

Whitley GMP Isolators

Cell Optimised Isolators



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Whitley GMP Isolators: Our Credentials



Don Whitley Scientific has been designing and producing modified atmosphere technology since 1976. We offer a range of cell optimised isolators for the cultivation of mammalian cells under physiologically relevant conditions. We are at the forefront of innovation, designing quality products and pioneering allogenic solutions for faster market access.

Our expertise has enabled us to manufacture a range of Whitley GMP Isolators for ATMPs, stem cells, organoids, tissue engineering and regenerative medicines requiring a Grade A/ISO5 environment with atmosphere control. Our range of GMP isolators is flexible and modular, allowing you to create custom arrangements for your unique processing needs.

Our experience in manufacturing GMP oxygen controlled isolators combined with the flexibility of our UK manufacturing site, enables us to support our customers to develop scalable and cost-effective cleanroom alternatives capable of saving \$20,000/m in operations.

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.

We also have in-house microbiology laboratories that 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:

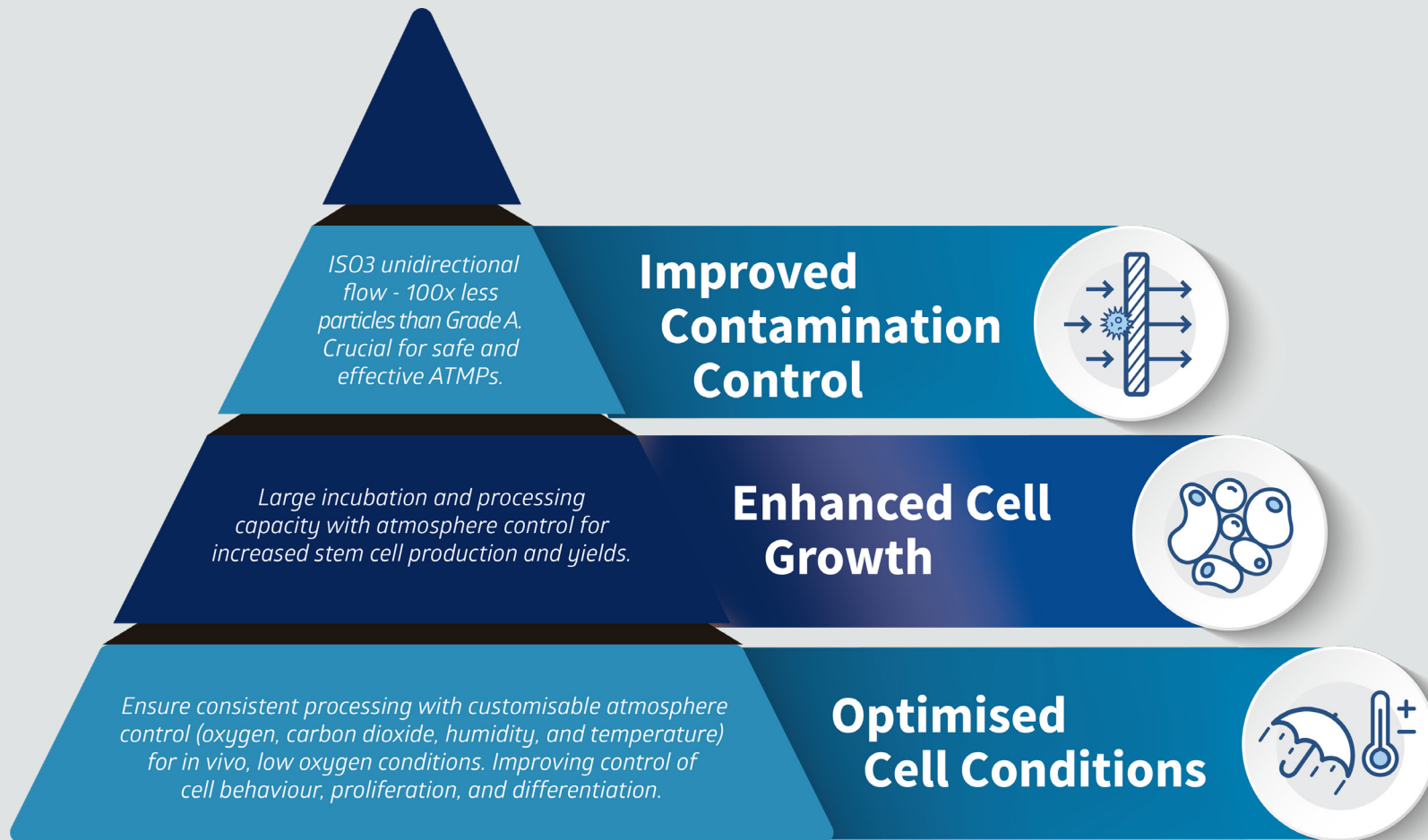
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Whitley GMP Isolators: Unique Innovations

