ESCO

VACCIXCELL

ADHERENT BIOPROCESSING SPECIALIST

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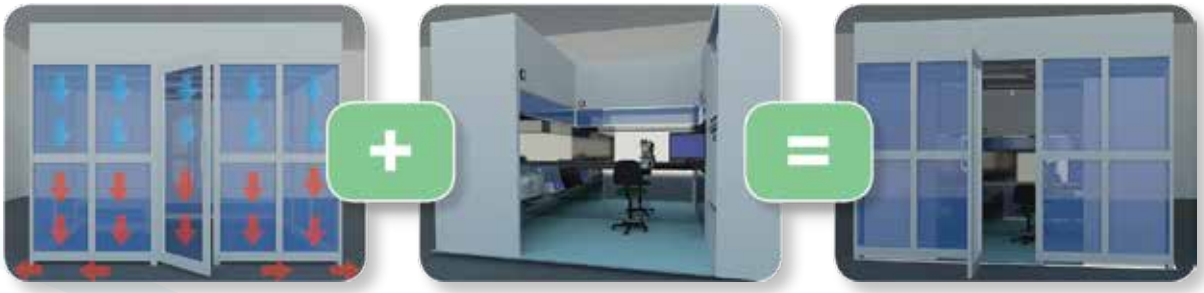
Upstream **BioProcessing** - Cell Therapy Processing

Cell Processing Center

Esco's bio-workstation is designed to help you produce biologics as well as cell therapy products efficiently. This economical workstation is a self-contained system that delivers an efficient and cost effective GMP-compliant processing and manufacturing solution for applications including regenerative medicine and stem cell therapy. It is equipped with all the necessary equipment used for cell processing such as a bioreactor, centrifuge, incubator, shaker, etc. and is designed to be easily customized depending on the client's requirements

The Concept



Esco's C-class (ISO Class 7) modular room | **Multi-functional Bio-work station** | **Self-contained system**

Cell Processing Center

Features

- Bio-workstation with HEPA-filtered airflow and UV sterilization
- Air circulation can be single pass or recirculating.
- Esco OrbiCult™ Incubator Benchtop Shaker
- Esco Versati™ Centrifuge
- Foot switch designed to start and stop centrifuge and incubator shaker.
- Pressure gauge to monitor differential pressure across filters and alert user if filter replacement is necessary.

Applications

- Biologics
- Quality Control
- Cell Handling and Manufacturing
- Stem Cell Isolation
- GMP Production of Autologous and Allogeneic Therapy

Upstream **BioProcessing** - Cell Therapy Processing

Isolator facilitates the isolation of a product or process while providing the required conditions for a sterile/aseptic environment. The Cell Processing Isolator provides a comprehensive range of protection, including personnel, product, surrounding work area, and environment.

General Applications

- Cell Processing
- Research and Development
- Aseptic Processing
- Small-Scale Potent Material Handling
- Pharmacy Compounding (Chemotherapy/TPN)
- Quality Control

Containment Barrier Isolator (CBI)

Features

- Controls exposure/cross-contamination risk to hazardous/aseptic materials for a wide variety of equipment and processes
- Minimizes false-positive result for sterility testing
- Provides Operator Exposure Levels (OEL's) ≤1.0 µg/m3 during controlled operations
- Levels of ≤0.1 µg/m3 can be achieved via closed-transfer processes or based on client SOPs
- Provides GMP-compliant environment
- Quiet, energy-efficient and auto adjustable ECM fans to compensate for filter blockage
- Standard dimensions are easily configured to suit process requirements
- Safe glove change and low contamination filter change FDA-approved static seals
- Pressure tested as Class 2 Containment as per ISO 10648-2 standards
- System comes with a Semi-automated or Automated Pressure Hold Testing
- Available in the following models:
  - CBI - Unidirectional (CBI-U)
  - CBI - Turbulent (CBI-T)
  - CBI - Biosafety Cabinet Class 3 (CBI-III)
  - CBI - Hybrid Convertible Class 3/1 BSC (CBI-H)

Isoclean® Healthcare Platform Isolator (HPI-G3)

Features

- HEPA filters with a typical efficiency of 99.999% at 0.1 to 0.3 microns provide superior ISO Class 5 air cleanliness.
- Sentinel™ Gold Microprocessor Control System supervises all functions and monitors airflow and pressures in real-time.
- Safe glove change permits zero risk of contaminating the work zone or environment
- Robust construction and enhanced safety features qualify the Isoclean® Healthcare Platform Isolator for the most demanding laboratory applications.
- Ergonomically-angled front gloveports improve reach and comfort.
- Esco ISOCIDE™ antimicrobial coating on external surfaces minimizes contamination.
- Sharps disposal system and adjustable hydraulic stand are available as options

Upstream **BioProcessing** - Cell Therapy Processing

CradlePro-Iso

CradlePro-Iso fully encloses the entire cell processing procedure in a GMP isolator. It features Esco VacciXcell's CelCradle™ bioreactor system, Esco CO_2 Incubator, Esco Orbicult™ Shaker, and Esco Versati™ Centrifuge among others..

The CelCradle™ bioreactor system is capable of supporting high-density culture of adherent or anchorage-dependent cells. The CelCradle™ system operates under the tide motion principle, wherein cells entrapped within BioNOC™ II carriers are alternately exposed to aeration and nutrition. This provides cells with an environment of low shear stress, no oxygen limitation, and no bubbling or foaming which leads linear scale up. Esco CO_2 incubator provides the best temperature and CO_2 control, resulting in superior protection of cells. The Orbicult™ Shaker provides the automated shaking function during cell seeding and cell harvesting, while the Versati™ Centrifuge separates the live cells from other components during cell harvesting. The CradlePro-Iso can be easily customized depending on the client's requirements.

Features

- Specially designed incubator for isolator integration enables even heating inside the incubator
- Simple pressure test protocol
- Isolator provides ISO Class 5 environment in work zone
- SteriSafe ULPA-filtered gas injection lines
- Integrated 0.22 µm hydrophobic PTFE filter on the CelCradle™ bottle cap
- Individual control of CelCradle™ compression and Orbicult™ shaking function enables independent use of the CelCradle™ bottles
- Specially treated BioNOC™ II carriers support the growth of most adherent cells

Applications

- Autologous cell therapy – 1 CelCradle™ bottle per patient
- Vaccine research, especially for wild type and BSL 3/4 viruses
- Cell banking
- Protein research

Isolator Equipment Integration:

- Biobank
- Peltier Dry Well (-20° to 38° C)
- Refrigerators/ULTF (-30)
- Dry Shaking Bath
- Autoclave
- Vacuum
- Incubators
- Shaking Incubators
- Bioreactor (Tide/Wave/Shaker)
- Filling System with optional Single shelve freeze drier
- Centrifuge
- Microscope
- Glove leak tester

Upstream **BioProcessing** - Bioreactors and Fermenters

VXL™ Hybrid Bioreactor

The VacciXcell Hybrid Bioreactor is a unique and multifunctional bioreactor system for research and development. The control unit opens an innovative technology and robust flexibility suitable for your changing requirements. The system can perform four (4) types of culture namely: adherent culture using macrocarriers, adherent culture using microcarriers, suspension culture and fermentation. Whether adherent or suspension, choose your cultivation chamber from our range of multiple-use vessels:

