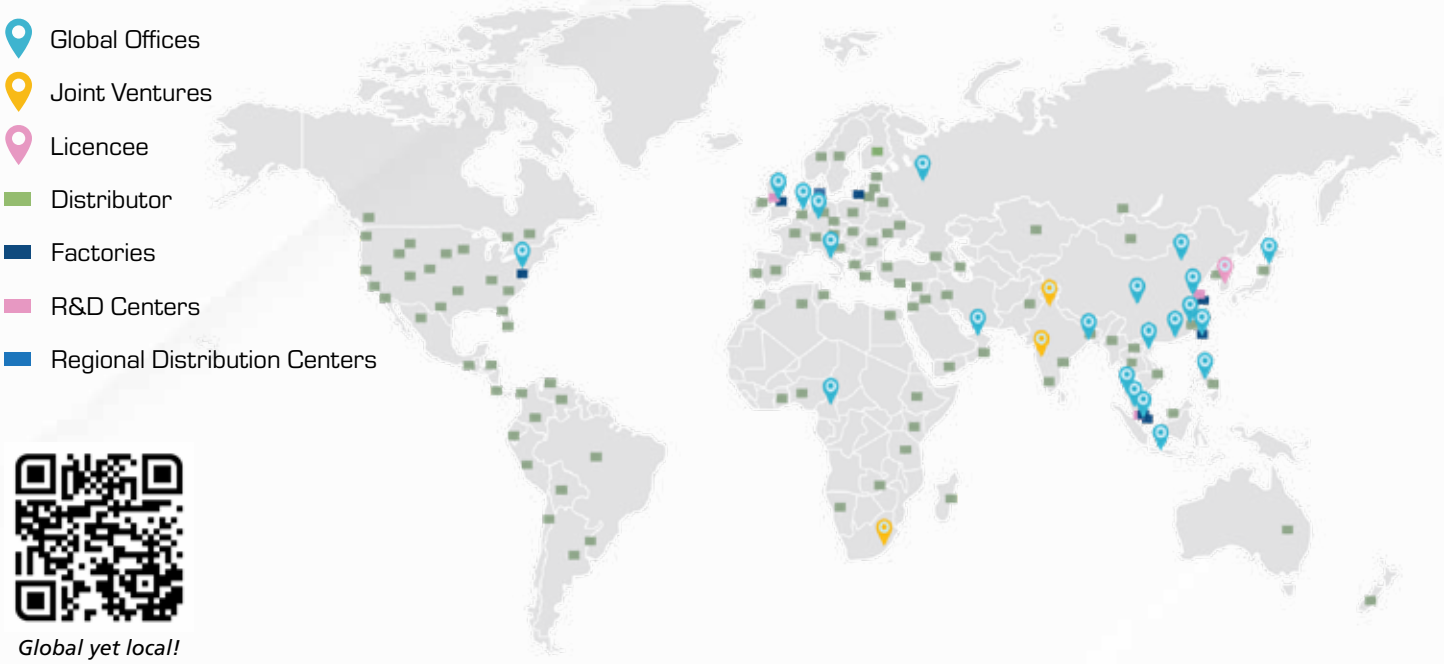
ESCO PHARMA

Esco Pharma
Product Guide

Providing enabling technologies to support you from Discovery to Delivery.

Esco Pharma provides specialist services, equipment packages, and process solutions from our core platform products. This leads to improved operator protection, mitigation of cross-contamination, and more efficient processing; thus, directly and indirectly advancing occupational health and human healthcare.

Esco Pharma's largest global network of localized application specialists and service offices, provide faster service response than others; translating into more competitive maintenance costs and shorter project life cycles.



Global yet local!

Esco Pharma Factories, Regional Engineering Offices, Sales/Marketing/Service Offices

Innovative Esco Pharma technologies are made in the three (3) main factories located in the USA, UK, and Indonesia, through Singapore, with ISO 9001, and ISO 14001 certified Quality and Environmental Management Systems.

CLEAN AIR
Providing ISO classified air quality for the aseptic manufacturing of sterile products.

OPERATOR PROTECTION
Containing hazardous particulates for the overall protection of operators.

ENVIRONMENTAL PROTECTION
Preventing industry-wide exposure against contaminants/hazardous materials.

PRODUCT PROTECTION
Preventing cross-contamination to promote product quality and integrity.

*Not quite sure of your process needs? Checkout **Esco Pharma's Questionnaires** tab! We can guide you in finalizing your equipment specifications according to your needs and applications. Just simply: download the specific questionnaire file, answer them completely, and attach & send it via email to mail@escolifesciences.com*

Esco Pharma's got you!

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Protection Guaranteed with Esco Pharma Turnkey Solutions

According to the Centers for Disease Control and Prevention (CDC) and the National Institute for Occupational Safety and Health (NIOSH), **Occupational Exposure Banding (or hazard banding)** is intended to assign chemicals into categories based on the range of exposure concentration for individual worker protection.

