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Introduction

What is Containment?
By definition, all Active Pharmaceutical Ingredients (API's) are biologically active, even at very low quantities. Therefore, it is vital not to expose operating personnel handling these compounds to levels that would result in adverse biological effects being experienced.

In order to facilitate this, a containment strategy needs to be employed. When dealing with API's, it involves preventing hazardous materials from escaping into the workplace and into the surrounding environment. Essentially this involves isolating the product from personnel and the environment. This in turn protects the product itself, personnel working on the process and the surrounding environment.

Here at Containment Service Providers (CSP), we design, manufacture and install flexible isolators for this exact purpose. Our business is based on the well known philosophy “contain at source” and we incorporate this into our designs. The “contain at source” philosophy is now the most favoured philosophy among containment engineers and all the regulatory bodies. In fact the following quote highlights a requirement from all regulatory bodies in this day and age – “so far as reasonably practicable, the prevention or adequate control of exposure of employees to a substance hazardous to health shall be secured by measures other than the provision of personal protective equipment”.

Why Is Containment Needed?
Containment is essential for the following:

- Protect the work environment
- Protect the health and safety of fellow employees and the public
- Protect the product against contamination
- Professional ethical responsibilities to fellow employees and to the public
- Prevent product waste
- Protect environment in general
- Protect against insurance claims
- Good Business
- Legislation
- Big reduction in cleaning costs
How much containment is needed?

Once it has been decided that containment is needed, the question then arises “how much containment is needed?”. Most chemical agents have an Occupational Exposure Limit Value (OEL) associated with it and these values can typically be found in the chemical agents Material Safety Data Sheet (MSDS). It is this OEL value that will determine the type of containment that is required on a particular step of the process.

The OEL value is the maximum permissible concentration of a chemical agent in the air at the workplace to which workers may be exposed, either in relation to an 8 hour (time weighted average (TWA) exposure) or a 15 minute (short term exposure limit (STEL)) reference period. An 8 hour reference period is taken because it is deemed to be the average shift duration worked per day by an employee. The 15 minute reference period is defined as the concentration to which workers can be exposed for short periods of time, 4 times per day, without suffering adverse effects. The higher the level of potency of a chemical agent, the lower its OEL. For example, drugs with an OEL of less than 100µg/m$^3$ are considered to be potent and those with OEL’s below 10µg/m$^3$ are considered to be highly potent.

Once all this information is known, a containment strategy can be designed. The containment strategy will encompass both the engineering competencies (e.g. process design, containment devices, maintenance) as well as management issues (e.g. good operational techniques, training) that are necessary for the safe handling of hazardous chemical agents.

The following chart compares typical containment levels that can be reached by different containment techniques. This data was taken from ISPE and other presentations by industry experts. It is provided as a general guide to containment levels and all readings are TWA ratings.
Introduction
All of our flexible isolators are custom designed to suit our customers’ requirements. Our flexible isolators can be manufactured from one of the following anti-static materials:

1. CSP PharmaFlex PU (Polyurethane)
2. CSP PharmaFlex PE (Polyethylene)

The majority of our flexible isolators are manufactured from PU as this is the most transparent and user friendly material. However, if the PU is not suitable for our customer, due to solvent compatibilities or other reasons, we have the capability to manufacture the flexible isolators from one of our other materials which will satisfy the customer’s requirements.

We currently have custom designed over 2500 flexible isolators for the pharmaceutical industry and these are installed on processes throughout the world ensuring safe and contained operations.

Materials
1. **CSP Pharmaflex PU (Polyurethane)**

CSP Pharmaflex PU has been developed in conjunction we our new range of Pharmaflex films. This film is extremely popular amongst pharmaceutical manufactures globally. The transparent film is our most commonly used film for flexible isolators. CSP Pharmaflex PU has many features that make this unique film an attractive choice for our customers some include:

- Transparent material.
- Anti-static material.
- Anti-static shelf life of 5 years.
- EU compliant material
- FDA compliant material.
- User friendly material.
- Very strong material.
- Very good resistance to acids and bases.
- High melting point.
- Data sheets available on request.
Our Flexible Isolators

2. **CSP Pharmaflex PE (Polyethylene)**

Along with the help of our customers, CSP have developed a new barrier film to achieve a new advancement in film technology. CSP Pharmaflex PE is quintessential for flexible isolators and flexible enclosures; the base film has superb solvent resistance along with many other beneficial features.

- Transparent material.
- Anti-static material.
- Anti-static shelf life of 5-years.
- EU compliant material.
- FDA compliant material.
- User friendly material.
- Very strong material.
- Very good resistance to acids and bases.
- High melting point.
- Data sheets available on request.

