Filling Line
Isolator

Boosting Your Aseptic Fill Capabilities

ESCO® PHARMA

Filling lines enclosed in an isolation technology are now widely utilized for the aseptic manufacture of sterile pharmaceuticals in various container formats. Esco Pharma's filing line isolator provides an ISO Class 5 / Grade A environment, ensuring the sterility of the work zone for the most demanding sterile/aseptic operations.

The Filling Line Isolator provides a ready-to-use and easy-to-validate filling, stoppering, and capping system for flexible small batch pharma production after the formulation step. The entire fluid path is designed for single-use, making cleaning validation simple and permits fast changeover between various liquids. The universal format parts supplied can be used for a wide range of vials, stoppers, and caps. Changeover between vials, stoppers, and caps can be done within minutes by operator without any special tools or technical support from staff outside the cleanroom area.

Applications

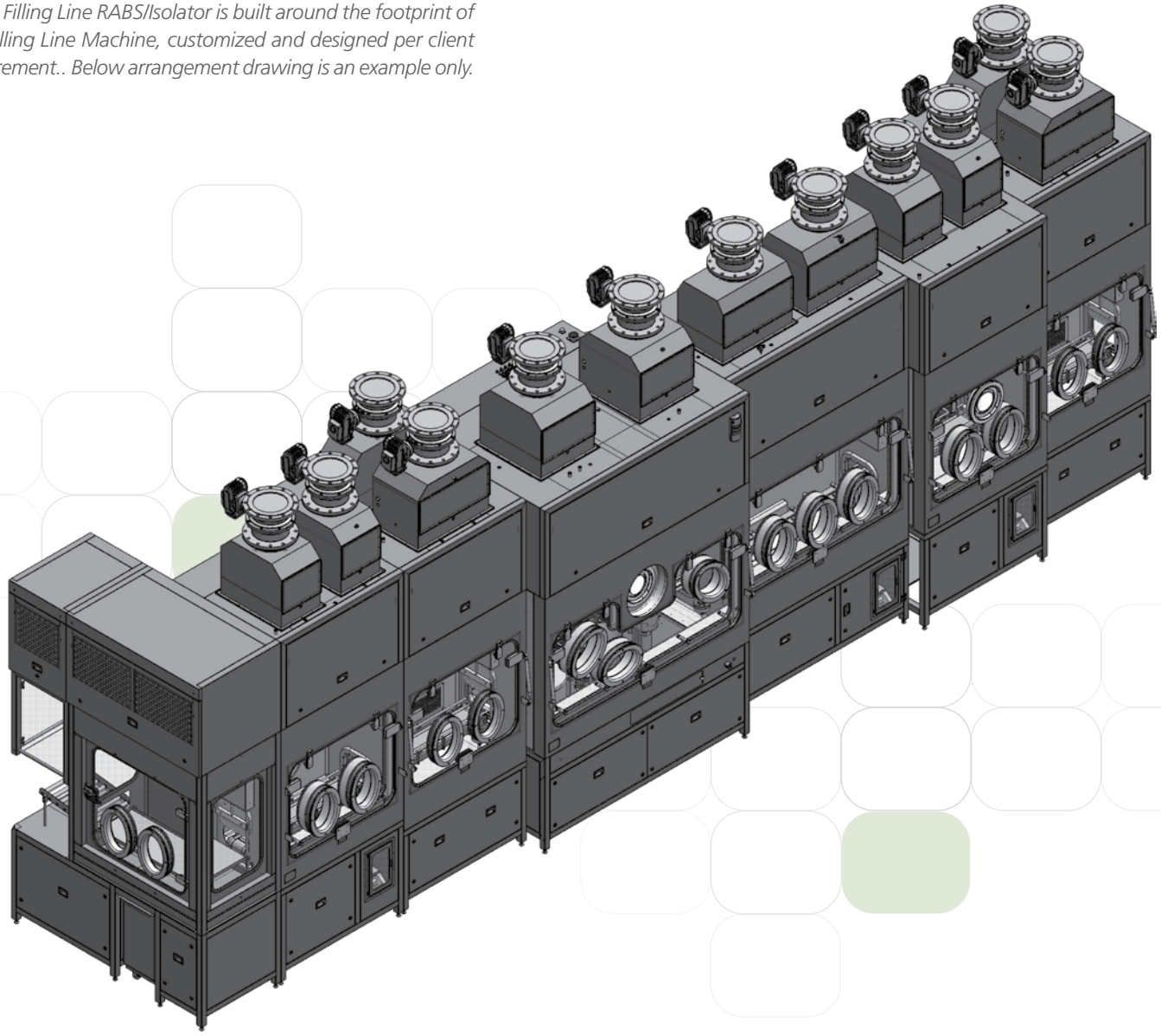
- Aseptic manufacture of cell therapy and injectables
- Aseptic Processing
- Continuous manufacture
- Processing of materials with high Occupational Exposure Band (OEB) levels
- Research and Development
- Vaccine Manufacture