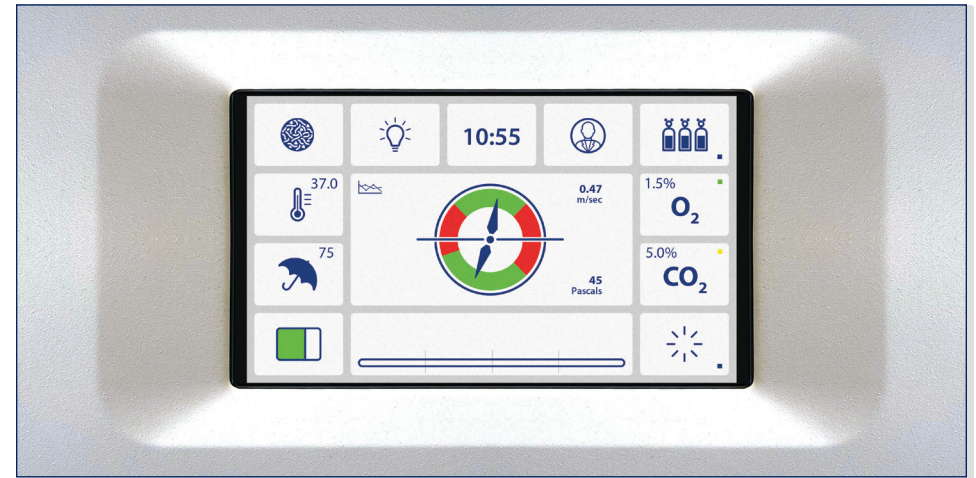
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03 | Whitley GMP Isolators: Features

FEATURES

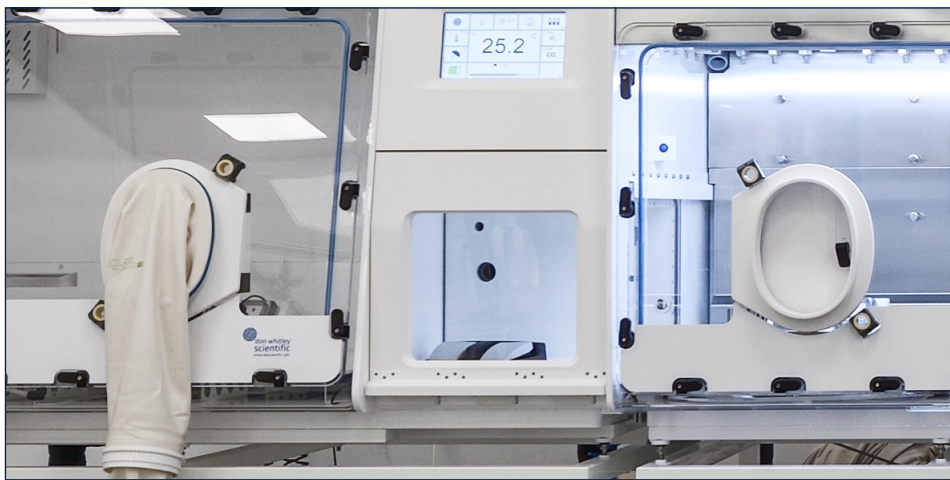
- Precise O₂ control between 0.1% and 20.0% and CO₂ between 0.1% and 15.0% for effective, efficient running costs.
- An H14 HEPA filter combined with uni-directional airflow maintaining EU GMP Grade A conditions.
- Recirculating technology creating an ISO3 environment - 100x less particles than Grade A/ISO5.
- Continuous viable and non-viable particle monitoring with microbial air sampling. Optional air sampling ports can be fitted for external monitoring systems to be connected.
- 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 & BMS interfaces.