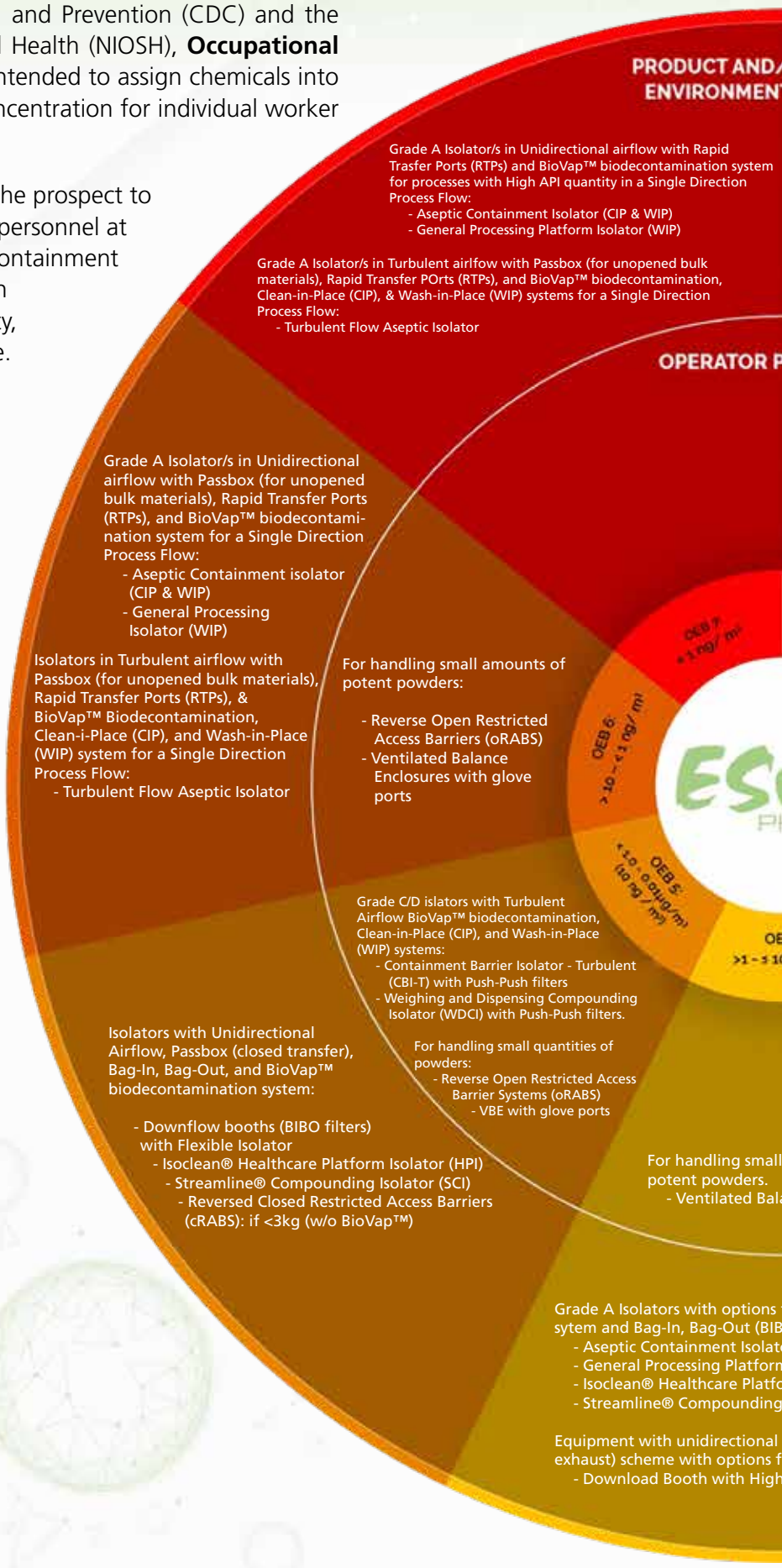
Active Pharmaceutical Ingredients (APIs) have the prospect to bring about severe to serious health effects in personnel at very low airborne concentrations. The use of containment systems or equipment, as an integral part of an efficient method to potent compounding safety, is recommended to control personnel exposure.

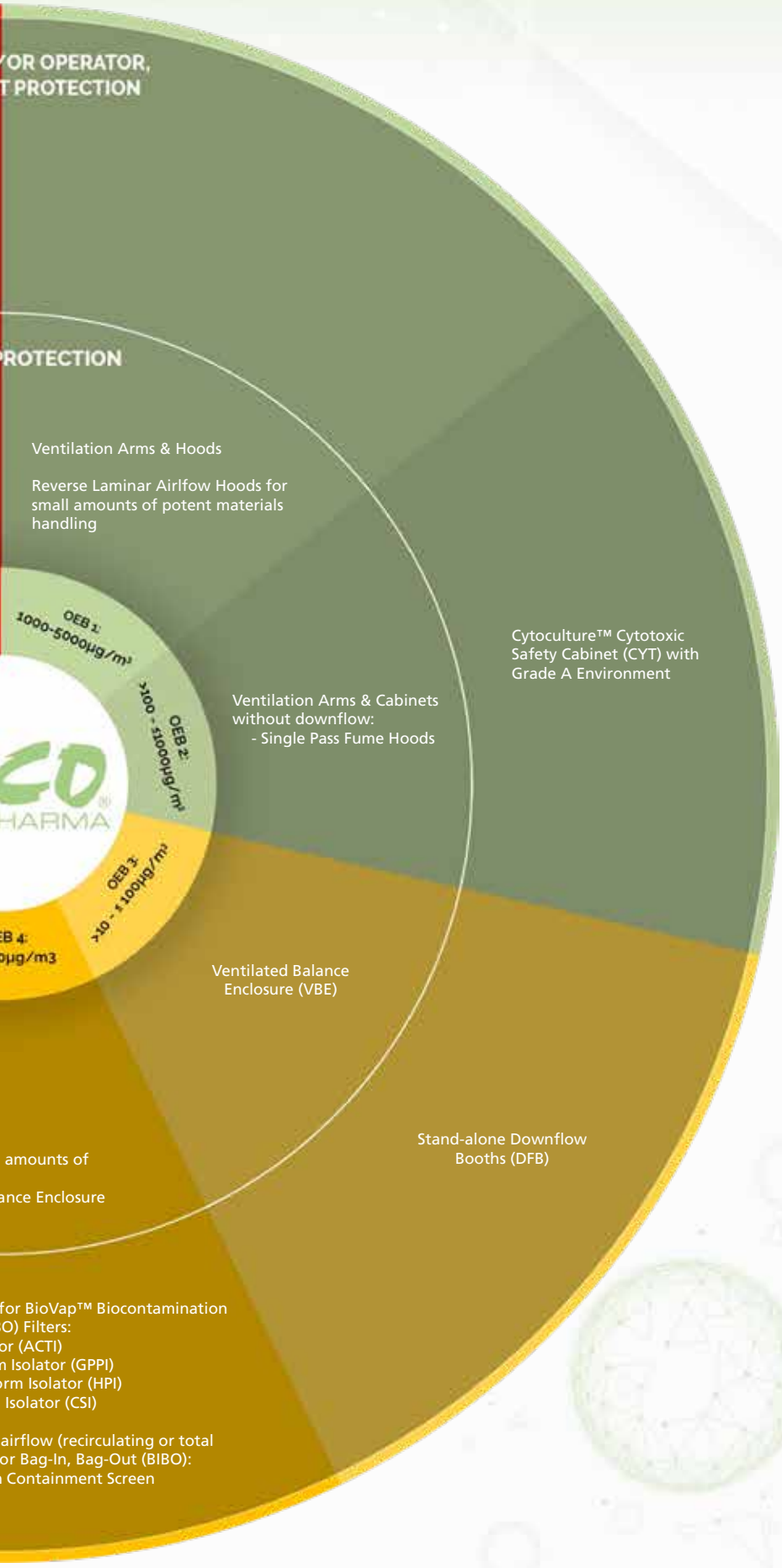
Hazard Banding (OEB) Criteria:

These include qualitative, semi-quantitative, and quantitative data for each toxicological endpoint.

- Acute toxicity
- Carcinogenicity
- Germ cell mutagenicity
- Reproductive toxicity
- Respiratory and skin sensitization
- Serious eye damage/eye irritation
- Skin corrosion/irritation
- Specific target organ toxicity, both single and repeated exposure

Check out the OEB diagram and know the perfect solution for your process!





DISCLAIMER

This diagram serves only as a guide for the assessment of current and future equipment and facilities for the handling of potent pharmaceutical ingredients.

Containment levels depend on various factors such as: product dustiness, type or nature of the product, process, the time taken to carry out the process, and the quantity of the product (powder, liquid, solutions, reagents) to be handled at any given time.

The Occupational Safety and Health Administration (OSHA) website provides a detailed occupational exposure limit (OEL) for various chemicals in the industry. With that information and this containment map. Users can easily choose the proper equipment that would best suit their needs.

The combination of different engineering controls - often with additional PPE, administrative controls (working only on a short-term exposure limit or task base duration) and SOPs in waste handling, disposal, safe handling of processing potent powders (e.g., non-removal of contaminated hands out of VBE/CYT/FH), and better cleaning SOPs can help in higher banding OEB/OEL levels.

Please contact Esco for more information.

Protect and Contain!

Airflow Containment

BioBooth®

Protecting Your Research Equipment from Medium to Large-scale!

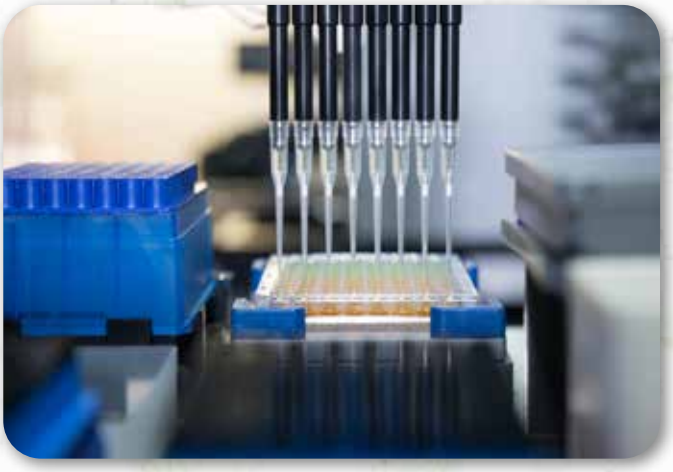
Introduction

Esco's BioBooth® is similar to a Biological Safety Cabinet Class II providing operator, product, and environmental protection during critical processes.

The unit is designed with an ISO Class 5 work environment to house relatively larger research devices, machineries and operating robotics under controlled cleanroom conditions.

Standard Features

- Unidirectional downflow of air in the work zone
- ISO Class 5 air cleanliness as per ISO 14644-1
- HEPA (H14) filter as per EN 1822 with a typical efficiency of >99.999% at 0.1 to 0.3 microns
- Electrogalvanized steel finish with Isocide™ antimicrobial coating construction
- Esco Sentinel™ Gold microprocessor controller
- Stainless steel easy-to-clean interior work surfaces



Design your BioBooth®

Ceiling Laminar Airflow (CLAF)

Unidirectional All the Way – Mounted, Suspended, or Standing!

Introduction

Esco Pharma's Ceiling Laminar Airflow (CLAF) supplies a constant downflow of HEPA-filtered clean air, maintaining an ISO Class 5 (as per ISO 14644-1) environment beneath the zoned area for optimal product/process protection, and cGMP compliance.

Standard Features

- Easy-to-clean stainless steel 304 material of construction, cGMP-compliant design
- Gel-sealed HEPA (H14) filter better than the conventional gasket-sealed design
- Control option varying from simple switches to Sentinel™ controller with audiovisual alarms for airflow monitoring
- Differential pressure across filter monitoring (analog/digital)
- Optional 2/3/4-side PVC curtains

Applications

- Filling Line System ISO Class 5 Coverage
- High-End Electronics
- Medical Industry (i.e., operating theatre)
- Nanotechnology
- Pharmaceutical Industry
- Research and Development Laboratories
- Space Industry

CLAF Laminar Solution

Airflow Containment

Cytoculture® Cytotoxic Safety Cabinet

Your Premium Solution in Handling Cytotoxic Hazardous Compounds

Introduction

Esco's Cytoculture® Cytotoxic Safety Cabinet (CYT) is the premium solution for cytotoxic/antineoplastic drug processing; providing the highest level of patient, personnel, and environmental protection.

This revolutionary product builds on Esco's experience of more than 20 years as a global leader in biological safety containment technology.

Applications

- Biologics
- Chemical Dispensing
- Community Pharmacy
- Hospital Pharmacy
- Pharmaceuticals
- Research & Development

Standard Features

- Provides you with the highest level of operator safety to protect you and your personnel from cytotoxic and other hazardous compounds
- Dual long-life ULPA filters for supply and exhaust airflow
- Additional secondary HEPA exhaust filter
- Filters can be changed without exposing the ambient environment and service personnel to potential hazards
- Meets the requirements of the European Standard EN 12469 for microbiological safety cabinets
- Spacious knee room maximizes operator comfort, 245mm (9.6") inward

You're safe with CYT

Pharmacon™ Downflow Booth

Flexibility Unrivaled!