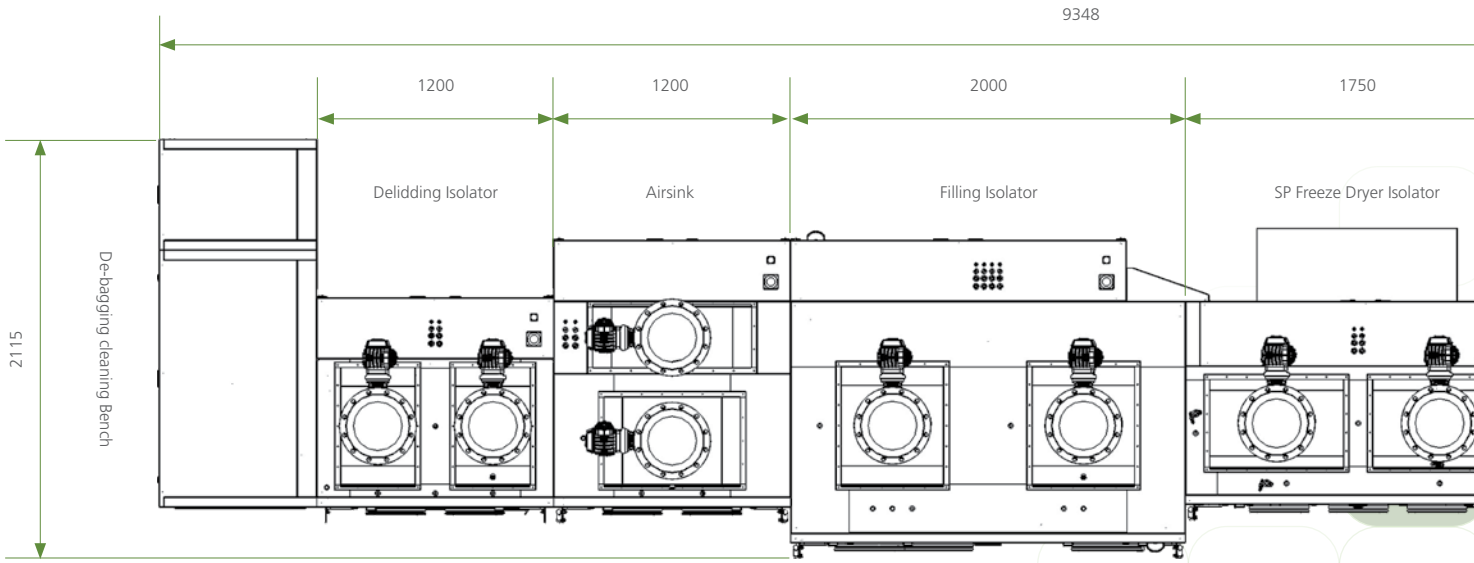
Features

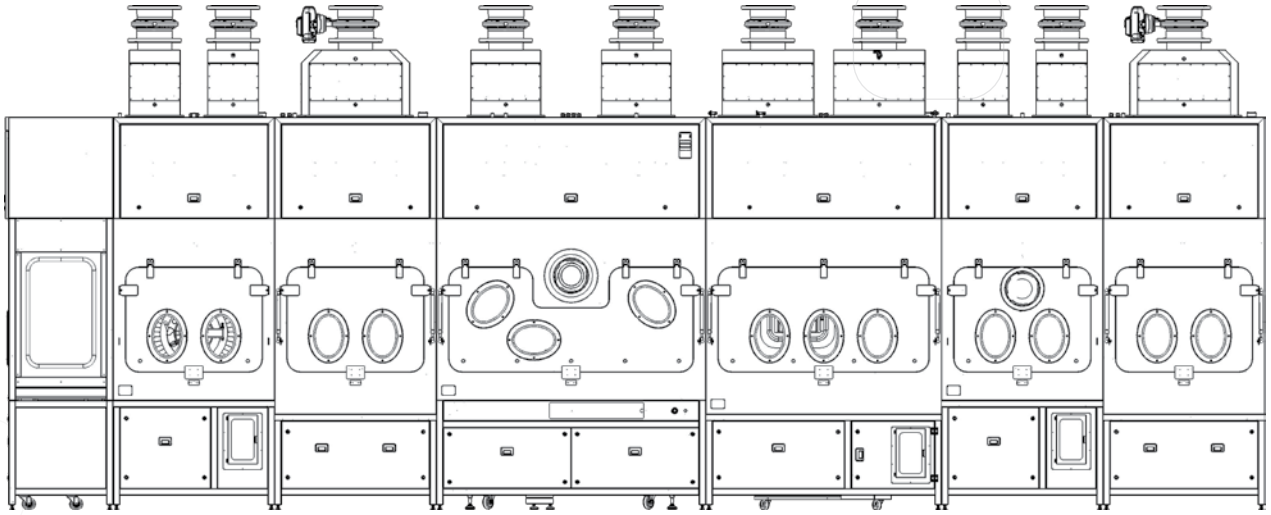
- ISO Class 5 air cleanliness classification as per ISO 14644-1
- Factory-configured to operate in a positive or negative pressure regime, depending on client requirements.
- Configured to operate in single pass/total exhaust or recirculating airflow
  - Unidirectional airflow
  - Turbulent airflow
- Automated Pressure Hold Test
  - With on-board compressed air supply
  - With client supplied compressed air
- Biodecontamination System
  - Esco Pharma's BioVap™ biodecontamination cycle ensures a 6 log reduction in bioburden.
- Audio/Visual Alarm System
- Touch-Panel Interface
  - Siemens HMI/PLC
  - Allen-Bradley PLC
- Surface Finish Options:
  - Grained Finish-Directional
  - Orbital Finish-Upcharge Required
- Barrier Technology:
  - *Restricted Access Barrier System (RABS)*
    - Material Entry
    - Closing open Restricted Access Barrier System (oRABS)
    - Both operate in ISO Class 5 environment and can be configured in positive or negative pressure depending on the application.
  - *Isolator*
    - Filling Line Isolator
    - Allows the introduction of stoppers and fill media via closed transfer ports
    - Lyophilizer Isolator
      **Dependent on client requirements*