H135 GMP Workstation Touchscreen



HEPA Filter located in the chamber ceiling



Three-way airlock



Quick-change gauntlet system

- 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.

05 | Whitley GMP Isolators: Case Study

Client Needs

A UK-based biopharmaceutical company, were developing an off-the-shelf allogenic T-cell treatment for solid tumour cancers. They required a GMP cell processing suite for stem cells. Given the long processing times involved, ergonomic comfort and class-leading dexterity were essential for their operations.

Project Scope

Their strict requirements were to manufacture high quality cells with no contamination risks. A cGMP ISO5, closed-process, modular isolator suite with low oxygen control throughout was needed to process and incubate stem cells. A Grade A refrigeration chamber was crucial too. Contamination risk reduction was a critical factor for their cell processing operations. Don Whitley Scientific (DWS) proposed the Cell Optimised Isolator solution.

Solution/Features

DWS partnered with the purchasing team to generate the user requirements specification (URS) to engineer a customized, Grade A, cell optimised isolator with variable oxygen control, incubation, and refrigeration with VHP biodecontamination that fulfilled the company's needs. The finalised solution consisted of the following features:

1. cGMP standards to FDA Annex 1.
2. Modular design ensuring flexibility and scalability.
3. No air inlet from cleanroom to prevent contamination.
4. Smallest equipment footprint compared to competitors.
5. 3 interlocked modules to incubate, process and refrigerate.
6. Full IQ/OQ validation to ensure compliance and reliability.
7. Air locks between modules preventing cross-contamination.
8. Closed process with unidirectional airflow to maintain aseptic conditions.
9. 100x less particles than Grade A (ISO3) compliance to ensure the highest level of cleanliness.

10. VHP sanitisation with independent chamber gassing allowing simultaneous processing.
11. Innovative quick-change gauntlet design with easy change gloves that avoid compromising the Grade A environment.
12. Removable front to preload materials, equipment, and reagents for VHP sanitisation.

Incubation Module

1. Relative humidity control up to 80%.
2. Incubation at 37°C to support cell growth.
3. CO₂ control with 0.1% increments between 0.1% - 15.0% CO₂ in all modules.
4. O₂ control with 0.1% increments between 0.1% - 20.0% O₂ in all modules for hypoxic stem cell culturing.





Cell Processing Module

1. Capability for two operators to work simultaneously.
2. Equipment integration for seamless operation within the isolator.
3. Aseptic transfer system to facilitate use of external equipment inside the isolator.
4. CO₂ control with 0.1% increments between 0.1% - 15.0% CO₂ in all modules.
5. O₂ control with 0.1% increments between 0.1% - 20.0% O₂ in all modules for physioxic stem cell culturing.

Refrigeration Module

1. Relative humidity control.
2. Grade A refrigeration for cell culture reagents at 7°C.
3. CO₂ control with 0.1% increments between 0.1% - 15.0% CO₂ in all modules.
4. O₂ control with 0.1% increments between 0.1% - 20.0% O₂ in all modules for hypoxic stem cell culturing.