➤ **Conventional stirred tank autoclavable vessels**

➤ **Tide Motion matrix vessel**

Applications

- Research and Development
- Vaccine Development
- Vaccine Production
- Protein Production
- Antibody Development
- Antibody Production
- Cell Therapy
- Gene Therapy

Cells

- Mammalian
- Microbial
- Yeast
- Fungi
- Insect

Process Modes

- Batch
- Fed-Batch
- Perfusion

Key Features

- Automated control of pH, DO, aeration, foaming, temperature, agitation, and level
- Glass water jacketed vessel heats to 37°C (±) 0.3 in just 30 minutes
- Inoculation and sampling in a closed system
- Working volume of up to 50 L
- Touch Screen HMI Controller. One touch screen HMI controller can be connect and control up to four (4) utility stations making DOE recording and analysis easier

StirCradle™

The StirCradle™ is a benchtop stirred tank bioreactor system that can double up both as a fermenter and as a bioreactor, suitable for microbial fermentation and suspension cell culture. It is a versatile system, capable of supporting the growth of different types of bacteria, yeast, plant cells, insect cells, and mammalian cells. This system is available in three capacities with total volumes of 5 L, 7.5 L, and 10 L.

The StirCradle™ system features a control tower with four built-in peristaltic pumps, configurable for automated fluid addition. It also has a patented agitation system designed to effectively enhance the oxygen transfer rate.

The StirCradle™ system is expandable and compatible with a variety of accessories such as oxygen enrichment devices, multiple gas devices, external pumps, and exhaust gas analyzer, making it suitable for the client's culture process requirements.

Features

- Built-in memory for real-time culture trend data-logging
- Free VNC application compatible with smart phones, laptops, and PC for instant remote monitoring
- Adjustable Touch Screen HMI
- Glass vessel made of tempered glass from Pyrex (US) or Schott (Germany)
- User-friendly interface with dynamic real-time display of the culture process
- Various impeller designs available for different culture conditions
- Various levels of authority access ensure data protection
- Fifty Step Control program effectively achieves detailed segmentation control

Applications

- Fermentation
- Cell Culture
- Research and Development
- Biopharmaceuticals
- Proteomics
- Laboratory-scale productions

Upstream **BioProcessing** - Bioreactors and Fermenters

CelCradle™

Cradle for Your Cells

Laboratory Scale Tide Motion Bioreactor

CelCradle™ is a cost-effective, single-use, benchtop bioreactor system capable of supporting high-density culture of adherent or anchorage dependent cells. It is designed based on the concept of bellow-induced intermittent flow of media and air through porous matrices where cells reside. This provides a low shear stress, high aeration, and foam-free culture environment. During operation, the CelCradle™ bottle is partially filled with culture medium and inoculated with cells. The culture medium is raised and lowered alternately, to submerge in culture medium and expose the matrices to oxygen, creating a dynamic interface between air and media on the cell surface to maximize nutrient uptake and oxygen transfer. When matrices are exposed to air, cells uptake oxygen while protected by thin layer of media in matrices.

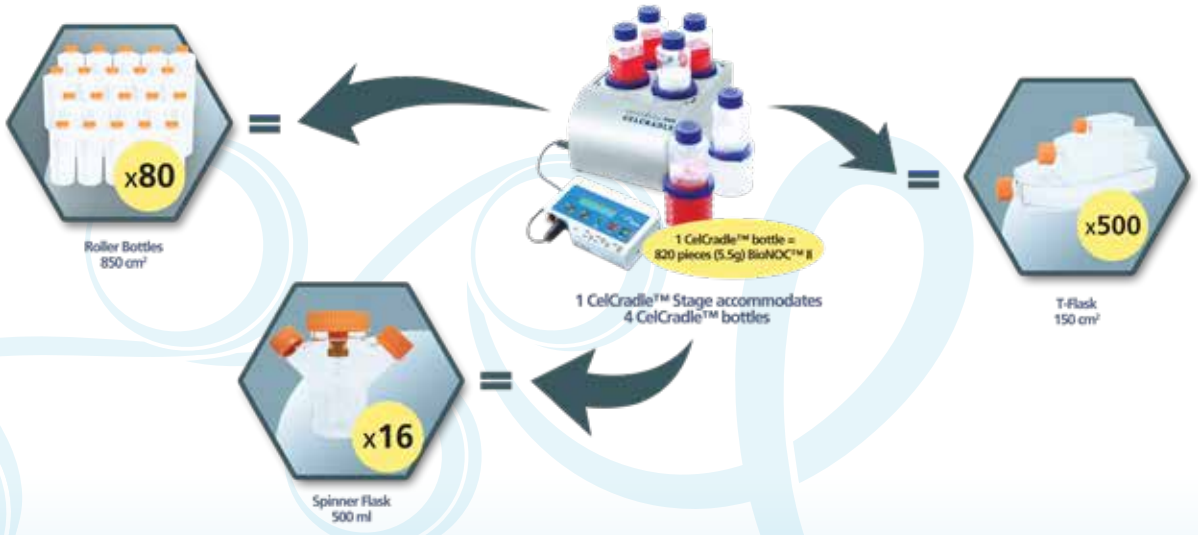
The CelCradle™ bioreactor is the laboratory scale system of VacciXcell's Tide Motion system, which is the only bioreactor system that is truly scalable up to 5,000 L packed bed volume.

Features

- Pre-sterilized, ready-to-use, disposable bottles
- Low shear stress, foam-free, no O_2 limitation
- High productivity: One CelCradle™ bottle has a productivity equivalent to 18-20 of 850 cm^2 roller bottles
- Compact design: fits in $6ft^3$ CO_2 incubator
- Easy process optimization
- Linear scale up to production scale
- Choice of batch, fed-batch or recirculation culture modes
- Scale-up by multiplying the number of bottles or upgrade to TideXcell® system
- No special culture media needed
- Specially treated carrier surface to grow most anchorage-dependent cells
- Allow easy harvest of cells and secreted components

Applications

- Human and Animal Vaccines
- Autologous and Allogeneic Cell Therapy
- Culture of anchorage-dependent or adherent cells
- Mammalian and insect cell research
- Recombinant protein research and production
- Switching from a 2D system to a single-use closed system cell culture
- Replacement of microcarrier-stirred tank bioreactor technology



Upstream **BioProcessing** - Bioreactors and Fermenters

TideXcell®

The Gentle Giant of Adherent Bioprocessing

The TideXcell® Bioreactor System is the world's largest single-use bioreactor system, which can be linearly scaled from seed preparation to production scale of up to 5,000 L packed-bed volume. It is a complete platform that supports laboratory research to process development and final production and final production.