      - » Facilitates in the loading and unloading of the lyophilizer.
      - » With ISO Class 5 air quality inside via laminar airflow
      - » The lyophilizer is pressure-tested as a combined system with the isolator
      - » Automated entry/exit door system
      - » Rapid Transfer Port (RTP) rapid upgrade capability
      - » With clean gasket finish
- Channel with fill-line base
  - Able to accommodate multiple filling line base types:
    - Full Stainless Steel
    - Stainless Covered Aluminum Base
  - Repeated fitment (no damaged gasket)
  - Guaranteed air-tight sealing
  - Flush/Smooth crevice-free transition between filler base and isolator shell
- Single Wall or Double Wall design
  **Dependent on client requirements*
  - Single Wall design-Remote HVAC Skids
  - Double Wall design-Remote HVAC Skids
  - Double Wall design-Non-Remote HVAC Skids
- Heating, Ventilation, and Air Conditioning (HVAC) system
  - Remote
  - On-board
- Cleaning Processes
  - Wash-in-Place (WIP)
  - Clean-in-Place (CIP)
- Integrated systems for filling process
  - Vial washer
  - Depyrogenation tunnels
  - Automatic loading/unloading system
  - Automated tub conveyor and Automated nest transporter
  - Filling/Stoppering Inserting Machine
  - Lyophilizer
  - Robotic Arm (for filling, stoppering, and capping)

