

Guide to Esco Pharmaceutical Products

Worldwide Edition, 2013/2014



ESCO
PHARMA

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Pictured: Esco Micro Pte. Ltd. is headquartered in Singapore, a modern city state located in Southeast Asia with a population of more than 4 million. From Singapore, Esco manages operations throughout the world.



Welcome to Esco

Esco's Vision is to provide enabling technologies for scientific discoveries to make human lives healthier and safer.

- A leader in the development of controlled environment, laboratory and pharmaceutical equipment solutions.
- A world leader in biological safety cabinets.
- Esco has established offices in 13 countries such as Bahrain, China, India, Japan, Korea, Malaysia, Philippines, Singapore, South Africa, UK, US, Indonesia and Vietnam and is continually expanding.
- North American facilities in Pennsylvania; sales, service, logistics for US & Canada.
- Group total of more than 600 employees.
- Distributors in more than 100 countries.
- Products independently tested to international standards.
- Large R&D investments, world leading technologies.
- State-of-the-art production; vertically integrated manufacturing floor space.
- Worldwide service played out over a geographic expanse so broad that the sun never sets on what we do.



Pictured: Esco's state-of-the-art manufacturing facility

Products and Application

Esco Pharmaceutical Products

Airflow Containment

- Pharmacon Downflow Booths.
- Esco Straddle Unit Single, Esco Straddle Unit Double, Custom LF Cabinets.
- Esco Garment Storage Cabinet, Laminar Flow Storage Cabinet
- Laminar Flow Vertical Trolleys, Laminar Flow Horizontal Trolleys
- Ceiling Suspended Laminar AirFlows, Fan Filter Units
- Laminar Flow Booths, Modular Enclosures.