One of the main advantages of VacciXcell's Tide Motion bioreactor system is that it features the same bioprocess method from seed preparation to production scale. As certain cell lines do not grow well when first cultured in 2D (for seed preparation) then cultured in3D (for cultivation), VacciXcell's Tide Motion system allows cell cultivation in 3D system from seed preparation to production by using CelCradlle™ system and successive TideXcell® systems with same Tide Motion principle. Esco VacciXcell's Tide Motion System is the highest yield and lowest cost packed bed bioreactor that can be placed inside a GMP isolator at Grade C-D environment, making it an ideal system for the production of wild-type viruses. This feature reduces the costs of cleanrooms by decreasing the requirements for personnel protective equipment (PPE), utilities, viable/non-viable monitoring and gowning airlocks, which are all needed in larger Grade A and B cleanrooms.

Upstream **BioProcessing** - Bioreactors and Fermenters

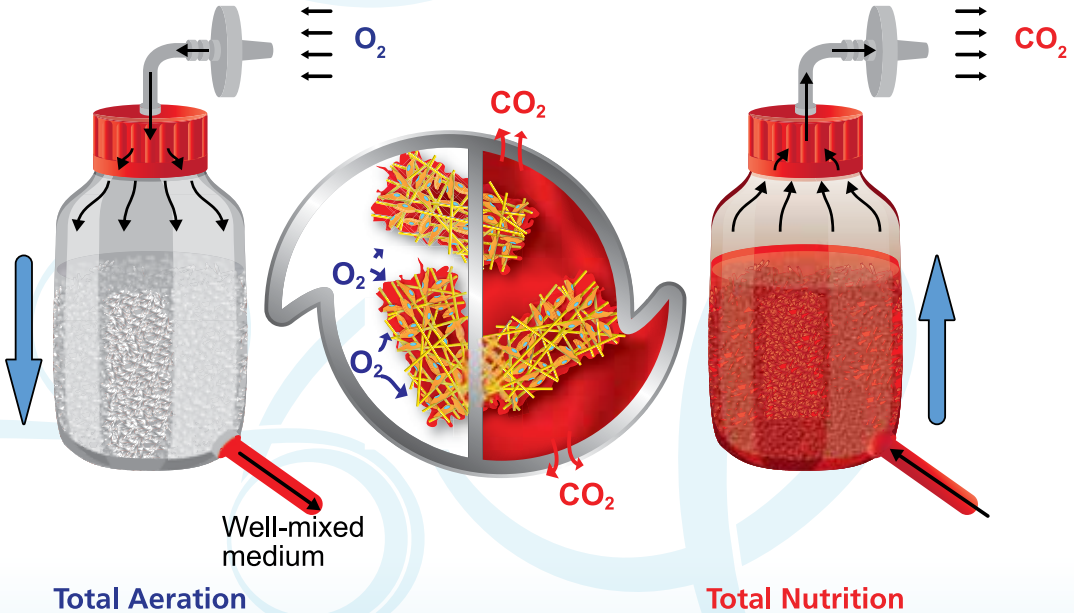
Principle

The two main components of the TideXcell® System are the TideXcell® Incubation and Control System (TCICS) and the TideXcell® Mixing System. The TideXcell® Incubation and Control System (TCICS) houses the matrix vessel that holds the BioNOC™ II carriers, which cells attach to and grow, while the Mixing System holds the culture medium. The culture medium flows between the Mixing System and matrix vessel using an air pump.

When the matrix vessel is filled with the culture medium, the cells are exposed to nutrition. On the other hand, when the culture medium is pumped back to the mixing tank, the cells are exposed to aeration in which exchange of O_2 and CO_2 occurs. The intermittent flow of media and air exposure are similar to the principle of roller bottle system.

Key Benefits and Features

- Linearly scalable up to 5,000 L
- High productivity
- Lower downstream processing costs due to lower cell debris
- Closed, automated, and controlled culture process
- Small space, utilities, and labor requirements
- Minimal bioprocessing optimization time from R&D to pilot and production scale due to faster and easier technology
- Proven vaccine production cases for various indications including Hepatitis A and rabies
- The only pilot/production scale bioreactor that can be integrated into cGMP isolator



Upstream **BioProcessing** - Bioreactors and Fermenters

System Comparison

Model	Fixed-Bed Volume (L)	Culture Surface Area (m^2)	Equivalent Roller Bottles (850 cm^2)	Equivalent CS-40 (25,200 cm^2)	Equivalent Cytodex II (0.44 m^2/g)
CelCradle™	0.1	1.65	20	0.65	3.75 g
TideXcell®-002	1-4	66	800	26	150 g
TideXcell®-010	5-10	165	2,000	65	375 g
TideXcell®-020	10-20	330	4,000	130	750 g
TideXcell®-100	50-100	1,650	20,000	650	3,750 g

Applications

- Culture of adherent (anchorage-dependent) cells
- Switching from roller bottles to a closed and controlled system
- Human and animal vaccines including wild virus production
- Protein and antibody production
- Allogeneic Cell Therapy
- Biosimilars and biobetter production
- Low cost vaccine production for neglected tropical diseases and orphan diseases
- Cell Mass Train production
- Perfusion and continuous processing at lower costs

Upstream **BioProcessing** - Bioreactors and Fermenters

Incubation and Control System

The TideXcell® Incubation and Control System (TCICS) features two HEPA filters. The first HEPA filter is used to ensure the air quality inside the incubator, while the second HEPA filter is used for the exhaust air that allows the cultivation of BSL 3-4 virus strains. The incubation system further provides operator, environment, and sample protection with its magnetic door interlock and UV light. The TideXcell® Incubation and Control System (TCICS) includes a glass window on the front door, which enables the user to observe the matrix vessel without the need to open the incubator door, reducing fluctuations in parameter values. VacciXcell offers two different models of the TideXcell® Incubation and Control System: 2-20 L and 100 L. The system has a user-friendly design and interface with 21 CFR Part 11 compliant controls.

Matrix Vessel


Single-Use Matrix Vessel


Multiple-Use Matrix Vessel

VacciXcell provides a wide range of matrix vessels depending on user's production requirements.

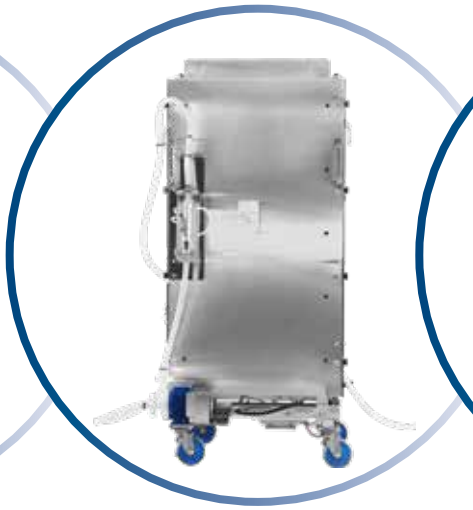
Features	TCICS: 2-20L					TCICS: 100 L	
Matrix Vessel	2 L		10 L	20 L		100 L	
	Multiple-Use	Single-Use	Multiple-Use	Multiple-Use	Single-Use	Multiple-Use	Single-Use
Matrix Volume	1-2 L	2-4 L	5-10 L	10-20 L		50-100 L	
Closed Sampling Port No.	0	1	0	0	1 - 4	0	1 - 5
Pre-packed carrier (g)	0	110 - 220	0	0	550 - 1100	0	2,750 - 5,500
Material	Glass	PP	Glass	PP	PP	PP	PP
AutoFeeder	Integrated/AF-1200					AF-1200	

Upstream **BioProcessing** - Bioreactors and Fermenters

Mixing System

Esco VacciXcell's TideXcell® offers three different types of mixing systems depending on the mixer volume and type of system required by the user.

