits

- **High level of process control**
  Continuous maintenance of optimal conditions, including hypoxic to hyperoxic environments.
- **Reduced contamination risk**
  Full containment throughout all process steps.
- **No sterile gowning**
  Enhanced operator comfort.
- **Versatility**
  Basic cell propagation to isolation of primary cells from human tissue.

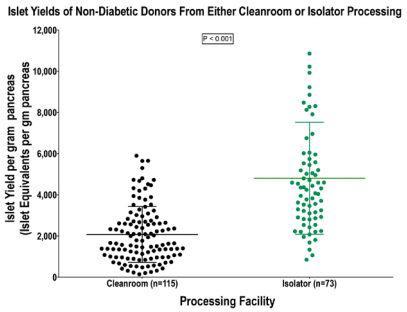
Isolating islets for transplantation: Cleanroom vs Isolator

The SVI Islet Transplant Program isolates pancreatic islets from deceased donors, for transplantation into type 1 diabetics with severe hypoglycaemic unawareness.



To date 188 pancreata from non-diabetic donors have been processed. The majority (n=115) of these isolations were performed in a conventional cleanroom; however the last 73 have been processed within the SVI Isolator Facility.

Data indicates that islet yields from the isolator-processed pancreases are significantly higher than those that were obtained within a conventional cleanroom setting. Refer to the graph below.



While several factors may have contributed to this improvement, the optimised and highly reproducible processing conditions afforded by the Isolator has almost certainly played a significant part in improving islet yields.

The **VCCT** is an association of over 20 public and private organisations with the vision to:

Facilitate clinical translational of cell therapies in Australia through the provision of affordable and versatile facilities, and the sharing of cell-based therapy knowledge and technical expertise.

For further information, including access requirements, and to view the facility, please contact the Operations Manager:

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M 0439 923924

The Australian Red Cross Blood Service is assisting SVI through the provision of operational support to the SVI Isolator Facility.