

# Clean Air Solutions by IsoTech Design

Cost effective, safe and USP <797> compliant clean air solutions for sterile and hazardous compounding. We protect life with contamination control, sterility assurance and containment management. Why build a constructed clean room?

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Founded:	1994	
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# **Company Background**

Since 1994, IsoTech Design is a leading designer and manufacturer of USP <797> clean air solutions, such as isolators and clean rooms. We have been serving pharmacies for 20 years in sterile compounding, chemo compounding, hormone compounding, and sterility testing. Our mission is Protecting Life. Our clean air solutions protect the products that go inside the patients, protect the operators from the hazardous products and also protect the environment. We have over 1000 certified facilities across the United States & Canada, who are using our clean air solutions for sterile and chemo compounding while complying with the USP <797>, their state board of pharmacies, OSHA and NIOSH regulations and requirements. These clean air solutions, such as isolators or modular clean rooms, are cost effective when compared to traditional constructed clean rooms. Pharmacy facilities in 15 countries and five continents use our clean air solutions, which have been validated and certified according to their respective norms and regulations.

# **Product Lines**

**IsoTech offers the following products and services:** CAIs, CACIs, modular cleanrooms in positive and negative pressure, powder and fume hoods, clean air workstations, sterility testing isolators, fan filter units, total service plans, and USP <797> essentials.

MicroSphere<sup>™</sup>: Compounding Aseptic Isolator for sterile compounding. ChemoSphere<sup>™</sup>: Compounding Aseptic Containment Isolator for chemo compounding.

CleanSphere™: Modular cleanroom.

SafeAirx™: Powder hood for hormone compounding.

**CleanFlow™:** Clean air workstation for sterile compounding in a clean room. **MicroSphere™-ST:** RABS for small volume sterility testing.

**IsoSphere™-ST:** Isolator for medium and large volume sterility testing. **DesignAir™:** Fan Filter units for clean rooms.

**TSP:** Total service plans that include certification, extended warranty, technical support, updated SOP, training, and other services such as environmental monitoring.

**Clean Air Essentials <797>:** All essentials such as cleaning and disinfecting products, sterile gloves, sterile IPA 70%, safety kits for hazardous compounding, sleeve kits for CAIs and CACIs, and environmental monitoring kits.

# Features & Options

We offer standard and customized ergonomic clean air solutions, based on need assessment, regulations requirements, space availability and budget.

## **Product Specifications**

**MicroSphere™:** ISO 5, positive pressure, ergonomic, USP <797> compliant CAI for sterile compounding; available in standard 4', 5', 6', 8' and custom design, IV pump integration and does not need to be put in a clean room.

**ChemoSphere™:** ISO 5, negative pressure, USP <797> compliant CACI for chemo compounding; available in 4', 6' and 8', ergonomic, custom integration and does not need to be put in a clean room.

**CleanSphere™:** ISO 4 to ISO 8 positive and negative pressure modular cleanrooms.

SafeAirx<sup>™</sup>: Ductless powder, fume and vapor extraction, ergonomic, USP <795> compliant enclosure with visual and audible alarms for toxic powder compounding, transfer and weighing, available in 3', 4', 6', custom integration and ergonomic.

**MicroSphere™-ST:** ISO 5, positive pressure, ergonomic, cGMP, FDA validated, RABS with custom integration for sterility testing.

**IsoSphere™-ST:** ISO 5, positive pressure, ergonomic, cGMP, FDA validated, isolator with custom integration for sterility testing.

## Testimonial

"All our Clean Air Solutions have been certified and validated according to their respective norms."

- USP <797>; FDA; cGMP; State Boards of Pharmacy

# Additional Product Lines

**RadioSphere™:** ISO 5, negative pressure, USP <797> & cGMP compliant CACI with 1" lead shielding for radio and nuclear pharmacy compounding and research.

## **Key Customers**

CTCA, UMASS, Stanford, FDA, Robert Wood Johnson, Duke University

#### **Markets Served**

Hospital Pharmacies, Compounding Pharmacies, Sterility Testing, Pharmaceutical Aseptic Filling

## **Trade Shows/Meetings Attended**

ASHP, IACP, Health Connect Partners

#### **GPO Affiliations**

MedAssets, Premier, Amerinet

#### **Ordering Information**

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