**CSP Pharmaflex PE**

CSP’s specialist product packaging film has been developed in accordance with CSP’s new Pharmaflex technology film range. This film is ideal for product packaging and is used as the liner material for the CSP continuous liner system. The film possesses multiple attractive features including:

- Transparent material.
- Anti-static material.
- Shelf life of 5 years.
- EU compliant material.
- FDA compliant material.
- User friendly material.
- Very strong material.
- Very good resistance to acids and bases.
- High melting point.
- Data sheets available on request.
Our Flexible Isolators

Advantages of Flexible Containment

By applying proven methods of flexible containment we can offer a way forward that will improve your equipment capability for an ever increasing containment standard and reducing investment.

Flexible Containment Systems have many advantages for clients, including:

• Forgo the cost of expensive plant by reducing capital costs.
• Ability to rapidly upgrade existing equipment to handle highly potent products.
• Custom designed to suit the operator’s needs.
• Improved ergonomics.
• Allow for safe, effective and operator-friendly use.
• Reduced need for PPE.
• Lower risk of cross contamination.
• Reducing process downtime.
• Faster project start up.
• Protecting the product from contamination.
• Protecting the operating personnel and the environment from harmful products and emissions.
Industrial Hygiene Monitoring and Site Evaluation

Here at CSP we use the basic principles of occupational hygiene in the prevention of occupational ill health and compliance with legislation and company policies. These basic principles include the anticipation and recognition of chemical, physical, biological or ergonomic hazards.

We assess and control exposure of our client’s workforce to hazardous chemicals and physical agents including noise and vibration. This includes undertaking measurement surveys, interpreting the data and advising on the best methods of control. We use the latest techniques and most up to date equipment to ensure the most accurate results are obtained. Our qualified, experienced occupational hygienists have experience in a wide variety of industries and only use UKAS accredited laboratories for the analysis of the samples.
Services Provided

Other Services Provided

Here are some other services that we provide to our clients:

- Provide procedures and training for personnel in proven decontamination methods in the Chemical and Pharmaceutical industry.
- Review companies existing cleaning procedures and assist in modification and improvement of same.
- Provide consultancy on control access procedures for personnel working in a contaminated area so as to prevent egress (spread of contaminant).
- Provide spill procedures and non-routine procedures dealing with contamination control.
- Design and installation of decontaminating equipment and de-gowning areas.

- Provide solutions and procedures for planned breaks in containment.
- Perform training in any containment issues or procedures that you may have.
- Consult original equipment manufacturers (OEM’s) when requested on incorporating containment into the design of the unit.
(API) Primary

Pharmaceutical Plant

Raw Materials In

Dispensing

Reactor

Filtration

Milling

Drying

Centrifugation

Crystallisation
Different Types of Flexible Isolators

CSP can custom design a flexible isolator for most API applications used in a production process. Each flexible isolator can be made from a material of the customer’s choice depending on product compatibilities.

The following are different examples of flexible isolators used throughout a production process in an API plant:

Sampling Flexible Isolators:

The sampling flexible isolator allows the operator to take a sample from a vessel in a contained and safe manner. The operator can pass sample jars into the flexible isolator through the feed in sleeve and disconnect the full sample jars from the feed out sleeve.

Seeding Flexible Isolators:

The seeding flexible isolator allows the operator to seed product into a vessel in a contained and safe manner. The operator can pass packages of seed material into the flexible isolator using the feed in sleeve, open the seed package and charge the seed into the vessel through the charge port and finally throw the waste materials into the trash sleeve supplied on the flexible isolator.

Filter Change Out Flexible Isolators:

The filter change out flexible isolator allows the operator to change out a dirty or blocked filter in a contained and safe manner. The dirty filter is removed from the process line within the flexible isolator and disconnected from the flexible isolator in the trash out sleeve. A new clean filter is passed into the flexible isolator through the feed in sleeve and is then connected using the gloves provided.
Product Charging Flexible Isolators:
The product charging flexible isolator enables the operator to charge product into a vessel in a contained and safe manner. This flexible isolator replaces the traditional open manway charging, thus providing a safer and cleaner transfer method.

The bags of product can be fed into the isolator through the transfer chamber, opened up within the flexible isolator and then charged down the manway which the isolator is attached onto. The waste material is then disposed of in the trash out sleeves provided on the flexible isolator.

Heel Removal Flexible Isolators:
The heel removal flexible isolator enables the operator to remove the heel from a vessel in a contained and safe manner. It allows the operator to feed the required tools into the enclosure and they can then be used to scrape the product out of the vessel and into the required product holding devices.
Seal Cleaning Flexible Isolators:
The seal cleaning flexible isolator enables the operator to inspect and clean the seals of a module in a contained and safe manner. The operator can pass the cleaning tools into the flexible isolator using the feed in sleeve provided on the isolator, open the door of the module using the glove sleeves, perform the cleaning procedure, close the door and finally dispose of the dirty materials in the trash sleeve provided on the flexible isolator.