Introduction

Esco's Pharmacon™ Downflow Booth (DFB) is fully equipped to provide operator, process and/or product protection during open handling processes such as weighing/dispensing or charging of powder into intermediate bulk container (IBC), bins or equivalent, and sampling in cGMP warehouses.

Applications

- Animal
- Biological
- Cosmetics
- Electronic
- Food
- Nutraceutical
- Pharmaceutical
- Robotic

Standard Features

- cGMP modular design with minimized joints and seams
- Standard Esco DFB has over 420 possible dimensional models with approximately 3.5 million possible system configurations
- 6 different filter configurations available utilizing combinations of G4, F8, Carbon, H13, H14 and PLF screens

Configure your own DFB!

Airflow Containment

Evidence Drying Cabinet

Your Samples are Safe and Secured with EDH/VC

Introduction

Esco's Evidence Drying Cabinet (Horizontal/ Vertical, EDHC/EDVC) is a negative pressure cabinet designed to provide security, and tamper-proof chamber. The goal is to protect the integrity and credibility of evidence by preventing cross-contamination. This equipment also provides operator protection by impeding the escape of harmful airborne pathogens and putrid odors/other gases.

Standard Features

- Construction
  - External MOC: Electrogalvanized steel coated with Isocide™ antimicrobial powder.
  - Internal MOC: Stainless steel (SS) floor
- Designed with pre-filter, carbon filter and HEPA filte to provide highest operator and environmental protection
- Designed with programmable Sentinel™ Gold Microprocessor with audible and visual alarm
- with energy-efficient blower with low noise and vibration levels

Applications

- Biologics
- Chemical Dispensing
- Forensic Science
- Laboratory Testing Centers
- Pharmaceuticals
- Research & Development

Nothing can Escpe with EDH/VC

Esco Garment Storage Cabinet

The Positive Cleanroom Addition!

Introduction

The **Esco Garment Storage Cabinet (EGSC)** is the perfect solution for storing all your laboratory coats, suits, and scrubs. Our cabinets are designed with airflow and purging technology, so you can be sure your cleanroom is protected from contamination.

Standard Features

- Clean, simple and affordable
- All components are designed for maximum chemical resistance and enhanced durability for a long service life
- Isocide™ technology eliminates 99.9% of surface bacteria within 24 hours of exposure
- Minihelic pressure gauge helps you ensure your cabinet is operating at the perfect level

Hassle free log-out!

Airflow Containment

Esco Glassware Hood

Protecting your Research Equipment from Medium to Large-scale!

Introduction

Esco Glassware Hood revolutionizes the way you work with hazardous chemicals. Esco's line of innovative and high-quality glassware hoods are customized to the specific needs of your institution. With our best-in-class features, we ensure process containment and operator protection for a hassle-free operation!

Standard Features

- Reduces operator exposure to hazardous fumes / vapors / gases
- Provides a controlled environment to house specialized equipment and processes
- Industrial fume hood with corrosion resistance against a large volume of solvents/chemicals
- Highly customizable to contain glassware set-ups for batch reactions/chemical syntheses

Optional Accessories/Configurations:

- Door Options:
  - Sliding or hinged doors
  - Vertical sliding sashes
- Local Exhaust Ventilation system (LEV)
- Carbon Filter
- Material handling (*conveyors, turntables, etc.*)
- Hazardous area configurations to meet ATEX and NEC 505 requirements

Our hood's got you covered!

Laminar Flow Horizontal/ Vertical Trolley

Laminar Flow on-the-Go!

Introduction

Esco Pharma's Laminar Flow Horizontal/Vertical Trolley (LFHT/LFVT) enables mobility across facilities in an aseptic manner. The unit provides ISO Class 5 (as per ISO 14644-1) clean environment inside the chamber and is configurable to be in recirculating or single-pass airflow, and positive or negative pressure depending on the material load.

Application

- Temporary storage of critical materials or products
- Transfer of sterile/aseptic materials (e.g., autoclaved substances) from cleanroom to a cleanroom, via a non-cleanroom area
- Transfer of materials within cGMP facilities
  - also applicable for institutions unable to upgrade their cleanroom facilities to comply to cGMP standards; and
  - upgrading facilities from clinical to commercial sites while preventing production losses due to long turnover when building new cGMP sites.

Keep it rolling!

Airflow Containment

Enterprise™ Laminar Flow Straddle Unit

The Leading Solution for Industrial Process Protection

Introduction

Esco Pharma's Enterprise™ Laminar Flow Straddle Unit, Single/Double (ESUS/D) is the leading solution for large-scale industrial sterile processes wherein multiple units and devices are interconnected in an assembly line.

Standard Features

- Provides ISO Class 5 air cleanliness classification within the work zone (ISO 14644-1)
- Utilizes high quality HEPA (H14 Filter) with an efficiency of 99.995% at 0.1-0.2 µm (EN 1822)
- Coated with Isocide™ antimicrobial powder which eliminates 99.9% of surface bateria within 24 hours
- Available in single and double sided models

Applications

- Aerospace
- Cleanrooms with electronics assembly
- Clinical pharmacy and hospital use
- Medical devices industries
- Mycology and food microbiology
- Pharmaceutical
- Plant and mammalian cell culture
- Semiconductors

Strengthening your process lines!

Esco Sputum Booth

Containment Solution for Highly Contagious Samples

Introduction

Esco Sputum Collection Booth (ESB) controls exposure risk to harmful aerosols/airborne diseases by providing containment using airflow to capture and exhaust out aerosols from sputum during expectoration, handling, or processing. We provide both operator/patient and environmental protection.

