

Whitley GMP Anaerobic Isolators





01 Our Credentials



Don Whitley Scientific (DWS) has been a global leader in variable atmosphere workstations since 1976. Our extensive range features patented anaerobic and microaerobic technologies that have advanced scientific discoveries and modern medicines. Whitley GMP Anaerobic Isolators offer the highest levels of quality and control, ideal for applications such as live biotherapeutics, probiotics, FMT, and botulinum toxin development and manufacturing.

With almost half a century of scientific innovation and collaboration with leading scientists and institutions, we have developed the Whitley GMP Anaerobic Isolator for higher quality and superior control over your microbiome products.

The physical isolation, sterile laminar airflow and positive operating pressure maximises product protection within a generous processing area. It's the only anaerobic chamber with laminar flow on the market.

DWS is a family-owned company, headquartered in the UK with subsidiaries in Germany and Australia. We design, develop, manufacture, sell and service our product range ensuring the highest quality products.

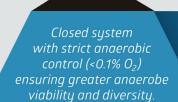
Our in-house microbiology laboratories not only conduct third party studies but are invaluable to our research and development activities.

For more information or discuss your requirements, please contact us:

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Strict Anaerobic Conditions



GMP ISO3 environment- 100x less particles than ISO5/Grade A. Uni-directional airflow with re-circulation technology protects against unwanted bacterial growth.

Contamination Control



Large incubation and processing capacity with equipment integration for culturing, suspension, and analyses.

Large Processing Area



03 Whitley Isolators: Main Features

FEATURES

- Precise anaerobic atmosphere control for efficient running costs.
- 0₂ levels < 0.1%
- Anaerobic Mixed Gas: 10% H₂ / 10% CO₂ / 80% N₂
- Palladium catalyst + Anotox[™]
- An H14 HEPA filter combined with uni-directional airflow maintaining EU GMP Grade A conditions.
- Recirculating technology creating an ISO3 environment 100x less particles than Grade A/ISO5.
- Continuous viable and non-viable particle monitoring with microbial air sampling.
 Optional air sampling ports can be fitted for connection to external monitoring systems.
- Integrated VHP biodecontamination with isolated chamber sterilisation processing in adjacent modules.
- Whitley Intelligent Monitoring environmental and atmospheric sensors measuring and controlling airflow, airspeed, positive pressure, O₂, CO₂, temperature and humidity.
- Data logging audit trail captures all user logins, events and alarms ensuring data integrity and traceability.
- Ethernet-enabled for data download to servers, remote access review and control.
- Easy connection to EMS and BMS interfaces.
- Innovative, quick-change gauntlet system allows easy, rapid glove replacement without loss of conditions or risk of contamination.
- 'Standby' feature (Eco mode) automatically decreases fan speed when the chamber is at rest to optimise energy usage.
- Bespoke trolley with heavy-duty castors provided as standard. Motorised, height-adjustable trolley available.
- Other optional features are available to tailor the system to your requirements, including 3-way airlocks, refrigeration modules, and equipment integrations.



HEPA Filtration

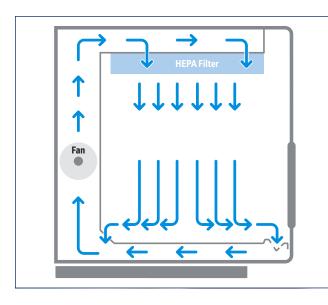
Whitley GMP Workstations feature an H14 HEPA filter housed in the ceiling of the cabinet to provide sterile unidirectional airflow. HEPA filter face velocity and uniformity of laminar flow testing to validate system integrity and performance to ISO 14644. The ULPA filter upgrade option replaces the standard H14 HEPA filter with a higher specification U15 ULPA (Ultra-Low Particulate Air) filter. The standard H14 HEPA filter is better than 99.995% efficient at the most penetrating particle size (MPPS), and the upgraded U15 ULPA filter is better than 99.99995% efficient at the MPPS.