Inspection Flexible Isolators:
The inspection flexible isolator enables the operator to inspect the internal areas of a module in a contained and safe manner. This flexible isolator allows access to within the module, without turning the room into a contaminated area.

Mesh Removal Flexible Isolators:
The mesh removal flexible isolator enables the operator to remove a blocked or damaged mesh from a module in a contained and safe manner. The door of the unit is opened and the mesh is removed using the glove sleeves provided. The dirty mesh can then be removed from the flexible isolator within the trash sleeve provided. A new clean mesh can then be fed into the isolator using the feed in sleeve provided and can then be fitted in place within the flexible isolator.

Centrifuge Cloth Removal Flexible Isolators:
The centrifuge cloth removal flexible isolator enables the operator to remove a dirty cloth from a centrifuge in a contained and safe manner. The centrifuge is cleaned down as much as possible before the flexible isolator is attached. Once the isolator is attached, the cloth can be removed from the centrifuge and the CIP phase can begin again. There is a transfer sleeve on the flexible isolator to transfer the waste solvent and powder to a holding tank. Once the centrifuge is fully cleaned, the isolator together with the dirty centrifuge cloth can be removed and disposed of. A new centrifuge cloth can then be fitted in order to have the centrifuge ready for production.
Valve Removal Flexible Isolators:
The valve removal flexible isolator enables the operator to remove a valve from a production line in a contained and safe manner. The flexible isolator is attached onto the production line and around the valve that is to be removed. The required tools can be introduced into the isolator through the feed in sleeve and the valve can be taken off line. The valve is then removed from the isolator in the trash sleeve provided. A new valve can be fed into the enclosure and fitted to the production line.

Flexible Covers for Process Equipment:
Flexible covers around process equipment enables the equipment to remain clean and it is part of a good housekeeping plan.
Flexible Containment in a Secondary Pharmaceutical Plant:

Flexible containment has many different uses and advantages throughout a secondary pharmaceutical plant. We can custom design a flexible containment solution to suit any module in order to provide a safe and contained environment for the operator to carry out their duties.

We can supply:

- Full flexible isolators,
- Flexible isolators mounted on a stainless steel raised edge and
- Flexible isolators sealed onto a module itself.

Full Flexible Isolators:

Our fully flexible isolators are stand alone containment isolators which provide the operator with a contained enclosed space where they can perform certain operations. Materials can be passed in and out of the flexible isolator using the chambers or sleeves provided.

Flexible Isolators Mounted on a Stainless Steel Raised Edge:

We have two types of flexible isolators mounted on a stainless steel raised edge:

- A flexible isolator mounted on a stainless steel table. The required procedure can be carried out within the flexible isolator on top of the stainless steel table top.
- A flexible isolator mounted on a stainless steel tray within which a module is contained. Any work to be carried out on this module can be carried out through the flexible isolator.
Flexible Isolators
Sealed onto a Module:

We also have flexible isolators with attachment flanges to allow them to be sealed directly to a module. These are custom designed to suit each individual module and enables the operator to perform their task in a contained and safe environment.
CSP FIBCs

A flexible intermediate bulk container (FIBC) is defined as an intermediate bulk container, having a body made of flexible fabric; FIBCs are designed for transporting and storing bulk products. CSP supply a wide range of FIBC bags to leading Pharmaceutical companies globally. CSP provide a variety of sizes ranging from 25 litre capacities to an 850 litre capacity.

Features: CSP FIBCs:

- The FIBC’s consist of a combination of a woven polypropylene Type C ATEX compliant conductive restraint and an inner liner manufactured from our CSP PharmaFlex PE material.
- The FIBC restraints have lifting loops, typically four, as loading and transporting is done by lifting the FIBC by the loops.
- Are designed with a charging spout at the top and a discharge spout at the bottom with a pyjama tie enclosure, which makes filling and emptying very convenient.
- A5 pockets stitched to top seam of the FIBC can be used for label holders.

CSP Bottle Bags

CSP have engineered and designed two different types of bottle bags to suit customer requirements. These products include the CSP Pinch welded bottle bag and the CSP lap welded bag. The CSP bottle bag is manufactured from CSP Pharmaflex PE and comes in a variety of sizes ranging from 5 litre capacity to 50 litre capacities with 3", 4" & 6" attachment ferrule. The CSP bottle bags are manufactured and produced at our certified independent cleanroom facility.

Features:

- CSP Pharmaflex PE material.
- Transparent material.
- Range of sizes.
- Flexible.
- Gravity feed system.
- Material contact compliance.
- Minimized cleaning.