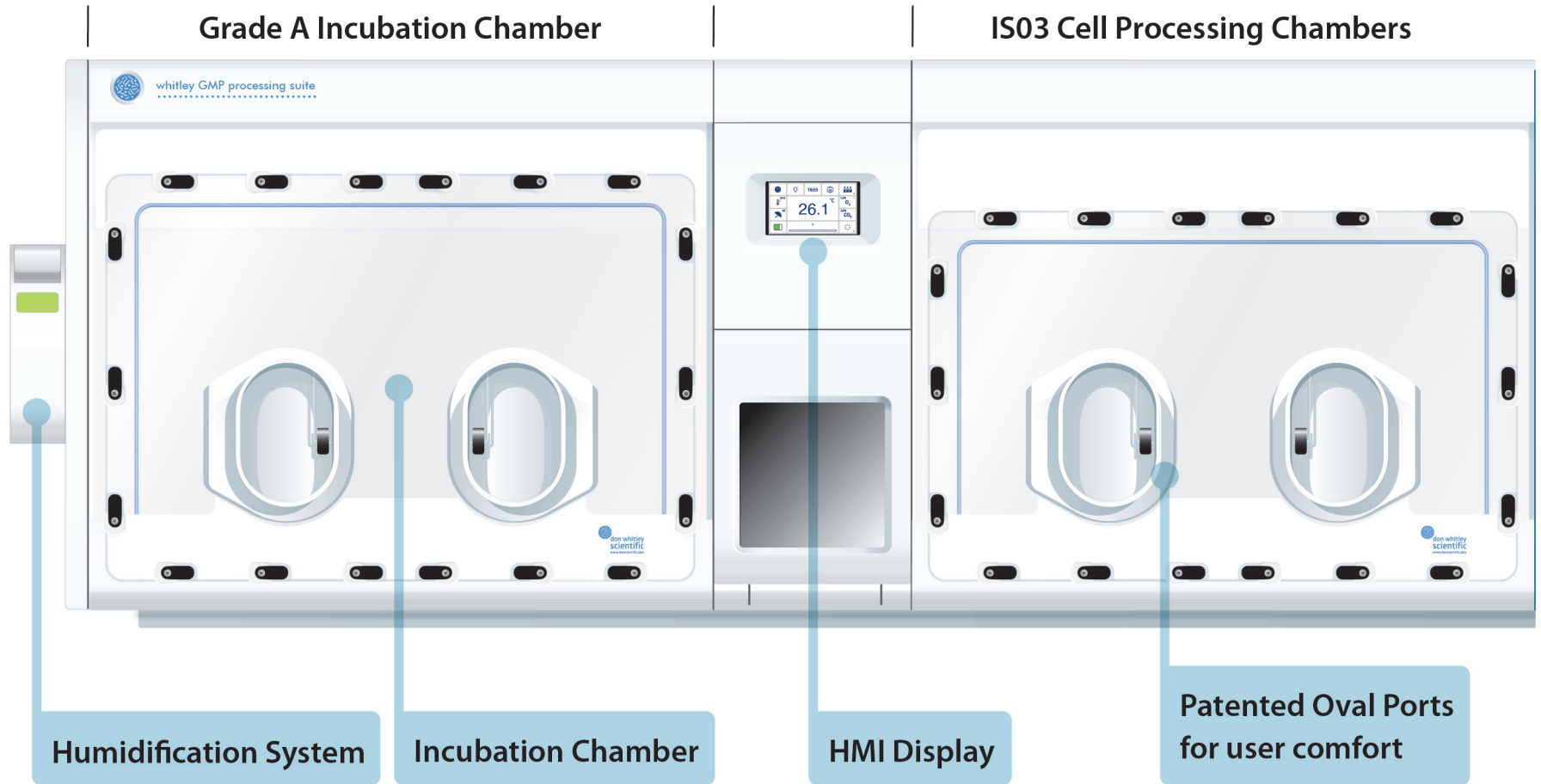
Design Features

The customised cell optimised isolator comprised the following components:

1. Three Grade A (ISO3) aseptic cell optimised Isolators.
2. One 4-glove main chamber with dual entry-exit airlocks.
3. Two 2-glove main chambers each with a single entry-exit airlock.
4. Onboard vapour phase hydrogen peroxide (VHP) gassing system with a catalyser for room return following aeration.
5. Full-colour touch screen HMI for intuitive control and monitoring.
6. Power and data sockets for equipment connectivity.
7. Glove integrity testing system linked to the PLC/HMI for online reporting, ensuring operator safety.
8. 500 lux lighting within the main chamber for optimal visibility.
9. Aerotrak 9510 particle counter, with an isokinetic funnel attached, within the processing chamber.

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Whitley GMP Isolators: Example



IS03 Cell Processing Chambers

Grade A Refrigeration Chamber



Large capacity processing area

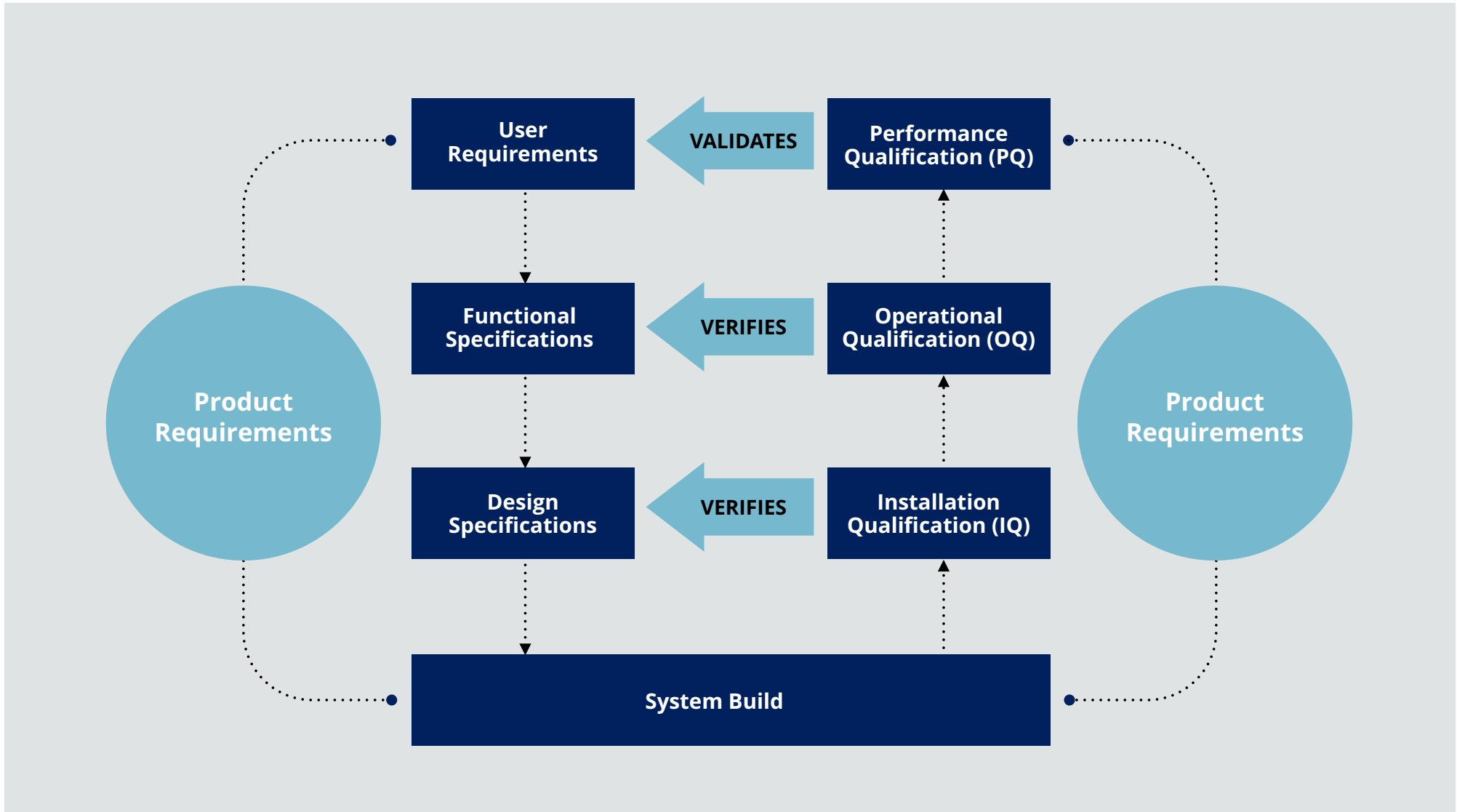
Dual operator functionality

Large, 43 litre 3-Way Airlock

7°C Reagent storage

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Whitley GMP Isolators: GMP Validation Model