Magnetic Stirring System



Recirculation Thermostatic Mixing System

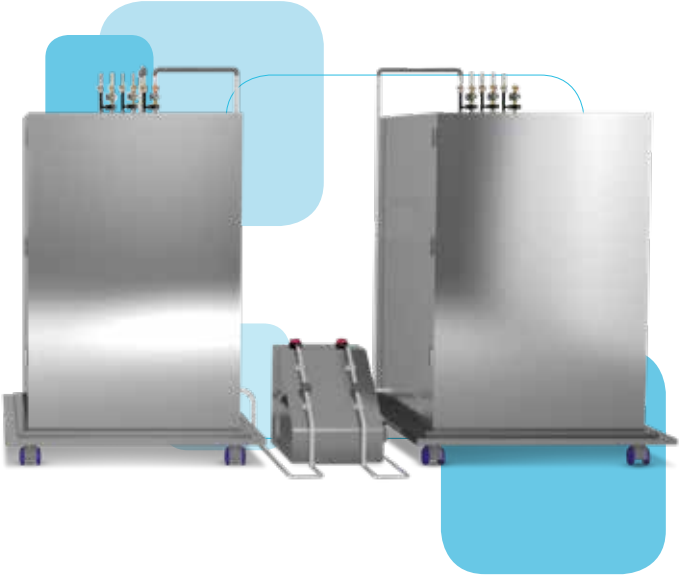
Stirred Tank Mixing System

Mixing System	Magnetic Stirring System	Recirculation Thermostatic Mixing System	Stirred Tank Mixing System
Single/Multiple-use	Multiple-use	Single-use	Multiple-use
Container Volume	10 L, 20 L	50 L, 100 L, 200 L, 500 L, 1,000 L	30 L, 50 L, 100 L, 200 L, 500 L, 1,000 L
Material	Glass Vessel	PP Bag	Stainless Steel 316 Vessel
Incubation System	2 L Matrix Vessel	2-100 L Matrix Vessel	2-100 L Matrix Vessel

Upstream **BioProcessing** - Bioreactors and Fermenters

Feed/Harvest Tank

Feed/Harvest system is an optional system that allows users to run the cultivation in perfusion/ continuous mode for extended periods of time. The Feed/Harvest System controls the volumetric flow of the medium in and out by checking the mixing tank weight. In the fed-batch mode, the volume of the medium to be added is set and pumped into the mixing tank using the autofeeder system. In the perfusion mode, the total weight of the mixing tank is measured and the system automatically adjusts the volumetric flow of the medium to and from the mixing vessel, allowing the same medium exchange volume between the feed and harvest tanks.



AutoSwitch System

The AutoSwitch System is recommended if there are two feeding tanks used during perfusion culture. It is connected in between the two feeding tanks. The pinch valve inside the system will detect bubble and automatically switch from one tank to anothear once the first reservoir is empty. An alarm light will turn on once the media in the tank is depleted; there are two individual alarm lights to indicate which feed tank is empty. Also, the AutoSwitch System includes in-line and non-invasive bubble detector.

TideXcell® Cell Harvesting System

The TideXcell® Cell Harvesting System (TCCHS) allows the automated and closed harvesting of cells from the matrix vessel. The automated system allows 95% viability of cell harvest within 1 to 3 hours depending on the harvest cycles. During detaching procedure, the equipment shakes the matrix vessel at a distance of 10 cm and speeds of up to 300 rpm.

Models:

TCCHS-002
TCCHS-002/020
TCCHS-050/300

Upstream **BioProcessing** - Cell Culture Products

Carriers

Analytical Tools and Reagents

BioNOC™ II are matrices for the growth of anchorage-dependent animal, human, and insect cells. BioNOC™ II supports the growth of many cell lines, including CHO, CHO-K1, rCHO-hIgG, rC-127 TPA, HEK293, Hybridoma, Vero, Sf-9, Hi-5, BHK-21, rBHKFactor VIII, HepG2, Hela, Huh 7, RK-13, human foreskin fibroblasts, human muscle skeleton cells, human mesenchymal cells, and human embryonic stem cells.

Features

- 100% pure PET (Polyethylene Terephthalate) material
- Animal component-free
- Low lint
- Light weight: 1 gram of carriers occupies 15 ml of space
- High surface to volume ratio (S/V ≈ 150 cm-1)
- High capacity: 1 gram carriers provide space for up to $1x10^9$ cells to propagate
- Special surface treatment to enhance biocompatibility
- Stable hydrophilicity up to four years
- Special geometric design to enhance mixing and support load-bearing
- capacity in packed-bed
- Compressible for higher cell density
- Non-pyrogenic and non-cytotoxic
- Manufactured in GMP-compliant factory
- Sterilizable by autoclave, gamma irradiation, and EO sterilization

Applications

Growth of anchorage-dependent animal, human, and insect cells in fixed bed cell culture systems: VXL Hybrid, CelCradle™ and TideXcell® bioreactor systems, and other commercially available packed bed bioreactors.

GlucCell® Glucose Monitoring System

GlucCell® glucose monitoring system simplifies and accelerates glucose measurement during cell culture. The disposable glucose test strips enable the measurement of glucose concentration during mammalian cell and insect cell culture in a few seconds.
Just insert the strip, add the sample and read the result.

Features

- Calibration-free
- Ready-to-use
- Portable
- Disposable test strips
- Accuracy is independent with the ingredients of culture medium and serumrelated components.
- 99.5% correlation with other biochemical analyzers available on the market

Crystal Violet Dye (CVD) Nuclei Counting Kit

Crystal Violet Dye Nuclei Count contains crystal violet dye, citric acid, and detergent to disrupt cells and release cell nuclei for cell counting. This provides an efficient reagent for cell count in a porous matrix.

Upstream **BioProcessing** - Cell Culture Products

Cell Culture Media and Supplement

Plus™ MDCK

Plus™ MDCK is an animal component-free culture medium developed specifically for MDCK cell culture.

Features

- Animal component-free culture medium
- Enables serum-free culture with comparable cell growth rate to cell culture with serum
- Up to 10-fold higher viral titre compared to culture using commercial medium
- Available in powder or liquid form

Plus™ VERO

Plus™ VERO is an animal component-free culture medium developed specifically for VERO cell culture.

Features

- No animal or human origin components
- Completely defined with low protein content (≤ 5 µg/ml)
- Enables serum-free culture
- No hydrolysates, yeast extract, peptone, and/or other complex components
- Allows cells to adhere within 5 min and suitable for agitating culture system
- Superior virus output yield over other commercially-available media
- Available in powder or liquid form

Super Plus™

Super Plus™ is a cell culture supplement designed to reduce or eliminate the requirement for serum in the basal medium. Super Plus™ also minimizes culture variance due to inconsistent quality between serum batches. Super Plus™-added medium supports growth of many cell lines, including MDCK, VERO, BHK, ST, PK-15, HEK-293, and CHO.