Materials:

- CSP Pharmaflex PE is utilized to provide structural integrity and is manufactured from FDA and EU food grade materials. This material complies with EU food regulations and FDA federal regulations.
- EU and FDA compliant polyethylene ferrule.
- Atex Compliant material.
**Components:**
- Tri clover ferrule cover.
- Lifting Handle
- Weloc Clamp supplied with Lap welded bag.

**Applications**
- Charging and offloading applications.
- CGMP processing.

**Benefits:**
- Transparent material allows vision of the product without exposure
- Requires less storage space than other bulk containers.
- Simple to use.
- Interfaces with any vessel.
- Cost effective compared to expensive mechanical systems.
- Eliminates waste treatment of cleaning solutions.
CSP Continuous Liner

CSP Continuous Liner System

CSP’s continuous liner system is an easy to use contained packaging system that has been proven to be extremely effective in containing active pharmaceutical ingredients (APIs) and other hazardous substances. This continuous liner system assures a safe and effective powder transfer operation. An Occupational Exposure Band of Five (OEB5, <1μg/m3 occupational exposure level) has been demonstrated on this continuous liner system over an eight hour time weighted average (TWA).

Features of CSP Continuous Liner System

• Contained product flow – protects the operators and the environment.
• Current good manufacturing practice ensures the product is contained and protected at all times.
• High containment processing and ease of use.
• Easy installation onto existing plant hardware / vessel.
• One person processing operation.
• Inert atmosphere possible when offloading product.
• Significant reduction in cleaning time costs and waste material.
• The PE continuous liner cassette is pre-loaded ensuring ease of installation and minimising processing time.
• Contained liner change over.
• Canister SS support cage ensures continuous liner cassette is supported at all times.

Models Available: CSP Continuous Liner Systems

• 10” Standard, (250mm) Diameter Continuous Liner Cassette, 24m long. Hardware connection – 6 5/8” tri-clover ferrule.
• 10” Shorter, (250mm) Diameter Continuous Liner Cassette, 15m long. Hardware connection – 6 5/8” tri-clover ferrule.
• 15” Standard, (375mm) Diameter Continuous Liner Cassette, 50m long. Hardware connection – 10” tri-clover ferrule.
• 15” Shorter, (375mm) Diameter Continuous Liner Cassette, 25m long. Hardware connection – 10” tri-clover ferrule.
• 23” Standard, (575mm) Diameter Continuous Liner Cassette, 50m long. Hardware connection – 12” tri-clover ferrule.
• 23” Shorter, (575mm) Diameter Continuous Liner Cassette, 25m long. Hardware connection – 12” tri-clover ferrule.
Material: CSP Continuous Liner Cassette
- The flexible liner used in CSP’s continuous liner is an anti-static, FDA and EU compliant material called CSP PharmaFlexTM PE66. This polyethylene material is very durable and has a high tensile strength.
- If required, CSP can also use their client’s specified material and manufacture the cassettes from this material.

Components: CSP Continuous Liner System
Each CSP continuous liner system consists of the following components:
- SS offload chute / canister (Including all sanitary gaskets and clamps).
- SS support cage for continuous liner cassette.
- Polyethylene continuous liner cassette.
- Containment belt.
- Silicone O-ring.
- SS band clamp.
- Containment clamp.
- Relevant crimping kit (Crimping tool, crimp cutting tool and crimps).
- Pack of cable ties.
- Flexible Band Clamp cover to cover the SS band clamp.
- Polypropylene Continuous liners insert.

Applications: CSP Continuous Liner System
The following are some of the applications where our Continuous Liner System can be utilised in order to obtain a clean and contained offload point:
- Any vessel product offload – offloading the product into liners or drums.
- Solid Glovebox – used for offloading product or waste from glovebox.
- Flexible isolator – used for offloading product or waste from flexible isolator.
- Waste Lines – used for collecting waste from vessels, dust collectors etc.
Containment Systems

Containment Rooms

Using either fully flexible containment suites or a combination of rigid and flexible technology, we can supply and install full containment suites.

Applications include:
- Segregation of equipment or plant.
- Remote charging stations.
- Decontamination and safe-change areas.
- Temporary clean rooms.
- Safe storage areas.

Features of Containment Rooms:
- Fully sealed floors.
- Segregated room / areas within the suite.
- Pressure cascades and HEPA filtration. Easily seen on Magnahelic gauges.
- Material and personnel airlocks incorporated.
- Service panel provided.
- Emergency exits.
- One of our many fogging systems also built into the containment room in order to aid safe degowning.

Benefits of Containment Rooms:
- Any size achievable.
- Custom designed to fit around existing plant, equipment and pipe work.

- Flexibles are fully disposable when finished with.
- Solid panels can be cleaned and reused.
- Contains the contamination of a module at its source and doesn’t allow the whole production floor to be contaminated.