Applications

- Clinic
- Hospital
- Laboratory Testing and Isolation Centers

Standard Features

- ISO Class 5 air cleanliness (ISO 14644-1)
- Negative pressure keeps aerosol contained in booth:
  - Supplies 100% HEPA-filtered air to the downflow plenum
- UV lamp operates on programmable timer embedded in the Sentinel™ microprocessor system
- Constructed with Electrogalvanized steel coated with Isocide™ with reinforced stainless steel 304 floor.
- Reinforced stainless steel 304 floor

Containment--not a problem!

Cross-contamination Facility Integrated Barrier

Dynamic Pass Box and Dynamic Floor Laminar Hatch (DPB/DFLH)

Dynamic Construction and Function!

Introduction

Esco Pharma's Dynamic Pass Box and Dynamic Floor Laminar Hatch (DPB/DFLH) is equipped with a built-in blower and filtration system operating in a recirculating airflow pattern which guarantees ISO Class 5 cleanliness (as per ISO 14644-1) inside the chamber suited for aseptic material transfers.

Standard Features

- Easy-to-clean, cGMP-compliant design
- HEPA (H14) gel-sealed main filter with G4 prefilter to increase the main filter lifespan
- Selection of control from simple switches or Sentinel™ controller with audiovisual alarms and time-delay function
- Full stainless steel 304 material of construction with coved internal corners
- Electromagnetic interlocking doors with tempered glass window

Applications

- Automotive Industry
- cGMP facilities
- Cleanroom and Controlled Environments
- Manufacturing Facilities
- Nanotechnology
- Pharmaceutical Industry
- Semiconductors Industry
- Space Industry

Eureka moment in the lab!

Infinity® Pass Boxes and Cleanroom Transfer Hatch

Static and Classic!

Electromagnetic Interlock — SPB

Stainless steel (SS) doors with double-layered tempered glass viewing window

SS — Stainless Steel 304

Full SS 304, coved internal corners at the base, with indicator lights for door status

Mechanical Interlock — EPB-S

Tempered glass doors

SS — Stainless Steel 304

Full SS 304, all-coved internal corners with flanges (standard inclusion)

Mechanical Interlock — EPB-B

Stainless steel (SS) doors with polycarbonate viewing window

SS — Stainless Steel 304

Full SS 304, non-coved corners

Mechanical Interlock — EPB-A

Electrogalvanized (EG) steel doors with polycarbonate viewing window

EG — Powder-coated EG Steel

EG steel exterior and interior, SS 304 internal base, non-coved corners

Esco Pharma's Infinity® Pass Box and Cleanroom Transfer Hatch maintains cleanroom integrity with its reliable and maintenance-free interlocking mechanism by preventing both pass box doors from opening at the same time and by limiting personnel traffic during aseptic transfers in-between rooms.

Know the Right Box for You!

Cross-contamination Facility Integrated Barrier

Esco Cleanroom Air Showers

Your Solution for Maximum Assurance in Mitigating Cross-contamination in Between Controlled Environments

Introduction

Esco Air Showers (EAS) are self-contained chambers installed strategically at entrances to cleanrooms and other controlled environments. They minimize particulate matter entering or exiting the clean space to mitigate the risk for cross-contamination.

Applications

- Food markets
- Laboratory animal research
- Microelectronics
- Pharmaceutical
- Semiconductors
- Spray painting

Standard Features

- High-velocity shower jets running at 18-30 m/s to ensure efficient scrubbing action to remove particulate matter
- Operating modes can be programmed in the field
- HEPA (H14) main filter as per EN 1822 with a typical efficiency of 99.995% at 0.1 to 0.2 micron
- The air shower is constructed of electrogalvanized steel sheets with an abrasion-resistant oven-baked powder coated finish.

Scrub the dirt away!

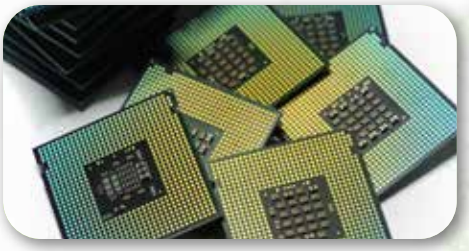
Infinity® Esco Air Shower Pass Box

The Cross-contamination Mitigation Solution

Introduction

Controlling the ingress of particulate contamination into cleanrooms and other controlled environments is paramount in order to maintain the integrity of products and processes.

Esco Infinity® Air Shower Pass Box is a cost-effective solution as it allows materials to be transferred into the controlled environment without actual personnel movement. It may also be used to protect the external environment from egress of contamination, for example, in biological safety laboratory applications.



Applications

- Food markets
- Laboratory animal research
- Microelectronics
- Pharmaceutical
- Semiconductors

Standard Features

- Equipped with high velocity (18-30m/s) H14 filtered air jets for material scrubbing action
- Air shower duration is adjustable up to 2 mins
- The air shower pass box is constructed with electrogalvanized steel coated with Isocide™ and perforated stainless steel 304 base
- With electromagnetically interlocking doors for cleanroom integrity

Your materials scrubbing solution!

Cross-contamination Facility Integrated Barrier

Soft Capsule® Softwall Cleanroom

The Flexible Solution for Cleanroom Application

Introduction

Ideal solution when clean air areas need to be created on a small to mid-scale. Flexible and economical, they may be easily relocated when application requirements change. Esco offers a complete range of soft wall cleanrooms to meet various construction, dimensional and cleanliness class requirements.

Applications

- Aerospace
- Biotechnology
- Contact lens packaging
- Electronics assembly
- Food industries
- Hospital pharmacy (USP 797)
- Medical devices, plastic injection moulding
- Nanotechnology
- Pharmaceuticals, Grade A filling suites
- Quality control

Standard Features

- Provides ISO Class 5, 6, or 7 environment (depends on client specifications) via high quality filtration system
- Utilize Isostat™ vinyl curtains to isolate the cleanroom while allowing easy passage of materials and personnel
- Cleanroom grade construction utilizing fully-welded, reinforced, steel tubular sections
- Entire structure is free-standing and does not require any suspending ceiling supports

ISO Class air quality, no hassle!