Anaerobic Control

Whitley Workstations provide perfect conditions for the processing, incubation, and examination of anaerobes. These workstations allow you to manipulate parameters such as temperature and humidity to create sustainable conditions ideal for anaerobe cultivation.

The optional HEPA filtration system flushes all the atmosphere through the filter hundreds of times an hour. With a Whitley Workstation, sample manipulation within a secure anaerobic environment is as easy as working aerobically a the laboratory bench.



Large Airlock

The standard 17.5 litre airlock provides effective transfer for up to $10 \times 500 \text{ml}$ Duran bottles to and from the workstation in just 2 minutes.

Alternatively, a larger, 43 litre airlock can be specified to facilitate transfer of larger items of laboratory ware, bottles of media, etc.

This larger airlock also allows a Corning CellSTACK® to be transferred into the workstation chamber.



O5 Whitley GMP Isolator: Case Study

Client Needs

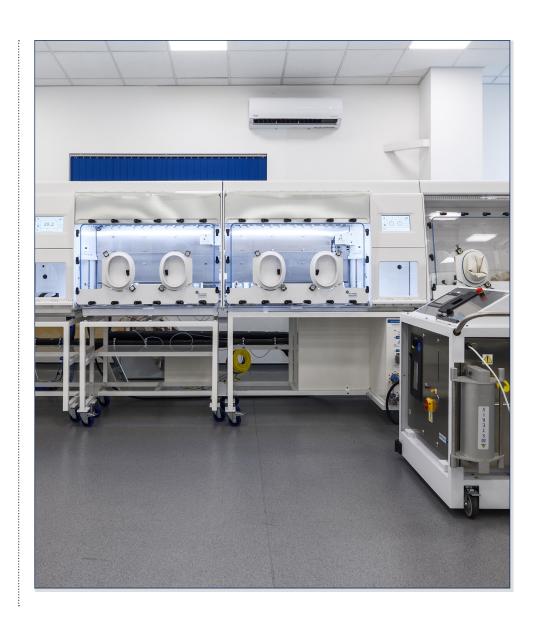
A leading FMT manufacturer, collecting, suspending and lyophilizing donor stool samples for patients suffering with C. difficile infection required a GMP, anaerobic chamber for FMT preparation.

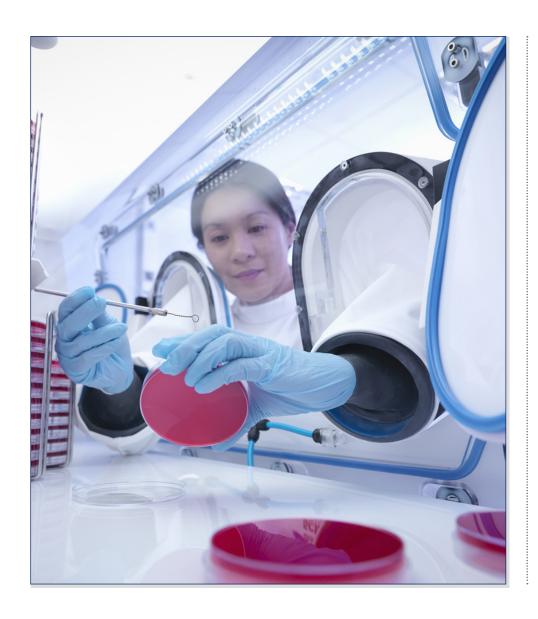
Project Scope

A Grade A, closed-process, <0.1% O2 isolator was required with strict anaerobic control and high throughput to preserve, suspend and lyophilize healthy donor stool samples.