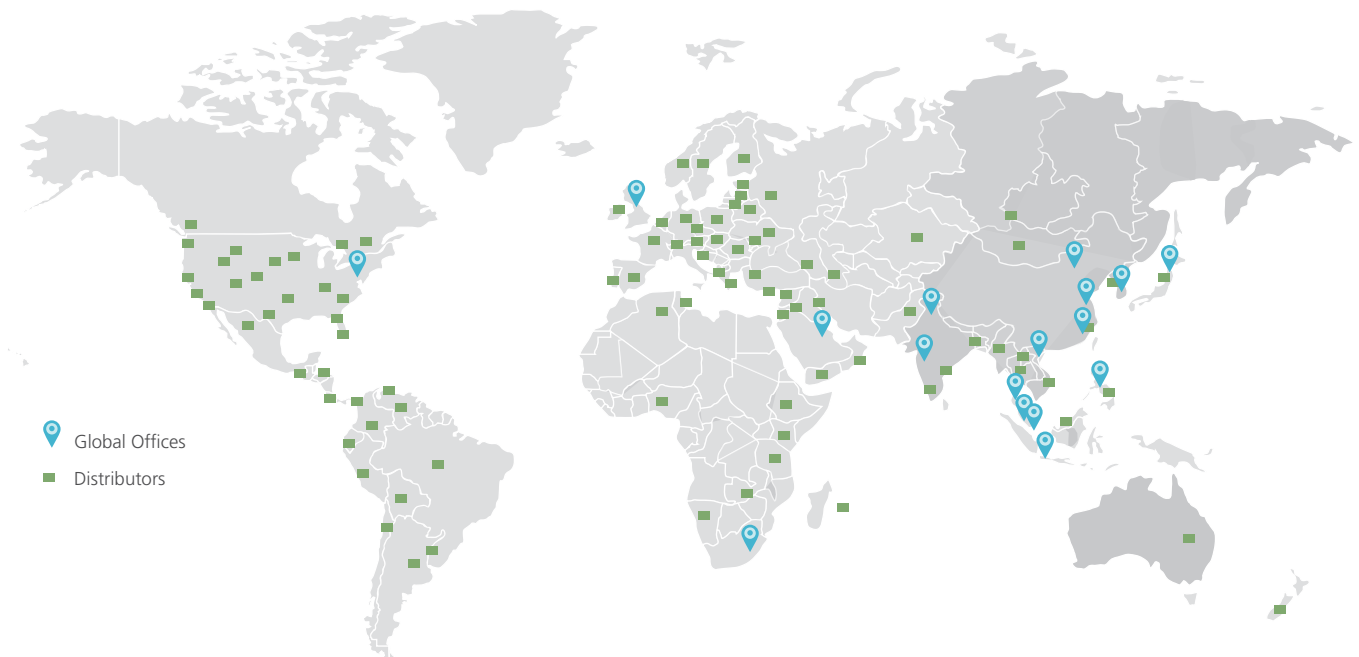
Isolation Containment

- Aseptic Containment Isolator (ACTI)
- Weigh / Dispense Containment Isolator (WDCI)
- CAI and CACI
- Custom Isolators

Cross Contamination Facility Integrated Barriers

	Static Barriers	Dynamic Airflow Barriers		Biodecon Barriers
		Air Shower	Vertical Airflow	VHP
Material wall mounted	EPB/SPB	EAS-PB	Dynamic Passbox	VHP-PB
Material Floor mounted	SPB Transfer Carts	EAS Dedusting Hatch	Dynamic Floor Laminar Hatch	VHP Airlocks
Personnel Entry/Exit	N/A	EAS	N/A	Biodecon Booths

Global Network



Pharama Product Research and Development

Esco Pharma R&D is carried out entirely in our new dedicated facility in Loretta, Pennsylvania, USA.



Our Esco Pharma Dedicated R&D Engineers have a combined 30 years of experience in systems design of a variety of containment and aseptic process equipment. Compared to industry averages, Esco invests a significant percentage of annual revenues in research and development. As a result of our investment, and with continuous feedback and idea evaluation among our research, global sales, marketing, purchasing and manufacturing teams; Esco products reflect the best contemporary designs in performance, ergonomics and customer satisfaction.

Manufacturing

Quality, Cost, Productivity, Effectiveness, Timeliness



Esco's manufacturing advantage stems from our extensive degree of vertical integration, enabled by our world-leading throughput. All processes, with a few exceptions, are performed in-house. This allows us to achieve quality and reliability that is truly world-class. Our plant capabilities include:

- Incoming materials inspection and warehousing
- CNC-controlled sheet metal fabrication and welding
- Environmentally-friendly powder coating lines
- Electromechanical final product assembly

- Electrical / electronics sub-assembly
- Multi-step electrical and physical performance testing
- Independent quality control at each step in the production cycle
- Microbiology, chemistry, containment test labs

Esco's focus on quality and timeliness is relentless. Continuous improvement is a mantra. Cross functional teams from Esco Production, R&D, Quality Assurance, Senior Management, are regularly assembled to review and implement areas for improvement.



Pharmacon Downflow Booths



Premium Dispensing and Sampling Suites for bulk, pilot and small scale powder applications.

Since 1978 as the pioneer in clean air / containment technology in the Far East , Esco has been installing downflow containment booths for use in Pharmaceutical Dispensing and Sampling Operations.

Esco Pharmacon Downflow Booths still operational since 1995!



Lower permissible exposure levels often create additional risk for technicians therefore Downflow Booths can be incorporated with safe change filter housings. Safe change filters can either be changed into the Downflow Booth or from a dedicated technical access space.

Esco Downflow Booths through generations of continuous R&D are currently surrogate powder tested to provide permissible exposure levels for pharmaceutical operators down to 50-100 μ g/m³ over an 8 hour TWA.

This can be lowered further with the use of containment screens or when required with additional Personal Protective Equipment (PPE).



For specific process requirements such as handling hygroscopic powders and when operator comfort is required, cooling coils working in either DX or chilled water systems are provided as optional add ons, these can come with additional humidity controls as well to bring down ambient humidity levels to client setpoint.



Esco Downflow Booths can be installed in warehouse facilities as well for sampling of bulk powders minimizing cross-contamination of the ambient environment thereby enhancing cGMP practices.



For enhanced downward airflow, PLF Screens can be incorporated with IP 65 lighting placed above the screens thereby providing enhanced uniform lighting and full laminar downflow.