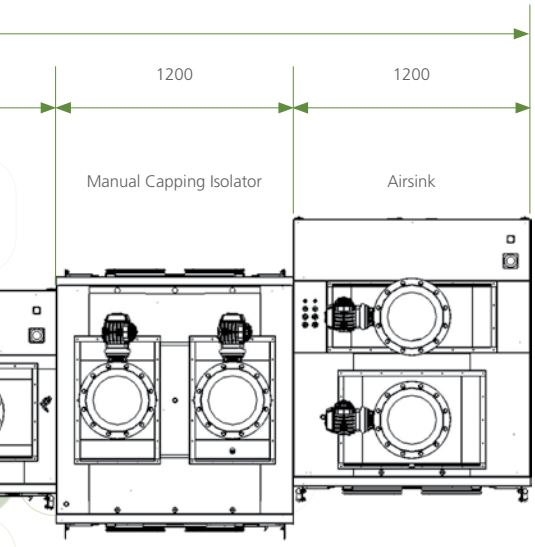
Sample Engineering Drawing:

Note: Filling Line RABS/Isolator is built around the footprint of the Filling Line Machine, customized and designed per client requirement.. Below arrangement drawing is an example only.





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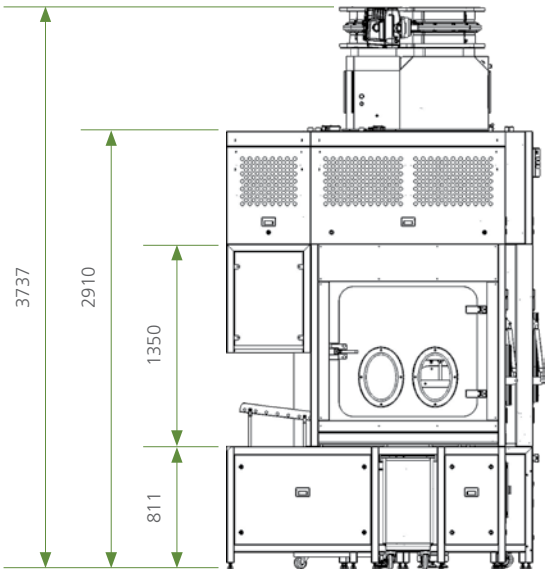
1200
Manual Capping Isolator
Airsink