BioPass™ Pass Through

Advanced Material Transfer Solution!

Introduction

BioPass™ Pass Through, a floor-standing airtight transfer chamber, is an all-in-one automated hydrogen peroxide (H_2O_2) based biodecontamination solution functioning as a pass through cabinet to facilitate in the transfer of materials in and out of controlled environments such as cleanrooms or biosafety laboratories.

Unlike ordinary pass through boxes or cabinets intended only for small material transfers, the **BioPass™ Pass Through** allows the passing of large equipment into an ISO Class 5 cleanroom in an aseptic manner.

Applications

- Food, Beverages & Confectionary
- Hospitals
- Manufacturing Facilities
- Pharmaceutical Industry
- Primary Healthcare Facilities
- Veterinary Surgeries

Standard Features

- BioPass™ Pass Through cabinet is designed in compliance with cGMP requirements
- Unit is constructed with stainless steel 304 exterior and interior surface is made of stainless steel 316L with smooth coved interior corners
- Integrated with Esco BioVap™ biodecontamination system with:
  - PLC control
  - HMI operator interface
  - Ticket roll printer for biodecontamination cycle result

Biodecontamination made easy!

Isolation Containment

Aseptic Isolators

are critical for the provision of an isolated ISO Class 5/Grade A environment required for the manufacture of sterile products and carrying out of aseptic processes. These type of isolators are capable of carrying out automated pressure hold tests, automated biodecontamination, and a continuous environmental monitoring to ensure the maintenance of the required condition.

Aseptic Containment Isolator (ACTI)

General Processing Platform Isolator (GPPI)

Containment Barrier Isolator – Unidirectional Model (CBI-U)

Isoclean® Healthcare Platform Isolator – Inflatable Seal Model (HPI-IS-BVP)

Standard Features

- EU GMP Grade A / ISO Class 5 Environment with 0.45 m/s unidirectional downflow velocity
- Automated Pressure Hold Test
- Typically equipped with biodecontamination system (hydrogen peroxide-based)
- HMI/PLC Controller System, with option for 21 CFR Part 11 Compliance
- Stainless steel 316L material of construction for all parts with possible product/process contact
- May be equipped with environmental monitoring parameters such as pressure, temperature, relative humidity, particle count, and viable air sampling.
- ISO 10648-2 tested containment enclosure

Applications

- Cell Therapy/Bioprocessing/Cell
- Electronics/Semi-conductors Production
- Pharmaceutical Manufacturing
- Research and Development
- Sterility Testing

Aseptic processing guaranteed!

Containment Isolators

are often designed with a negatively pressured system for the containment of the environment used for processing hazardous products and highly potent active pharmaceutical ingredients (HPAPIs). This type of isolators are typically in turbulent airflow, capable of carrying out automated pressure hold test, with breach compensatory mechanism to prevent the escape of the hazardous product. In this type of system, operator protection is the priority!

Weighing and Dispensing Containment Isolator (WDCI)

Turbulent Flow Aseptic Isolator (TFAI)

Containment Barrier Isolator – Turbulent Model (CBI-T)

Standard Features

- Negative Pressure System, in Turbulent Airflow Regime
- Automated Pressure Hold Test
- Typically equipped with Wash-in-Place and/or Clean-in-Place systems
- HMI/PLC Controller System, with option for 21 CFR Part 11 Compliance
- Stainless steel 316L material of construction for all parts with possible product/process contact
- May be equipped with environmental monitoring parameters such as pressure, temperature, and relative humidity.
- Equipped with safe change filters (Push-push filter type or BIBO system)
- ISO 10648-2 tested containment enclosure

Applications

- HPAPIs and Potent Powder Handling
- Pharmaceutical Manufacturing
- Research and Development
- Weighing and Dispensing of Powders/ Excipients

WDCI

Your Reliable Containment Solution

Isolation Containment

Class III BSC-Configured Isolators

can be configured to work as a Class III Biological Safety Cabinet. A Class III BSC is a closed-system airflow cabinet designed to provide protection from biohazards by maintaining negative pressure inside the cabinet and providing a rigid, leak-tight physical barrier between the worker and the source of the biohazard.

Containment Barrier Isolator – Class III BSC Configuration (CBI-III)

Streamline® Containment Isolator – Class III BSC Configuration (SCI-III)

Standard Features

- EU GMP Grade A/ISO Class 5 Environment capable of 0.45 m/s unidirectional downflow velocity
- Negatively Pressured (-125 Pa minimum) System, in Total Exhaust/Single-Pass Configuration
- Pressure Tested as per ISO 10648-2 Standard
- Stainless steel 316L material of construction for all parts with possible product/process contact
- Compliant to NSF and EN 12469 Standards

Applications

- Cell Processing/Bioprocessing/Cell Cultures
- Laboratory containment for handling biological agents of up to level 4
- Research and Development
- Virus and Vaccine Production

Your Containment Partner in Biohazardous Material Handling

Hospital Compounding Isolators

Isolators are now being increasingly utilized for Pharmacy Compounding applications. In the United States Pharmacopeia, two (2) types of isolators are being described for this process:

- **Compounding Aseptic Isolator (CAI)** - provides a safe and clean environment for compounding of non-hazardous, sterile drug preparations and IV admixtures in compliance with USP <797> criteria.
- **Compounding Aseptic Containment Isolator (CACI)** - provides a safe and clean environment for compounding of hazardous drug preparations in compliance with **USP <797> and <800>** criteria. It is suitable for work involving hazardous materials, antineoplastic, or cytotoxic compounding applications.

Esco Pharma can provide both CAI and CACI for your pharmacy compounding needs!

For your USP <797> and <800> compliance!