Features

- Compatible with commercial basal medium
- Save up to 90% serum or culture serum-free
- Completely defined with low protein content
- No hydrolysates, yeast extract, peptone, and/or other complex components
- Powder form

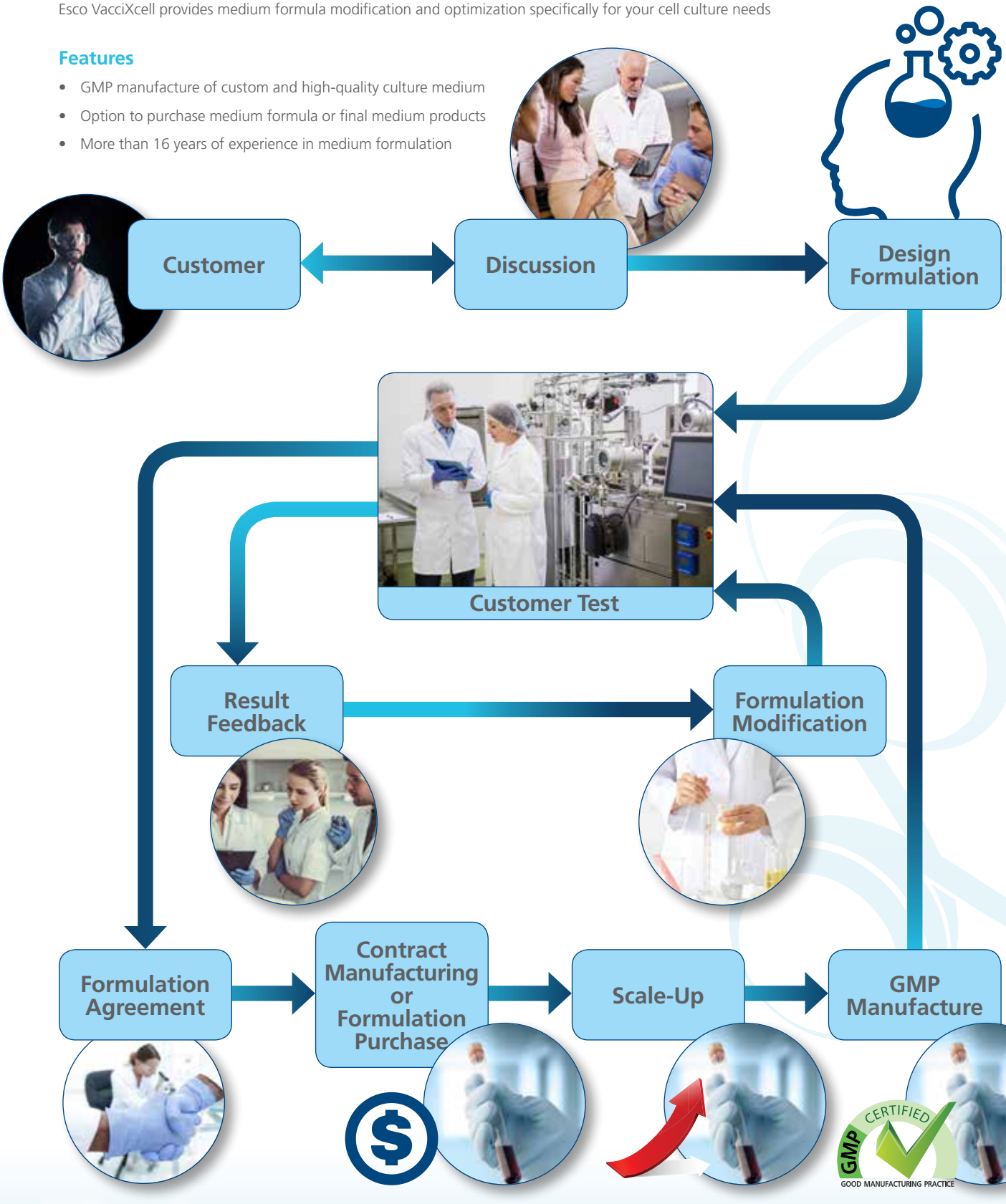
Upstream **BioProcessing** - Cell Culture Products

Culture Medium Formulation Platform

Esco VacciXcell provides medium formula modification and optimization specifically for your cell culture needs

Features

- GMP manufacture of custom and high-quality culture medium
- Option to purchase medium formula or final medium products
- More than 16 years of experience in medium formulation



Upstream **BioProcessing** - Cell Culture Products

Cell Culture Equipment

Biological Safety Cabinets

Biological Safety Cabinets (BSCs) provide ISO Class 3 work zone for cell therapy research and development procedures, including cell line establishment, cell passaging, cell transduction and more.

Class II Type A2
NSF Certified

Class II Type B2
NSF Certified

Class III
EN Certified

Biological Safety Cabinets

Features

- Energy saving DC ECM blower for most models
- ISOCIDE™ antimicrobial powder coating
- ULPA/H14 filter with > 99.999% efficiency at 0.1-0.3 µm
  *ULPA as per IEST RP CC001.3
  *H14 as per EN1822 EU
- Low noise
- Easy to clean
- Ergonomic design

CO_2 and CO_2/O_2 Incubators

CelMate®

CelCulture®

With Integrated Cooling System

Stainless Steel Exterior

Copper Interior

CelCulture® With High Heat Sterilization

Features

- Precised parameter control
- Fast temperature and CO_2 recovery
- Robust contamination control for optimum protection: SteriSafe™ ULPA Filtration System, validated SwiftCon™ 90°C Moist Heat Decontamination Cycle, 180° C High Heat Sterilization Cycle, filtered gas injection lines, and ISOCIDE™ antimicrobial coating
- Monitoring and control system for safeguarding of cell cultures available via Voyager® software system
- User-friendly controller software interface with user-configurable alarms, parts replacement reminder alarm system (CelAlert ™), and intelligent data and event logger with built-in 2MB flash memory
- HPA validated (for moist heat decontamination), UL-listed, and MEA (Mouse Embryo Assay) test certified.

Upstream **BioProcessing** - Cell Culture Products

Cell Culture Equipment

Versati™ Centrifuge

The Versati™ centrifuge is equipped with maintenance-free motors, robust mechanism and intelligent Versati™ microprocessor control system that offers extreme reliability and safety. Versati™ has a strong versatility covering micro centrifuge and low-to-high speed general-purpose centrifuge with variety of rotors, adapters, and accessories to fit all your application needs and suit various consumable tubes, strips, and plates.

Features

- Maintenance-free, Brushless Motor
- Diverse Choices of Rotor
- Emergency Switch
- Distinct Control Panel and Intelligent Versati™ Microprocessor Control System
- Genuine-Protec™ Safety Lid Lock

Esco Versati™ Tabletop Refrigerated Centrifuge TCR-1500-_

Esco Versati™ Tabletop Ventilated Centrifuge TCV-1500-_

Laboratory Shaker

Features

- TriDrive™: Esco's unique triple-eccentric counterbalanced drive supports heavy-duty and high-speed applications.
- RobustDrive™: This mechanism eliminates the need for lubrication as the Brushless DC Motor reduces maintenance.
- SmartRun™: Excellent out-of-balance sensor and propriety imbalance compensation algorithm adjust the optimum revolutions per minute (rpm) to ensure smooth operation without any vibration.