- Reduced cleaning and cleaning validation costs.
- Reduced operational time.
- Fast turnaround / installation.
- Low capital and operating costs.
- Clear flexible material allows the use of the existing light in the production area.
Containment Systems

Airlocks

Using either fully flexible or a combination of rigid and flexible technology, we can supply and install airlocks to suit the customer’s requirements. We can supply both personnel and material flow airlocks. These airlocks will provide an area of space where the operator can gown up or down, fog down dirty PPE, pass materials into a clean room and all in a safe manner.

Features of Airlocks:
- Fully sealed floors.
- Pressure cascades and HEPA filtration. Easily seen on Magnahelic gauges.
- Separate material and personnel airlocks can be provided.
- Service panels can be provided.
- Emergency exits.

Benefits of Airlocks:
- Any size achievable.
- Custom designed to fit around existing plant, equipment and pipe work.
- Flexibles are fully disposable when finished with.
- Solid panels can be cleaned and reused.
- Reduced cleaning and cleaning validation costs.
- Fast turnaround / installation.
- Low capital and operating costs.
- Clear flexible material allows the use of the existing light in the production area.

• One of our many fogging systems also built into the airlock in order to aid safe degowning.
Wall Mounted Fog Shower

Wall mounted fog showers are units that help in the safe removal of potentially contaminated personal protection equipment (PPE).

As the wall mounted fog shower is a relatively small unit it can be erected and used anywhere. The wall mounted fog shower uses a 3 jet fogging system which produces a light mist that encapsulates the dust on the PPE. The mist improves the quality of de-gowning by sticking the dust onto the PPE preventing the dry dust from becoming airborne. The fog shower is designed to use as little water as possible. The PPE can then be disposed of in a safe manner.

By using a wall mounted fog shower, the level of safety is increased when working with potentially toxic materials.

Features of Wall Mounted Fog Showers:

- 3 jet fogging system.
- Ran on plant air and water.
- The duration of the mist can be varied with the built-in timer.
- On / off lever.
- Emergency stop.
- Very fine mist due to the atomized air created inside the unit.
- The unit has built-in filters on both the air and water lines.
- Filters can also be installed on the air and water lines prior to entering the unit if required.

Benefits of the Wall Mounted Fog Shower:

- Fast turnaround / installation.
- Low capital and operating costs.

- Offers low-pressure, low-volume encapsulation cleaning.
- The mist provides full body coverage.
- Relatively small and light unit – occupies very little space.
- Can be taken down and mounted in a different location if required at a later date.
- A drain can be located near the unit or else absorbing matting can be used.
- Very easy to operate – turn lever on and the mist will stop automatically after a set time.
Fog Cart

Fog carts are mobile fogging systems, which run on a low pressure, low volume philosophy.

The fog cart is used for a number of different applications:

- The cleaning and containment of rooms, areas or surfaces which have potent dry powders exposed on it.
- The safe removal of potentially contaminated PPE.
- The fog cart can be used to support break in operations and maintenance work if containment has not been fitted.
- The safe removal and disposal of flexible containment systems.

Features of Fog Carts:

- Purified water or deionised water are the only solvents to be used in this unit.
- Pressurized with an air supply.
- Fogging Lance.
- Fogging Gun.
- Liquid Gun.
- 10 gallon tank.
- Pressure relief valve.
- Pressure gauges.
- Ball valves for all guns and lance.
- On wheels.

Benefits of Fog Carts:

- Fast turnaround / installation.
- Low capital and operating costs.
- Offers low-pressure, low-volume encapsulation cleaning.
- Relatively small and tidy unit – occupies little space.
- Very easy to operate.
- Unit is very mobile as it is on wheels.
- Provides either a fog or a good spray, depending on your requirements.
Rolling Stainless Steel Walk In Shower

The rolling stainless steel shower allows personnel wearing dirty PPE to safely wet down their PPE before they begin to degown. This wetting action encapsulates the dry powders onto the PPE and prevents them from becoming airborne when taking the dirty PPE off. This shower can also be used as a heavy wash shower to clean PPE. This needs to be specified when ordering.

These SS walk in showers can be fixed to an airlock in a production room or they can be a standalone unit within a bigger airlock or in a production floor. The operator enters the shower from one side, turns the valve to the on position, wets down the dirty PPE, turns the valve back to the off position and then exits the shower out through the second door.

Features of Rolling SS Walk In Showers:
- Fabricated from SS304 material.
- Two PVC doors with glass windows allow access to the unit.
- 12 nozzles strategically positioned to maximize the sprays coverage on the personnel using the unit.
- Pre-filtered plant water is used to run the system.
- There is a sump section in the bottom of the shower and a flanged drain piped off this section. This can be connected to the plant waste.
- There is also an air connection inside the shower, to provide air to any personnel who would be wearing an air hood or a full body suit.
- Shower built on lockable anti static castors.