When Handling both powders and solvents Pharmacon Downflow Booths can operate in single pass modes.

Other typical customizations include:

- Drum Tippers
- Perforated Anti-Vibration Work Benches.
- Facia cavities for computers, screens, printers.
- Services such as N₂, water, compressed air.
- Touchscreen and digital pressure alarms in lieu of switches and pressure gauges.



- Turnkey Sampling facilities with entry/exit airlocks, conveyor systems and automated sliding doors.
- Hazardous applications.
- Integrated pass-through systems.

Custom small scale powder applications:



Atex Rated Dispensing Booth.

Enterprise Esco Straddle Unit Single, Esco Straddle Unit Double, Custom LF Cabinets.



Industrial Premium Solution for Aseptic Cabinets

Esco is an industry leader in the development of custom professional quality laminar flow clean bench cabinets. With tens of thousands sold throughout the life sciences market worldwide.

Esco has reinforced its reputation for dependability by providing reliable protection for samples and work processes in a multitude of applications.

Our selection of Vertical, and Specialty clean bench cabinets offers a variety of choices for installations where high quality construction is essential. Our clean bench cabinets are aerodynamically engineered and use only premium quality filters with integrated motor/blower assemblies for quiet operation and long service life.

Since 1978, Esco has emerged as the industry leader producing laminar flow cabinets that are the premium selection for the discerning researcher and offering a combination of value, high quality construction, low operating noise levels, and a wide product range to suit all budgets.

Optional Features

- Knife edge gel sealed filters.
- Cold room (4°C) application.



- Blackout curtains.



- Full SS304 or SS316L Construction.
- Custom dimensions.

Ceiling Suspended Laminar Airflow (CLAF)



Introduction

Ceiling Laminar Airflow units provide enhanced aseptic work zones by utilizing uni-directional airflow to positively pressurise and purge working environment from contaminants.

Ceiling Laminar Airflows are customizable units that are:

- Utilized as open restricted access barriers over filling and capping machines.
- Stand alone units mounted via eye bolts and drop rods overspecific applications.
- Stand alone units mounted over mobile stands for mobile aseptic zones.

Basic Principles

- Room air is drawn pre-filtered via an EU6 prefilter before entering via the perforated diffuser into supply plenum.
- A special baffle system channels airflow via the knife edge gel seal Hepa filters as downflow supply creating an aseptic workzone with low noise.

Features

- Modular easy to clean design.
- HEPA/ULPA knife edge gel seal design is better than conventional gasket sealed.
- Sentinel Silver microprocessor control with audio/visual alarms for downflow velocity.
- Zoned Magnehelic gauges for filter loading.
- Energy efficient teardrop lightings away from downflow.
- Emergency stop.

Options

- Remote mounted Main Control Panel.
- Splashproof electrical outlets.
- PVC Curtains.
- Splashproof electrical outlets.

Weighing and Dispensing Containment Isolators (WDCI)

Introduction

Weighing and Dispensing Containment Isolators (WDCI) are advanced containment systems providing controlled negative pressure environments to maximize personnel protection during weighing and dispensing of potent compounds.

Esco WDCIs provide standard configurable designs able to adapt to various weighing and dispensing quantities and accuracies.



Basic Principles

- Turbulent airflow allowing maximum containment with low airflow and therefore improved energy efficiency.
- Low negative pressure to reduce operator fatigue whilst providing maximum containment.
- Stable weighing accuracy as a result of low chamber pressure and flow in conjunction with Anti-Vibration platform.
- Contained Pass In / Pass Out systems to allow safe material transfer.

Features

- Fully welded single piece SS316L internal chambers with rounded coved corners.
- Pressure tested to ISO 14644-7.
- Inflatable Anti-Bacterial, USP Class VI Compliant and Food grade FDA approved gaskets provides both proactive and reactive sealing.

- Safe change glove system allowing change of gloves whilst maintaining a contained system.
- Integrated Anti-Vibration granite platform for weigh scale placement.
- Integrated automated pressure decay testing.
- Clean interior and exterior finishing.
- Safe change filters to allow in-process filter replacement.
- Lighting external to isolator chamber for ease of servicing and process chamber cleanliness.
- Integrated automated height adjustment providing 280mm of motion for ergonomic comfort.