Esco OrbiCult™ Incubator Benchtop Shaker IBS-R-25-_

Esco OrbiCult™ Ambient Shaker AS1-NC-25

- Data are saved even after power failure.
- Apt to fit any application required for your operation.
- Offers multiple choice of accessories which allow to customize and satisfies the appropriate application.
- Two types of orbit (19 mm and 25 mm) that meets different application.
- External surfaces are powder coated with Esco ISOCIDE™ to eliminate 99.9% of surface bacteria within 24 hours exposure.
- Audible and visible alarm every end run.
- Easy-to-use design enables to set parameter precisely.
- Historical settings can easily track and review from the touchscreen.
- Audible and visible alarms alert any speed and temperature deviations.
- Shaker automatically restarts after power interruption for the non-volatile program saved in the memory.
- Each shaker is factory tested for performance assurance in accordance with international standards.

Upstream **BioProcessing** - Cell Culture Products

Cell Culture Equipment

HP Series Laboratory Refrigerators and Freezers

VacciXcell offers laboratory freezers and refrigerators that provide superior product and sample protection, long reliability and exceptional quality. VacciXcell freezers have temperature ranges of -10°C to -25°C with capacities of 128 L, 347 L, 620 L and 1,355 L and -20°C to -40°C with capacities of 360L and 544L while VacciXcell refrigerators have a temperature range of +2°C to +15°C with capacities of 128 L, 347 L, 620 L and 1,355 L.

Features

- Door Lock
- External surface coated with Esco ISOCIDE™, which eliminates 99.9% of surface bacteria within 24 hours of exposure
- High-quality stainless steel interior for sample protection.
- Internal LED lighting saves up to 70% power with less heat exposure compared to fluorescent or incandescent lighting
- Standard wheel/casters as well, for easy relocation

Forced air design

- Superior forced air design instead of a regular cold wall, for both refrigerator and freezer.
- Rapid cool-down and very fast recovery due to fan assistance
- Fast temperature equilibration and superior sample protection

Intelligent Automatic defrost for additional sample protection

- High-performance unit uses intelligent defrost to maximize sample protection
- Computer has thermocouple on the evaporator
- Detects ice formation
- Defrosts only when needed to keep units at optimum performance
- Keeps chamber temperature within safe limits
- No sample risk when cold wall freezer must be defrosted

HR1-140S-_ HF2-400S-_ HC6-700S-_ HR1-1500S-1

Upstream **BioProcessing** - Cell Culture Products

Cell Culture Equipment

Ultra-low Temperature Freezers

Ultra-low Temperature Freezers (ULTF) are widely used in scientific research for long-term storage of samples. As ULT freezers are often operated at -50°C to -80°C continuously for years, reliability is of paramount importance to the researchers. Esco Lexicon® II ULT Freezers provide top notch protection that can withstand the test of time to guarantee the integrity of your irreplaceable samples.

Key Features

- Energy-efficient
  - Approximately 11.52 kWh/day power consumption; consumes less energy than most conventional freezers
- Excellent Triple Gasket Door Seals
  - Uses 5" thick foamed-in-place polyurethane insulation, triple gasket seal and HeatRecycler™ technology
- Reliable Smart Controls
  - Advanced Eye-level display with a feature that can easily exchange data using the USB port to download freezer temperature and event logs (Gold controller only)
- Engineering excellence and strict process controls
  - Quality components, strict evacuation protocols and process controls to ensure a clean, dry, and leak-free system
- Environment-friendly
  - CFC and HCFC-free refrigerants are used, biodegradable, high-performance synthetic polyester oil is used
- ISOCIDE™ Anti-microbial coating
  - Esco's powder coat eliminates 99.9% of surface bacteria within 24 hours of exposure

Other Features

- Fast Pull-down time
- Fast recovery after door opening
- Robust, adjustable, lockable caster wheels
- Ergonomic door handle with integrated key lock ensures security of samples
- Freezer Capacity; 360, 480, 597, and 714 liters

Silver Controller
UUS -597A

Gold Controller
UUS -597B

Green Product

CFC AND HCFC-FREE

Formulation – Formulation and Filtration Isolator

Weighing and Dispensing Containment Isolator (WDCI)

Features

- Configurable designs able to adapt to various weighing and dispensing quantities and accuracies
- Fully welded single-piece SS316 L internal chambers with rounded coved corners
- Pressure tested to pressure testing/containment standard is ISO 10648-2
- Inflatable anti-bacterial, USP Class VI compliant and food grade FDA-approved gaskets for proactive and reactive aseptic sealing method
- Safe change glove system
- Integrated anti-vibration granite platform for weighing scale placement
- Safe change filters to allow in-process filter replacement
- Integrated automated height adjustment providing 280 mm of motion for ergonomic comfort

Typical Applications

- Formulation of not just cytotoxics but all "HPAPI" or highly-potent active pharmaceutical ingredient

Aseptic Containment Isolator (ACTI)

Features

- Full unidirectional airflow that provides superior aseptic work zone.
- Smooth flushed interior of isolator glazing that is made of toughened laminated safety glass.
- External sensors protected by instrument filters.

Typical Applications

- Handling of biopharmaceutical germ seed cells and aseptic cell processing
- Formulation of not just cytotoxics but all "HPAPI" or highly-potent active pharmaceutical ingredient

Upstream **BioProcessing** - Cell Culture Products

General Processing Platform Isolator (GPPI)

The Esco General Processing Platform Isolator (GPPI) is a highly adaptable and unidirectional/laminar airflow isolator that can be used for any process that requires an ISO Class 5 (Grade A) environment.

Features

- Unidirectional airflow
- User-selectable single pass or negative chamber pressures
- Single pass or recirculating airflow regimes
- Fully welded SS316L internal chambers with round coved corners
- Standard design incorporates GMP and GAMP compliant features
- Safe change glove system
- Low contamination filter change design

Isolation and **Containment** Systems

Pharmacon™ Downflow Booths

Soft Capsule® Soft Wall Cleanrooms

Ceiling Laminar Airflow Units

Laminar Flow Horizontal Trolleys and Laminar Flow Vertical Trolleys

Formulation and Filling

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.

ASEPTiCell™

ASEPTiCell™ is a fully integrated and highly flexible manufacturing system designed to aseptically fill-finish sterile injectable. ASEPTiCell™ advanced automated features that simplify the fill-finish process, provide flexibility and enhance sterility assurance.