3737
2910
1350
811

Formulation and Filling - Traditional Filling Line

Automatic Loading / Unloading System

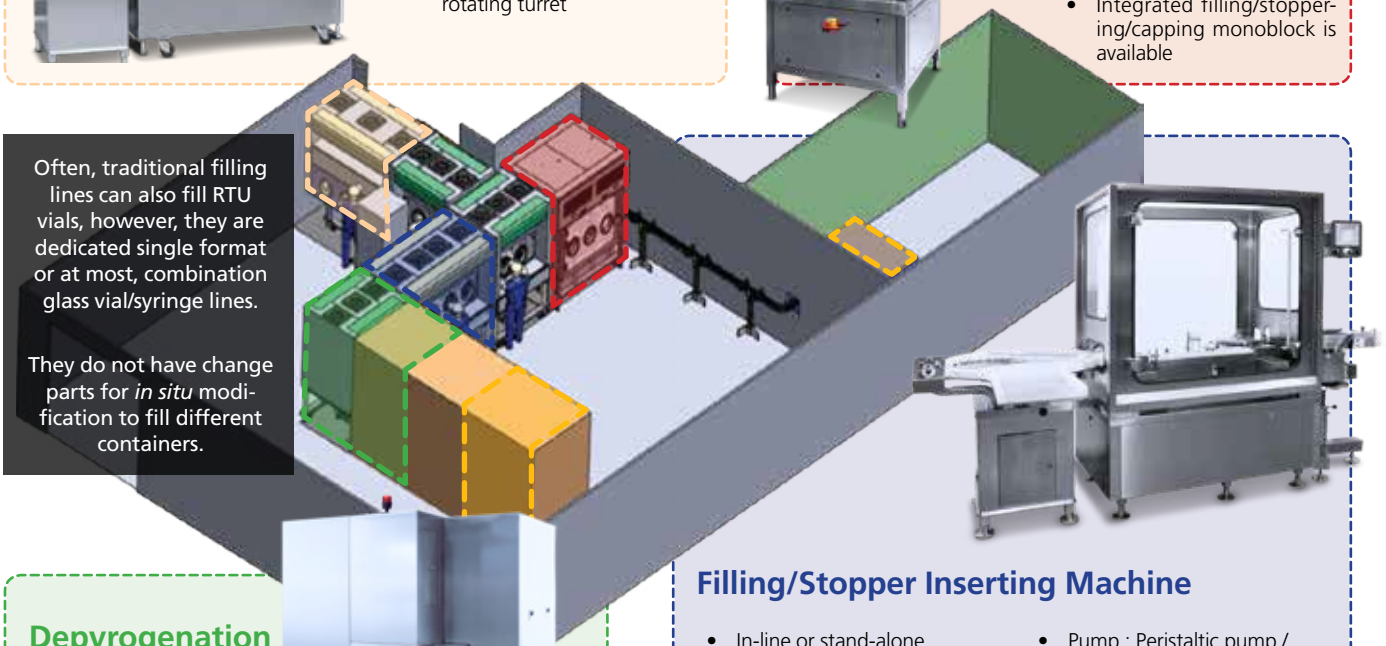
- Semi / fully automatic loading system
- Laser-Guided loading and un-loading systems
- Self-empowered via battery: no need for the x-rail
- Unit turns itself: no need for a rotating turret

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 Dryer + 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.

Formulation and Filling - Flexible Multi-Format RTU Filling Lines

Lyophilizer

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

Automated Tub Conveyor & Automated Nest Transporter

Stopper Vibratory Sorting Unit

Sterile Liquid Transfer Port

Rapid Transfer Ports

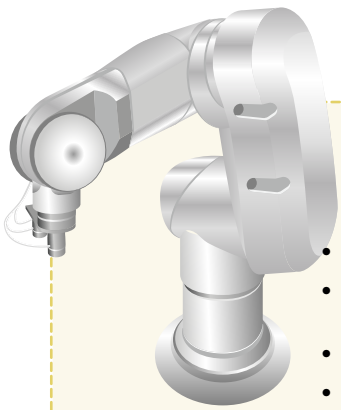
Peristaltic Dosing Pumps

- 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)

Rotary Piston Pump

Isolator Capping Module

(oRABS can be used for non-potent freeze-dried products and non-BSL 3 products)



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/syringes will form potent powders harmful to operators.

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ESCO LIFESCIENCES GROUP NETWORK

42 Locations in 21 Countries All Over the World

Air Shower
Aseptic Containment Isolator (ACTI)
Ceiling Laminar Airflow Units
Cleanroom Transfer Hatch
Containment Barrier Isolator (CBI)
Downflow Booth (DFB)
Dynamic Floor Laminar 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.

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