Aseptic Containment Isolator (ACTI)

Introduction

Aseptic Containment Isolator (ACTI) are advanced aseptic barriers providing controlled environments to minimize false positives during sterility test processes, or handling of cytotoxic drugs

Esco Aseptic Containment Isolator (ACTIs) work in conjunction with advanced material transfer techniques and bio decontamination agents providing a 6 log reduction in viable contaminants.

Esco ACTIs provide standard configurable designs able to adapt to various batch sizes and process flows. Through a fully user selectable operating system, the same Isolator can be setup to operate under recirculation or single pass airflow and operate in positive or negative pressure modes, allowing the system to be multi-functional and cater for all requirements of toxic or non-toxic aseptic materials. For toxic materials the system incorporates safe change filters.



Basic Principles

- Full uni-directional airflow provides superior aseptic work zones.
- Safety toughened laminated glass hinges upwards assisted with gas springs for batch loading.
- Airflow regime runs either in re-circulatory or single pass modes. Single pass for fast purging of bio decontamination agent during aeration period and recirculation option for reduced airflow taken from the room and exhausted during normal operation and during conditioning and decontamination phases.
- Safe Change U15 supply and exhaust filters suitable for either toxic or non-toxic aseptic materials.

Features

- Fully welded single piece SS316L internal chambers with rounded coved corners.
- Pressure tested to ISO 14644-7.
- Inflatable Anti-Bacterial, USP Class VI Compliant and Food grade FDA approved gaskets provides both proactive and reactive aseptic sealing method.
- Safe change glove systems allowing change of gloves whilst still maintaining an aseptic workzone.

Dynamic Passboxes and Dynamic Floor Label Hatches (DPB/DFLH)



Upgrade to Hydrogen Peroxide Passboxes for small material transfer and Airlocks for large material transfer

Introduction

Dynamic Passboxes and Dynamic Floor Label Hatches are aseptic architectural systems utilized to prevent contaminants from leaking into aseptic suits. They are utilized for aseptic transfer of materials into and out from the critical process environments.

Basic Principles

- Dynamic airflow provides an air barrier to prevent contaminant from entering into critical controlled environments during material transfers.
- Vertical purge, purges any trace contaminants that could have entered post material transfer.
- Airflow set at dual re-circulatory on both sides.
- Emergency stop.
- Food grade FDA approved, USP class 6 Compliant air tight seals.
- Toughened safety glass.
- Air tight Pharma grade latches with electromagnetic interlocks.

Features

- Modular easy to clean design.
- HEPA/ULPA knife edge gel seal main filter design.
- Sentinel microprocessor control with audio/visual alarms for downflow velocity and filter loading.
- Red/Green indicators for all operational parameters.
- Stainless steel hinges.
- Fully rounded interior corners with enhanced perforated grille system for full downflow in critical corners.
- Port for particle counter probe.
- Port for upstream PAO concentration.
- Pressure tested as per ISO standards.

Laminar Flow Horizontal Trolley (LFHT) / Laminar Flow Vertical Trolley (LFVT)



Introduction

Laminar Flow Horizontal or Vertical Trolleys provide enhanced aseptic work zones by utilizing uni-directional airflow to purge the working environment from contaminants allowing aseptic transfer of materials throughout the Pharmaceutical plant.

Laminar Trolleys are customizable units that can provide:

- Product aseptic zones with single pass or re-circulatory airflow.
- Operator or environment protection (only available in re-circulatory airflow) and in negative pressure with respect to ambient.

Applications

- Transfer of lyophilized vials to and from freeze driers.
- Transfer of process skids or feed hoppers.
- Aseptic workzones.

Basic principles

- Room air is drawn via an EU6 prefilter before entering perforated diffuser into the supply plenum.
- Airflow passes through a baffle system prior to Gel Seal HEPA Filtration, creating a low decibel aseptic work zone for operator comfort.

Standard Features

- Easy to clean design with single welded construction.
- Tempered glass doors.
- Stainless steel hinges.