Benefits of Rolling SS Walk In Showers:
- Fast turnaround / installation.
- Low capital and operating costs.
- Offers low-pressure, low-volume encapsulation cleaning.
Containment Systems

Splitting / Dispensing Flexible Isolators

The splitting / dispensing containment system consists of a flexible isolator mounted on a stainless steel table. This dispensing system can be used for both drums and bags full of product.

Drum Dispensing: The table or the frame of the unit will incorporate a drum attachment ring with a containment belt on it which allows the drum to be connected to the system in a fully contained manner. A drum lifter or scissors lift can be used if required and the design of the system will incorporate the need for this. The liners within the drum containing the product can then be accessed and opened inside the flexible isolator. The dispensing process can then begin and there will also be a weighing scales inside the unit for accurate dispensing.

Bags of Product: In this case, the dispensing system will consist of a number of chambers. These chambers will enable the operator to feed the bags of product into the dispensing system without exposing the working chamber. Again, the dispensing process can then begin and there will also be a weighing scales inside the unit for accurate dispensing.

Features of Splitting / Dispensing Containment Systems:

- Fully sealed system.
- Air handling can be incorporated. (see intelligent flow)
- Numerous chambers can be incorporated into the design to allow for safe feed in / out of materials or product.
- Service manifold can be incorporated.
- Weigh scales can be placed inside the system for accurate dispensing.
- Trash ports and sleeves also incorporated for safe disposal of waste.
- A split butterfly valve can be installed on the off-load port, enabling the use of product bags.
- Mobile unit – Stainless steel table has lockable antistatic castors.

Benefits of Splitting / Dispensing Containment Systems:

- Custom designed to suit the customer’s requirements.
- Flexibles are fully disposable when finished with.
- Solid parts of the system can be cleaned and reused.
- Reduced cleaning and cleaning validation costs.
- Fast turnaround / installation.
- Low capital and operating costs.
- Clear flexible material allows the use of the existing light in the production area.
- Good ergonomic performance.
- Very mobile containment system. Can be removed from the production floor when finished with and brought back again when needed.
- Utilities can be introduced to this system in a contained manner.
- Accurate dispensing.
Containment Systems

CSP Dispensing Flexible Isolator

CSP Dispensing system from Drum to PE liners

Splitting/Dispensing Flexible Isolators

CSP Dispensing and Splitting system

CSP Dispensing and Splitting flexible isolator system
Containment Systems

Vacuum Wanding System

Our vacuum wanding unit enables personnel to safely transfer powders into vessels. It is a fully contained system. Materials such as powders, pellets or granules are transferred via flexible pipe work to its end destination. Vacuum wanding provides a cost effective flexible solution to the safe conveying of bulk materials across a broad range of industries.

This form of transferring powders ensures a dust tight transfer is achieved. The closed-system approach for material transfer ensures that no dust escapes into the atmosphere and no contamination from the outside can enter the system. This method ensures all operators are protected at all times from hazardous products.

The vacuum wanding system consists of a stainless steel table and frame, flexible isolator, HEPA filter and vacuum wand. The drum that contains the product is connected to the underneath of the table and the liners within the drum containing the product can then be accessed and opened inside the flexible isolator. The vacuum wand is then lowered into the drum of powder and the product is then sucked up the wand and along the pipe work to its desired destination. As the wand is creating a vacuum within the flexible isolator, air must be filtered into the bag to prevent it from collapsing. We use certified HEPA filters for this need. Our vacuum wanding units have been specifically designed with the needs of the end user in mind.

Features of Vacuum Wanding Units:
- Fully sealed system.
- Vacuum is drawn on the system when product needs to be transferred.
- Trash port and sleeves also incorporated for safe disposal of waste.
- Mobile unit – Stainless steel table has lockable antistatic castors.
- Legs of the table and frame have pneumatic pistons built in to them in order to vary the heights of the unit.
- HEPA filter.

Benefits of Vacuum Wanding Units:
- Custom designed to suit the customer’s requirements.
- Flexibles are fully disposable when finished with.
- Solid parts of the system can be easily cleaned and reused.
- Reduced cleaning and cleaning validation costs.
- Fast turnaround / installation.
- Low capital and operating costs.
- Clear flexible material allows the use of the existing light in the production area.
- Good ergonomic performance.
- Very mobile containment system. Can be removed from the production floor when finished with and brought back again when needed.
- Improves productivity and efficiency compared with manual handling.
- Reduces loss of material.
Drum Sampling System

Our drum sampling system consists of a flexible isolator sealed onto the drum that is to be sampled. This drum sampling system enables the operator to access the product inside the drum to take a sample in a safe and contained manner.