Features

- Integrated
  - RTU (Ready-To-Use)
  - Single use
  - Isolator-barrier
  - Robotics
- Capacity
  - Vials : 2 – 30 ml
  - Syringes : 0.5 – 20 ml
  - Cartridges : 3 ml , 5 ml
- Options : semi-automated / mobile-transfer
- Option : tub exterior bio-decontamination

Supplementary Equipment

Raised-bed sanitary and non-sanitary conveyors

Loading and unloading tables

Sanitary rotary table

Cleanroom pass-through

Downed vial reject systems

Vial Washing

Features

- Semi / Fully automated
- Central column & outfeed mechanism
- Individually programmable intermittent spray valves
- Recirculation packages
- Non-penetrating Spray Nozzles

Formulation and **Filling** - Traditional Filling Line

Automatic Loading / Unloading System

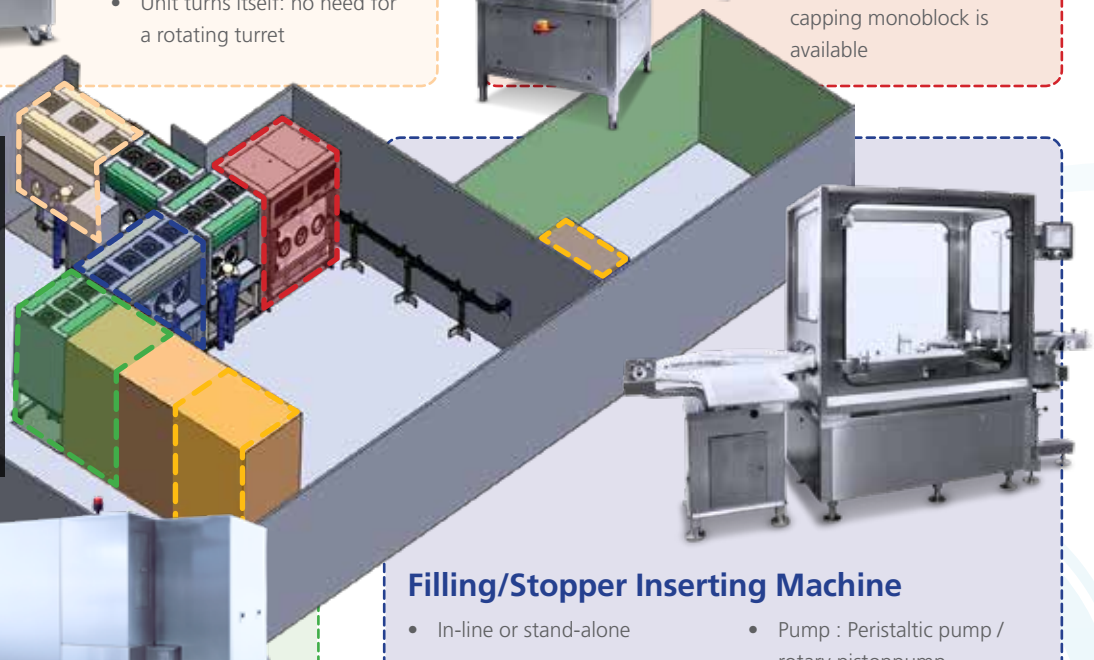
- Semi / fully automatic loading system
- Laser-Guided loading and unloading systems
- Self-empowered via battery : no need for the x-rail
- Unit turns itself: no need for a rotating turret

Capping Station

- Stand-alone capping machine
- Spinning vials
- Output: Up to 200 vials/min
- Vial range: 2-100 ml
- Center stationary disk
- Maintenance-free design
- ntegrated 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 pistonpump
- 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 full integrated system (Isolator + Filling lines + Freeze Drier + Auto-loading/unloading system) or provide a full integrated system according to client 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.

Formulation and **Filling** - Flexible Multi-Format RTU Filling Lines

Lyophilizer

- With options for denesting, automatic loading / unloading into freeze driers, and renesting before capping.

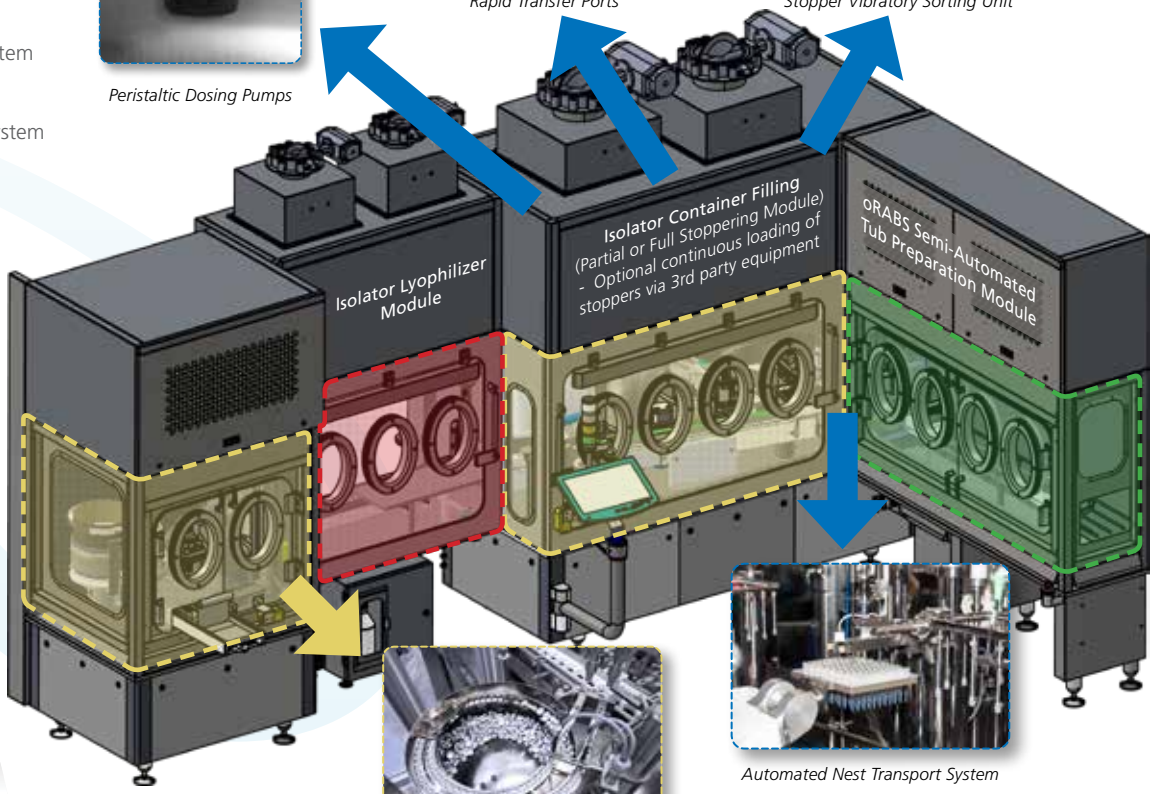
Automated Tub Conveyor & Automated Nest Transporter

Rapid Transfer Ports

Stopper Vibratory Sorting Unit

- An RTU system can process 200 containers per minute
- Additional Features
  - Stopper gap detection system
  - Quarantine location
  - Inspection and labelling system
  - Viable monitoring (active and passive)
  - Modular in-situ configuration to have changeable parts to fill multiple container formats (e.g. RTU vials/ syringes/cartridges/ IV bags)

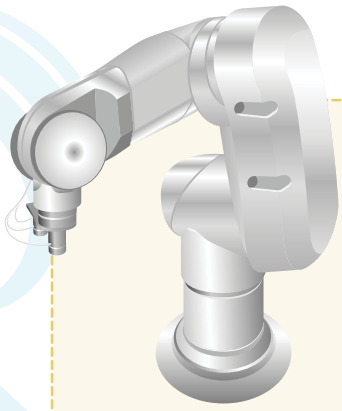
Peristaltic Dosing Pumps



Isolator Capping Module
(oRABS can be used for non-potent freeze-dried products and non-BSL 3 products

Automated Nest Transport System

Vial Cap Vibratory Sorting Unit



Robotic Arm for Filling, Stoppering, and Capping

- Increases product output
- Capable of handling multi-container formats
- Accurate dosing of products
- 'Zero loss' philosophy

External Vial Washer

Optional Equipment

- Optional external washer for post-freeze dried products
  - Required for potent liquid filling as some liquids on external surface of vials/syringe will form potent powders harmful to operators.