- HEPA/ULPA knife edge gel seal design is better than conventional gasket sealed.
- Sentinel Silver microprocessor control with audio/visual alarms for downflow velocity.
- Zoned Magnehelic gauges for filter loading.
- PU Wheels
- Special Food grade FDA approved air tight seal.
- 10mm glass windows with plastic latches.
- Magnehelic Differential Pressure Gauges for monitoring filter lifespan.
- Battery for onboard power when not connected to main building supply.
- E-Stop.

Typical Esco Pharma Project Cycle

- Project Lead Received.
- Initial contact by Esco Technical Sales Engineer On-Site Visit for site assessment (if required).
- Budget quotation is prepared (if required).
- First proposal submitted completed with submittal drawing and detailed quotation.
- Follow up visit(s) and Refinement(s) to Requirements.
- Final Proposal submitted , Agreement on Commercial Details.
- Customer issues PO.
- Esco Pharma issues As Ordered Specifications (AOS) for client approval.
- Internal handover from sales to engineering.
- Upon receipt of AOS, works order is raised to factory.
- Payment schedule and draft project gantt chart with delivery schedule is made (this being updated throughout the project cycle and regular updates provided).
- Detailed Technical Pack is made consisting of General Arrangement Drawings, Electrical Schematics, P&ID (Process and Instrumentation Diagrams) and Functional Specifications and Design Specifications are made as per as ordered specification.
- If required, Mock ups are done in our Manufacturing facility for ergonomic trails with client (option for onsite ergonomic trials if required).
- Detailed notes are taken and summary report issued to customer.
- Drawings are revised, re-issued and customer approval sought.
- Design freeze.
- Technical Pack is sign off by client before electromechanical design.
- Once Technical Pack is signed proceed into fabrication drawings from solidworks file.
- Fabrication drawings are released into sheetmetal production.
- Electromechanical assembly is carried out .
- Integration of externally sourced equipment (if required) .
- FAT is carried out with client.
- For containment equipment surrogate powder testing is carried out.
- For Aseptic equipment Gas Cycle Development is carried out.
- Design changes post FAT are made (if required).
- Upon completion of FAT unit is quality inspected and packed for export.
- Site installation and IQ/OQ is carried out by our validation team.
- For Aseptic Equipment site GCD is carried out .
- For Potent Equipment surrogate powder test can be carried out using client operators.
- Upon completion equipment is handed over to external client.
- Equipment is handed over internally to service department for PM contracts.



After Sales Services

Esco After Sales Services

Parts Availability

Whenever service is needed and parts are required, minimizing downtime is a critical objective. Statistical usage analysis helps Esco predict parts life, permitting Esco to manage logistics and stage proper inventories around the world. The combination of predictive maintenance, historical data and geospecific proximity assures our customers that parts and labor are available whenever service is scheduled through the local sales organization.



Registration, Documentation and Instruction

Quality control at Esco extends from research and development through engineering, manufacturing, shipment, delivery and customer feedback. Esco maintains an aggressive program to encourage warranty card registration by mail, email or online submittal so that we know where Esco products are located and how they are being used. Data from our warranty registration program is confidential and provides us with valuable contact information should we ever need to notify you about your Esco product.

All Esco products include unique serial numbers for identification.

Documentation for all performance tests is archived and maintained for customer reference.

Online Technical Information

Site preparation instructions are useful before product arrival and installation. Installation and start-up manuals, operation manuals and quick reference guides are available anytime from the Esco resources online. An interactive online LiveSupport™ concierge center accessible through the Esco website offers extended hours of operation. LiveSupport permits users to dialogue directly with Esco personnel.



References and Links

For more about Esco products, markets, employment opportunities, history, education, information resources, and Singapore, visit our information portal at www.escoglobal.com.

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Biological Safety Cabinets

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Esco is recognized as a global player in containment, clean air and laboratory equipment technology. We are highly oriented towards the international marketplace, with distribution in more than 100 countries and a direct presence in 10 of the key global markets. Esco represents innovation, forward-thinking design, coupled with the tradition of quality since 1976.

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