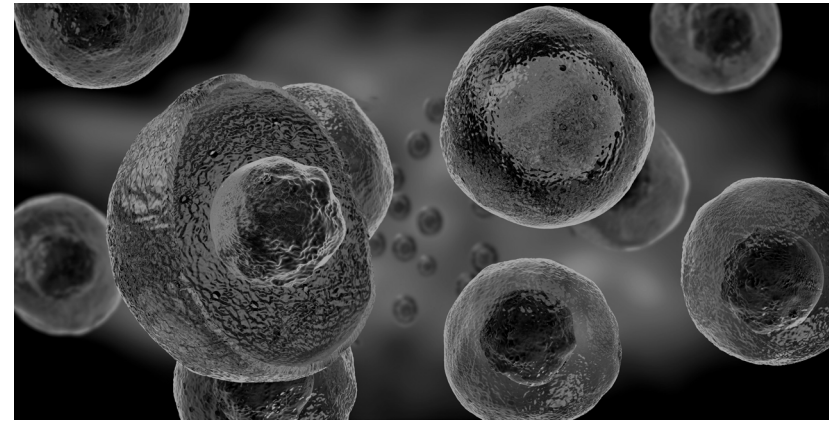
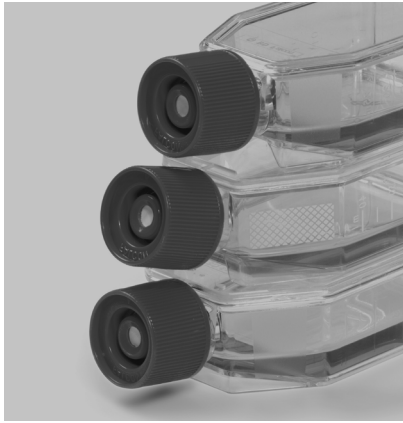


Whitley GMP Isolators: Specifications

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Features	Whitley H135 GMP Isolator	Whitley H155 GMP Isolator	
Chamber Capacity	900 Litres	1800 Litres	
Airlock Capacity	17.5 Litres or 43 Litres	17.5 Litres or 43 Litres x 2	
Porthole System	2x Manual Ports	4x Manual Ports	
Gas Supplies	CO ₂ / Air / N ₂	CO ₂ / Air / N ₂	
GMP Data Package	○	○	
HEPA Filtration	●	●	
ULPA Filter Upgrade	○	○	
Removable Front	●	●	
Remote Access	●	●	
Internal Mains Socket	○	○	
Pressure Decay Testing	○	○	
Internal Lighting	●	●	
Airlock Cycle Time	1 to 5 minutes	1 to 5 minutes	
Extra Cable Glands	○	○	
Humidifier	○	○	
Automatic Dehumidifier	●	●	
Workstation Trolley	●	●	
Footswitch	Wireless	Wireless	
Dimensions w/d/h (mm)	1500 / 1130 / 1080	2940 / 1130 / 1080	
Weight (lbs/kg)	649 / 295	1298 / 590	
KEY:	● Fitted as standard	○ Option available	- Not applicable



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