Streamline® Compounding Isolator (SCI)

Isoclean® Healthcare Platform Isolator – With or Without Filter Below Model (HPI-G3)

Containment Barrier Isolator – Unidirectional Model (CBI-U)

Standard Features

- EU GMP Grade A/ISO Class 5 Environment
- Factory-configured to Positive/Negative Pressure
- Recirculating/Total Exhaust configured based on application
- Manually Pressure Tested as per ISO 10648-2 Standard
- Stainless steel 316L material of construction for all parts with possible product/process contact
- Compliant to USP <797> and <800> Guidelines

Applications

- Chemotherapy/Hazardous Drug Handling
- Cosmetics/Cosmeceuticals
- Research and Development
- Sterile/Aseptic Compounding
- TPN Formulation and Compounding

Hospital Pharmacy Compounding Made Safer

Isolation Containment

Cell Processing Isolator (CPI)

is an integrated system that combines several types of equipment into one isolation technology. It is designed to isolate the process to ensure operator safety without compromising product quality. It also provides a sterile ISO Class 5/Grade A environment that is required to carry out aseptic processes.

Highly Adaptive and Modular Solution for Cell Processing

Isoclean® Healthcare Platform Isolator - Inflatable Seal Model (HPI-IS-BVP)

Cell Processing Isolator (CPI)

Standard Features

- Easily customizable, depending on client's requirements
- Modular and adaptable solution for cell and gene therapy, tissue engineering, seed banking, and cell processing
- Integrates Esco VacciXcell bioreactor systems
- Provides an ISO Class 5/Grade A Environment

Applications

- Allogenic Cell Therapy
- Aseptic Processing
- Autologous Cell Therapy
- Cell Banking
- Cell Processing
- cGMP Manufacturing
- Monoclonal Antibody Production
- Vaccine Research
- Virus Production

Cell Processing and Containment Solution

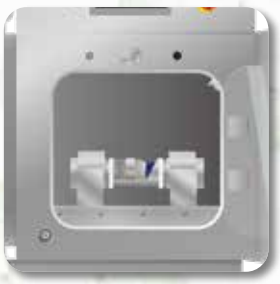
1. CelCradle X® Unit
2. Reagents and media
3. SS Rod (for hanging of bags/pipette and others)
4. Peltier well
5. CCX Bottle
6. Pipettor
7. Enzyme Media
8. Centrifuge Bottles
9. Centrifuge
10. Waste
11. Exit Pass-through chamber

Unidirectional Process Workflow

Incubation System
Integration of Tide Motion Bioreactors (may vary based on customer requirements)

Cell Processing Area
Integration of cell processing laboratory equipment

Monitoring and Harvest
Monitoring devices such as microscope and harvest system are placed in this area



Final Product
Pass-through chamber for final product removal from containment system

Isolation Containment

Formulation and Filling Line Isolator

Esco partners with filling line companies to create a client-specific technology, which utilizes cGMP compliant isolators and high-quality filling line accessories/technologies, to ensure product safety and sterility throughout the entire manufacturing cycle.

Enclosure systems for this technology can range from open and closed Restricted Access Barrier Systems (o/cRABS) to leak tight isolation technologies compliant to international GMP standards.

Applications

- Aseptic manufacture of cell therapy and injectables
- Aseptic processing
- Continuous manufacture
- Processing of materials with high OEB levels
- Research and development
- Vaccine Manufacture

Filling Good!

Automatic Loading / Unloading System

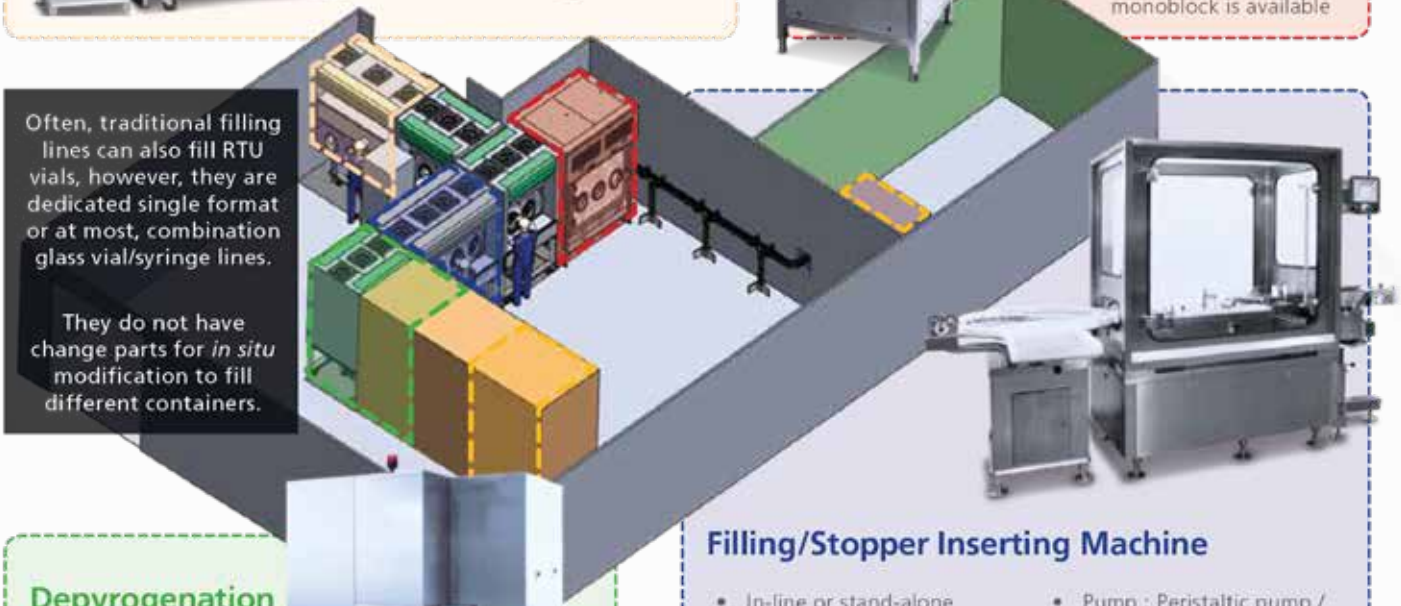
- Semi / fully automatic loading system
- Laser-Guided loading and unloading systems
- Self-empowered via battery: no need for the x-rail
- Unit turns itself: no need for a rotating turret

Capping Station

- Stand-alone capping machine
- Spinning vials
- Output: Up to 200 vials/ min (depends upon client requirement)
- Vial range: 2-100 ml
- Center stationary disk
- Maintenance-free design
- Integrated filling/ stoppering/capping monoblock is available

Often, traditional filling lines can also fill RTU vials, however, they are dedicated single format or at most, combination glass vial/syringe lines.