Solution/Features

- 1. Strict anaerobic control: (< 0.1% O2) with humidity and temp control to sustain gut microbiome viability and diversity.
- 2. HEPA filtration for sterility and contamination control.
- 3. Airlocks (10 x 0.5L bottle capacity) with rapid transfer and cross-contamination prevention.
- 4. Large processing area (w x d x h: $1075 \times 750 \times 608$ mm) to store and perform stool suspension.
- 5. Integrated anaerobic conditions monitoring ensuring traceability.
- 6. Integrated microscope for CFU counts.
- 7. Fully closed system.



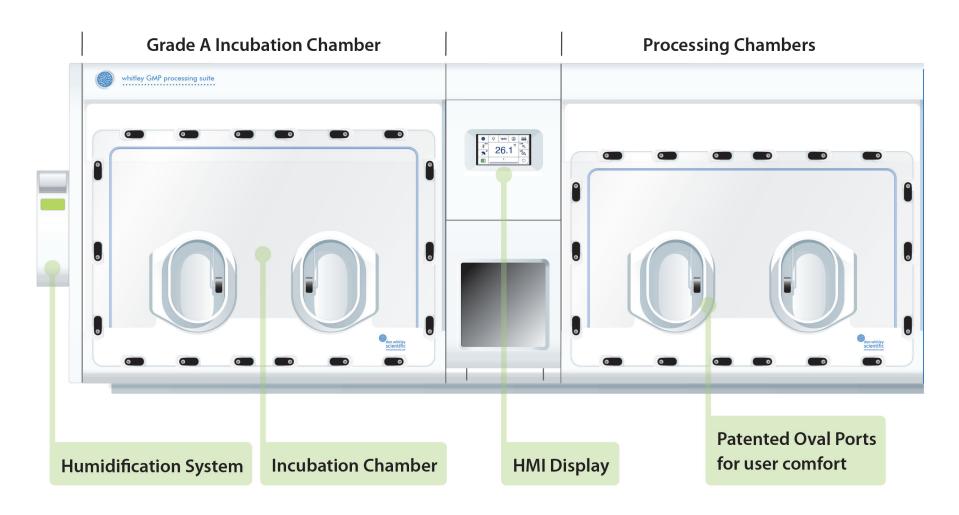


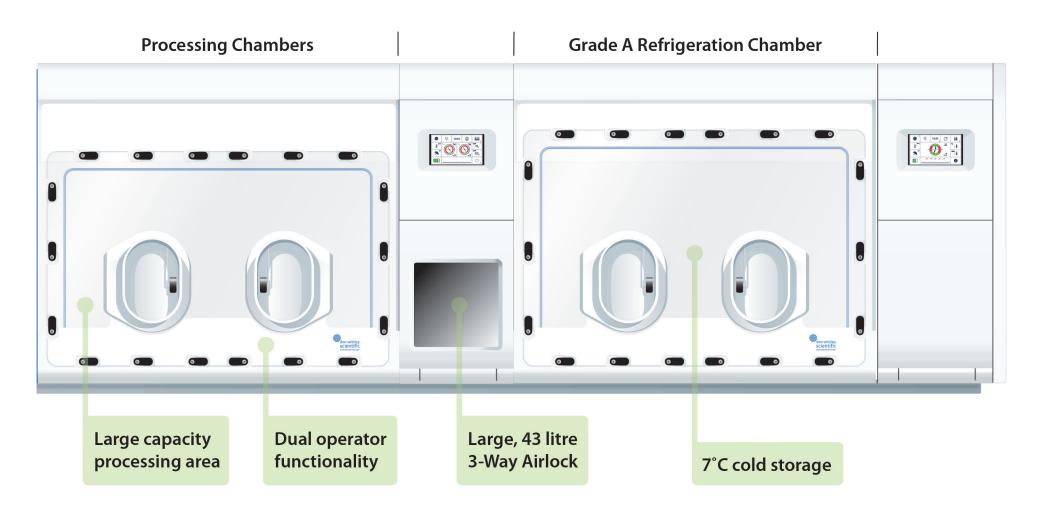




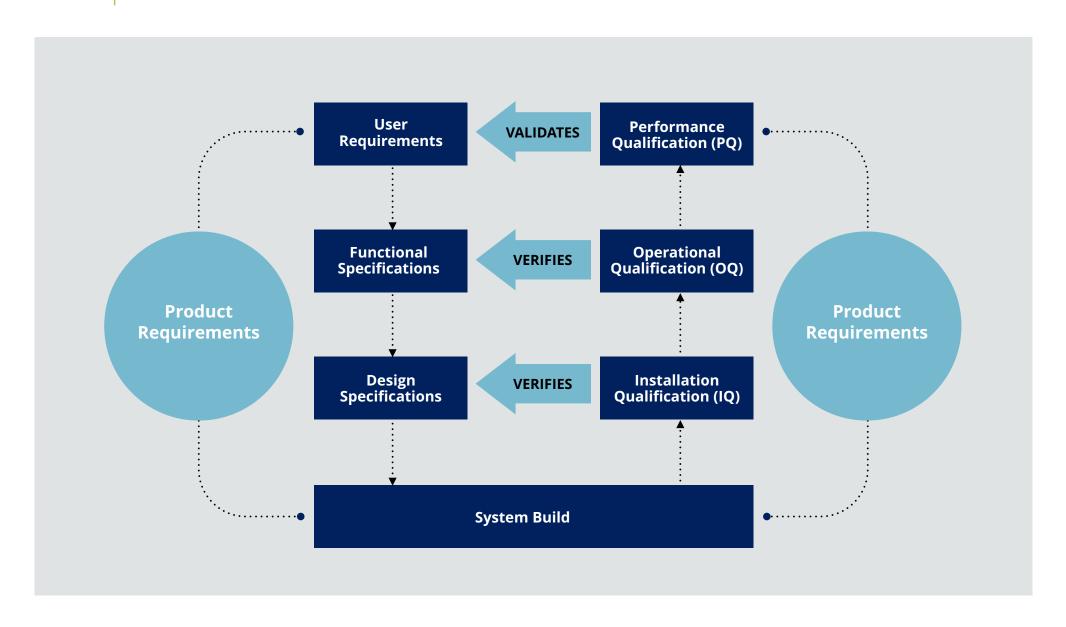


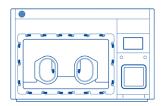
Whitley GMP Isolators: Modular Design

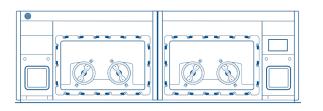




Whitley GMP Isolators: GMP Validation Model







Whitley A135 GMP Isolator		Whitley A155 GMP Isolator			Features
900 Litres		1800 Litres		Chamber Capacity	
17.5 litres or 43 litres		17.5 litres or 43 litres		Airlock Capacity	
2x Manual Sleeved Ports with gauntlets		2x Manual Sleeved Ports with gauntlets		Porthole System	
Anaerobic Mixed Gas or Anaerobic Mixed Gas + N₂		Anaerobic Mixed Gas or Anaerobic Mixed Gas + N ₂		Gas Supplies	
Wireless		Wireless		Footswitch	
0		0		ANO ₂ Conditions Monitoring	
0		0		Internal Mains Socket	
0		0		Pressure Decay Testing	
•		•		Internal Lighting	
0		0		GMP data Package	
1 or 5 minutes		1 or 5 minutes		Airlock Cycle Time	
0		0		Extra Cable Glands	
•		•		HEPA Filtration	
•		•		Automatic Dehumidifier	
0		0		ULPA Filter Upgrade	
•		•		Removable Front	
•		•		Workstation Trolley	
•		•		Remote Access	
1500 / 1130 / 1080		2940 / 1130 / 1080		Dimensions w/d/h (mm)	
649 / 295		1298 / 590		Weight (lbs/kg)	
Fitted as standard	Option	available	– Not applicable		KEY:







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