Before using the drum sampling system, the flexible isolator is preloaded with the required sampling tools and sample jars. We can also supply a feed in sleeve to enable the passing in of materials during the operation. The attachment sleeve of the flexible isolator is then stretched down over the drum itself and taped to the drum to create the seal. The flexible isolator is then supported by bungee cord onto a frame provided. Once the seal is created and the system is contained, the lid of the drum can then be removed inside the isolator. The inner liners containing the product can then be opened inside the flexible isolator using the glove sleeves provided. The sample can then be taken and removed from the system using the twist tie tape and cut procedure. The inner liners are resealed and the lid of the drum is reattached to the drum without the system being breached. The final step is to disconnect the flexible isolator from the drum and this can be done by again using the twist tie tape and cut procedure.

Features of the Drum Sampling System:

- Clear flexible material.
- Transportable.
- HEPA Filter.

Benefits of the Drum Sampling System:

- Custom designed to suit the customers drum size.
- Flexibles are fully disposable when finished with.
- Reduced cleaning and cleaning validation costs.
- Fast turnaround / installation.
- Low capital and operating costs.
- Clear flexible material allows the use of the existing light in the production area.
- This system can be used anywhere in the plant.
- Prevents cross contamination.
- Good ergonomic performance.
- Tidy system – doesn’t occupy much floor space.
- System allows the removal of the drum lid inside the flexible isolator.
Intelligent Flow

Intelligent Flow is a Programmable Logic Controller (PLC) controlled push – pull airflow unit designed to function on a sealed enclosure to provide a negative or positive pressure condition with a given volume change rate. It is available as a fixed or mobile device and can be used on a variety of applications in the pharmaceutical, medical and Biotech industries.

It was developed by CSP over a 3 year period at a number of European pharmaceutical plants in order to provide improved containment when dealing with gradually reducing occupational exposure limits (OEL’s). The process specification for the new system was to provide all the benefits of conventional flexible containment technology, with the added advantage of an airflow system that was capable of operating on any enclosure in a negative / positive pressure condition combined with a minimum total volume change rate. An additional requirement was to provide a breech airflow condition, for instance in the case of the loss of a glove or transfer sleeve. This facility is not available on any standard ambient pressure enclosure or glove bag system. The results of trials on the prototype equipment established that significantly lower OEL’s could be achieved using the equipment.

Traditionally containment systems operating in the pharmaceutical industry will be dealing with active pharmaceutical ingredients (API’s) and by subjecting an enclosure to a negative pressure airflow system it was necessary to install H14 HEPA filters to the supply and exhaust arrangements. These filters are sealed into the enclosure and are disposed of with the enclosure on completion of the production period; other filtration arrangements are also available.

A state of the art PLC with dedicated human machine interface (HMI) achieves the pressure / flow control and various other functions laid down in the process specification. The unit is programmed to cater for a range of functions but also is easy to understand from a user’s aspect. A dedicated touch screen HMI provides a display of internal pressure, extract filter pressure drop, etc.

Control Functions:
- Constant internal pressure display via HMI touch screen.
- Constant total air change rate display.
- Extract filter resistance display.
- Programmable internal pressure set point (by user).
- Programmable total volume flow rate set point (by user).
- Test function.
- Leak test function.
- Fan power consumption display.
- Modem link for remote problem solving, rectification, etc.
- Control link to central server unit if required.
- Auto deflation function.
- Machine code programme enables PLC to recognise enclosure type.
- Pressure failure shut down facility.
- Slow start up / shut down facility.
- Encryption facility.
Features and Benefits of the Intelligent Flow:

- Can operate at a pre-programmed set point pressure (negative and positive pressure), accurate to 1 Pascal.
- Provides a breach condition (minimum 0.8 meters per second) through an open aperture – open cuff or transfer chamber.
- Fan failure safe operation.
- High / Low pressure alarms (visual / audible) programmed by user.
- Filter blockage airflow compensation system.
- Enclosure disposed of complete with contaminated filters.
- Quick connect supply / exhaust airflow connections from fan unit to filters.
- Quick connect airflow sensor coupling complete with Mini HEPA filter unit.
- Mobile unit - can be used on any specified enclosure.
- Cost effective solution, can be used on any enclosure size and type.
- Existing ambient enclosures can be modified easily and cheaply to accept the Intelligent Flow by installing filters / pressure sensor connections.
- Multiple chamber systems available, capable of running at different pressures.
- Extract pre-filter unit (to prevent blockage of extract HEPA filter) available.
- System capable of running in conjunction with N₂ / Low humidity supply systems.
- Atex version available.
- Automatic enclosure deflation function available.