They do not have change parts for *in situ* modification to fill different containers.



Filling/Stopper Inserting Machine

- In-line or stand-alone
- Filling station with optional pre/post nitrogen flush
- Dual stopper inserting station
- Vial range : 2-100 ml
- Output : up to 100 vials/min
- Pump : Peristaltic pump / rotary piston pump
- Option : statistical check weighing / reject station
- Quick changeover
- Isolator / RABS (Restricted Access Barrier System) Ready

Depyrogenation Tunnel

- cGMP-compliant design and construction
- Full range of tunnels to choose from, depending on requirements
- Detect the air speed and keep it constant with a precision of 0.01 m/s
- HEPA-filtered air supply across tunnel chambers
- Capable of up to 6-log bacterial endotoxin level reduction
- Recycled in the Cooling Chamber
- Features a "Night Mode" to save energy while avoiding contamination

Vial Washer

- Hanging vials for complete underside exposure for cleaning and drying
- Servomotor main and height adjustment drives
- Universal change part (belts): 13 mm caps/ 20 mm caps
- Quick tool-free changeover
- Built-in low pressure, high volume centrifugal blower for drying
- Lower noise volume
- c/RABS or isolator enclosure ready

Disclaimer

Esco does not manufacture stand-alone filling lines, rather, it is always in combination with Esco's isolators or with open/close restricted access barrier systems (o/cRABS).

When necessary, Esco can: do the front end engineering design, ergonomic trials, URS write-up, and coordinate with its various partners for the provision of a fully integrated system (Isolator + Filling lines + Freeze Drier + Auto-loading/unloading system) or provide a fully integrated system according to the client's URS.

Esco also has an option to link the complete system to the client's SCADA/DCS system (PCS7, DeltaV, Wonderware or others) for eBatch records and eSignatures in compliance to GAMP 5, 21 CFR Part 11 compliance with computer systems validation.

Ventilation Containment

Ventilated Balance Enclosure (VBE)

Your Solution for Non-sterile Compounding and Dispensing

Introduction

Esco Pharma's Ventilated Balance Enclosure (VBE) is specifically designed for a stable and accurate handling and weighing of potent powders while ensuring a high containment level for operator protection. The aerodynamically designed sash and arm rest with its sectionalized baffle, guarantees that the airborne powders are well contained inside the enclosure and exhausted through a HEPA filter or directly to the laboratory exhaust.

Standard Features

- Airflow is directed inward towards the exhaust, suitable for applications requiring a high level of operator protection from hazardous airborne particles
- Disposal Port is equipped with O-Ring to provide a sealed trash bag for additional powder containment solution
- Modular Design using VBE modules allow the unit to be fully customized
- VBE can be equipped with a Filter Module or a Portable Filter Module, and for an added airflow control, a Blower Module can be added

Applications

- Chemical Manufacturing
- Food and Beverage Manufacturing
- Nutraceuticals
- Pharmaceuticals
- Research and Development

Hazardous chemicals contained!

Radiopharmacy

Standard procedures, best practices, facilities, and equipment for the preparation and dispensing of radiopharmaceuticals are essential to any radiopharmacy operation. Appropriate engineering controls and work practices are intended to ensure the sterility of compounded preparations as well as protection of the operator from exposure to radioactivity.

Radiopharmacy Equipment Solutions are available in Esco Pharma for a wide range of radioisotopes and for multiple stages in radiopharmaceutical handling.

Esco® Frontier Radioisotope™ (Fume Hood

Lead-shielded Biological Safety Cabinet

Technetium Dispensing Isolator

GMP-compliant Radioisotope Dispensing Isolator

Standard Features

- Lead-shielding of work zone and compartments are customizable according to clients requirements
- Modular and easily customizable with desired equipment integration inside the workstation
- Isolators are pressure tested as per ISO 10648-2 standard
- Stainless steel material of construction for all parts with possible product/process contact

These sets of equipment are customizable as per the client's specific application needs.

The following are available as options:

- Generator Integration
- Dose Calibrator Compartment
- Waste Compartment
- Centrifuge
- Particle and Viable Air Monitoring
- Biodecontamination System

Superior Protection for Radiopharmaceuticals Handling

Esco Lifesciences Services

Ensures Compliance to Legal Guidelines and ISO Standards. Minimizes Equipment Downtime. Increases Company Productivity.

Services We Offer:

Approved Replacement Parts

- Filters / Seals / Gaskets / Electrical Components Instrumentation

Validation/Calibration Services
(Esco and other vendors equipment)

- Calibration of PDTs, Pressure Switches, Verification of Flow/Temperature/Humidity Sensors
- Airflow Testing
- Filter Integrity Testing
- Particle Count Testing
- Pressure Testing & Diagnosis of Gloveboxes/Isolators
- Full System Revalidation-SAT/IOQ
- SMEPAC Testing
- Operator/Maintenance Training
- Decontamination System Cycle Development

General Maintenance/Annual Service Visits
(Esco and other vendors equipment)

- Filter Changes
- Calibration of PDTs
- Repairs
- Retrofit: Material & Personnel Airlocks, High containment screens, N2 Purge, Software Changes, HMI Upgrades, Instrumentation Upgrades, Software Modifications

Preventative Maintenance Packages

Annual/Bi-annual, 1yr/3yr Packages to minimize downtime; Tailored to suit your needs.

Benefits:

- Equipment downtime is minimized and the number of major repairs is reduced.
- Better conservation of assets and increased life expectancy of assets, thereby eliminating premature replacement of machinery and equipment.
- Timely, routine repairs circumvent fewer large-scale repairs.
- Improved safety and quality conditions for everyone.

ESCO LIFESCIENCES GROUP

ESCO PHARMA

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