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Cross Contamination Facility Integrated Barrier

Dynamic Passboxes and
Dynamic Floor Label Hatches

Cleanroom Air Showers

Infinity® Pass Boxes,
Infinity® Air Shower Pass Boxes,
Infinity® Cleanroom Transfer Hatches

Quality Control and Assurance

Sterility Testing Isolator

The sterility testing isolator provides a cost-effective pharmaceutical-grade isolator for sterility testing and other QC testing applications.

Features

- Positive or negative pressure operation available for both sterility testing and QC testing applications
- Available in various configurations: 2-, 3-, or 4-gloved main chamber and with or without a transfer chamber
- Transfer chamber with independent operation and bio-decontamination
- Full SS 316L construction with critical chamber thickness of 4 mm and technical housing thickness of 1.5 mm
- Front visor of the main chambers and transfer chamber manufactured from 10 mm thick toughened safety glass. The main chamber visor being inclined for ergonomic comfort
- FDA-approved inflatable seals
- Biological Class III mode available meeting BS EN 14629:2000 standards
- Leak tightness meeting that of type 1 isolator in ISO 10648-2

Avona® Stability Test Chamber

Green Product

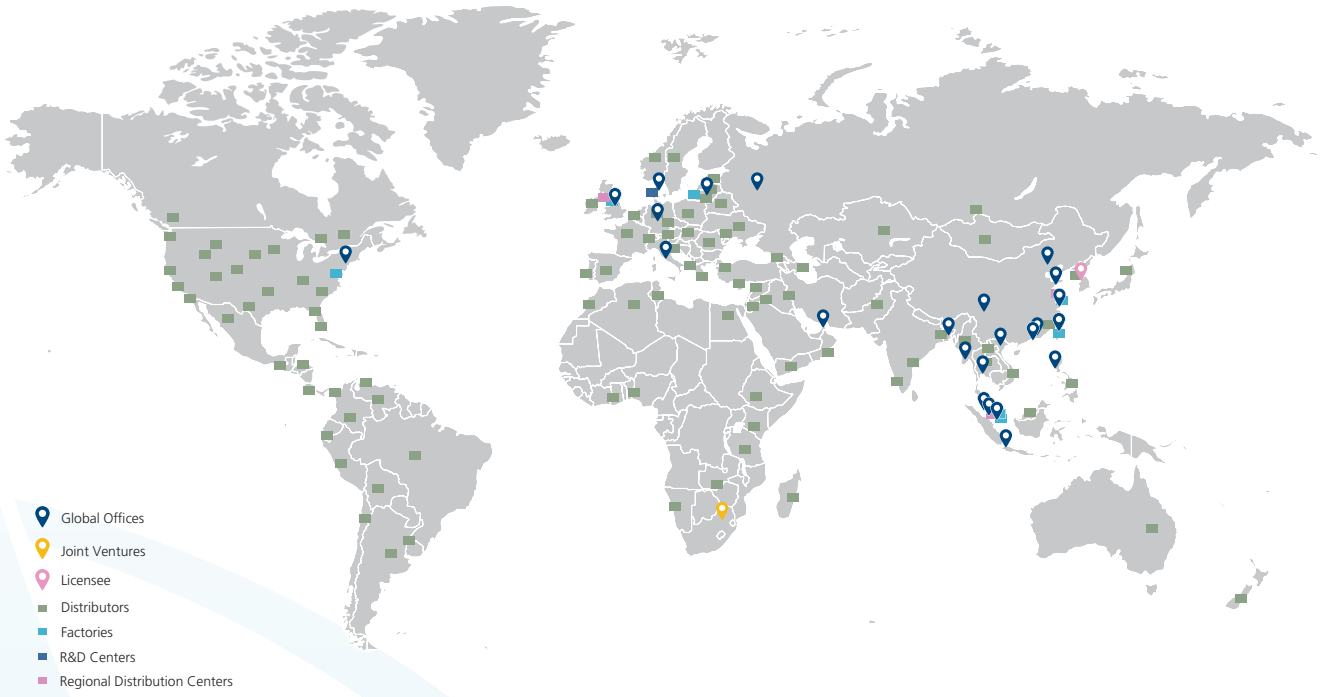
Stability Chambers provide a temperature and humidity-controlled environment intended for life science related researches and wide range of pharmaceutical applications. These practices were performed to establish shelf lives and product stability.

Avona® Stability Chamber delivers excellent performance, compliant with ICH & FDA guidelines along with precise temperature and humidity control which permits extremely accurate and consistent control that is vital for pharmaceutical shelf life testing.

Features

- Automatic Humidification and Dehumidification System
- Flexible Interchangable illumination system for homogeneous lighting conditions
- Intuitive PLC-Based Touch Screen Controller
- ISOCIDE™ Antimicrobial powder coating

ESCO GLOBAL NETWORK



Air Shower • Aseptic Containment Isolator (ACTI) • Ceiling Laminar Airflow Units • Cleanroom Transfer Hatch • Containment Barrier Isolator (CBI) Downflow Booth (DFB) • Dynamic Floor Label Hatch • Dynamic Pass Box • Evidence Drying Cabinet • Garment Storage Cabinet General Processing Platform Isolator (GPPI) • Laminar Flow Horizontal Trolley • Laminar Flow Straddle Units, Single and Double Laminar Flow Vertical Trolley Pass Box • Soft Wall Cleanroom • Sputum Booth • Ventilated Balance Enclosure (VBE) • Weighing and Dispensing Containment Isolator (WDCI)

Since 1978, Esco has emerged as a leader in the development of controlled environment, laboratory and pharmaceutical equipment solutions. Products sold in more than 100 countries include biological safety cabinets, fume hoods, ductless fume hoods, laminar flow clean benches, animal containment workstations, cytotoxic cabinets, hospital pharmacy isolators, and PCR cabinets and instrumentation. With the most extensive product line in the industry, Esco has passed more tests, in more languages, for more certifications, throughout more countries than any biosafety cabinet manufacturer in the world. Esco remains dedicated to delivering innovative solutions for the clinical, life science, research and industrial laboratory community. www.escoglobal.com.

ESCO Healthcare "Discovery to Delivery"

ESCO® Healthcare

"Discovery to Delivery"

ESCO VACCIXCELL

ADHERENT BIOPROCESSING SPECIALIST

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