- Housed in a mobile stainless steel enclosure. HMI can be incorporated with the enclosure or be supplied on a flying lead with bracket to allow fixing to enclosure support framework.
- Turbulent airflow system with EC GMP Grade A internal conditions.

Intelligent Flow

Programmable Logic Controller
Containment Systems

Air Handling Units

The main purpose of our Air Handling Units (AHUs) is to suck contaminated air out of a production room through the ducting provided, filter the air within the AHU and the clean filtered air then leaves the AHU out the exhaust. As the AHU is sucking air out of the room, filters will need to be strategically placed around the room to allow sufficient amounts of clean air into the room to replace the air that is sucked away by the AHU.

The damper on the AHU can be adjusted so as to control the number of air changes per hour within the room. There are also Magnahelic gauges on the AHU to show the efficiency of the filters within the unit. When the filter blocks, there is a procedure for the safe change out of the filter, using the glovebag provided with the AHU.

Features of Air Handling Units:

- Mobile units.
- 2 filters built into AHU.
- Safe change out of filters available.
- Damper provided to control air flow.
- Magnahelics on AHU.
- Flashing beacon.

Benefits of Air Handling Units:

- Fast turnaround / installation.
- Low capital and operating costs.
- This system can be used anywhere in the plant.
- Prevents cross contamination.
- Tidy unit – doesn’t occupy much floor space.

- Easy to move AHU from one area to another.
- Easy safe change procedure to remove blocked filters.
- Simple damper to regulate the air flow.
- Flashing beacon provides visual sign that unit is operating.
Air Hood Washer

The main purpose of our stainless steel air hood washer is to enable the operator to wash their contaminated reusable air hood in a safe and effective manner after exiting a dirty production area. The air hood washer consists of a stainless steel shower unit with two water tight glass doors. The operator can pass the contaminated air hood into the unit through one door, hang it on the hanger provided, wash the hood by turning the water valve on and then remove the clean air hood out through the other door once the air hood is sufficiently cleaned.

This unit operates on plant water alone. The plant water is piped to and from the unit and is connected using the flanges provided. Inside the unit, there are three adjustable nozzles on the ceiling. The spray from the nozzles can be adjusted by rotating the head of the nozzle, and this arrangement helps maximize the waters coverage on the air hood. Extra heads can also be fitted depending on the size of the air hood.

Features of the Air Hood Washer:

- Stainless steel body and frame.
- Removable stainless steel grid in the units’ sump in order to keep the air connections and plugs out of the water.
- Flanged inlet and outlet connections for the water.
- Two water tight glass doors.
- Hand valve to operate unit.
- Three adjustable nozzles inside unit.

Benefits of the Air Hood Washer:

- Fast turnaround / installation.
- Low capital and operating costs.
- This unit can be used anywhere in the plant.
- Prevents cross contamination.
- Tidy unit – doesn’t occupy much floor space.
- Unit easy to clean as it’s manufactured from stainless steel.
- Reduced cleaning and cleaning validation.
- Adjustable nozzles maximize the waters coverage on the air hood.
- More efficient way of cleaning air hoods.
- Glass doors allow the use of existing light from process area.
Flexible Curtains

Our flexible curtain along with its stainless steel curtain rail and runners is an excellent and effective way to provide a temporary containment barrier / airlock in any area where it is required. Once this system is installed, the flexible curtain itself folds up in very little space and it can be opened out in a matter of a few seconds to provide the barrier required. This is ideal for process segregation and downflow booths.

Features of our Flexible Curtains:

- The stainless steel curtain rail is fixed to the ceiling of the area where the barrier is required.
- The stainless steel runners are preloaded onto the curtain rail.
- The flexible curtain is attached to the runners and can run along the curtain rail as required.
- Can be set up to negotiate several corners.

Benefits of our Flexible Curtains:

- Any size achievable.
- Custom designed to suit the customer's requirements.
- Flexibles are fully disposable when finished with.
- Reduced cleaning and cleaning validation costs.
- Fast turnaround / installation.

- Clear flexible material allows the use of the existing light in the production area.
- Flexible curtain folds up into a small tidy bundle when not in use.
- Flexible curtain can be opened out fully in a matter of seconds.
Repackaging

Repackaging is when a raw material or product is transferred from one product holding device to another. Product can be held in a number of different devices, such as FIBC’s (Flexible Intermediate Bulk Containers), stainless bins, flexible lined drums, stainless drums or flexible liners.

There are a number of reasons why a company might want to repackage some raw materials or product, for example a company's process might be set up to suit FIBC’s and they received their raw materials packed in drums. Therefore the need to repackage the raw material would arise before the material could be processed.

We offer a product repackaging service here at CSP. We will design up a system to specifically suit your needs and do the repackaging in a safe and contained manner.
Sterile Isolator Systems

The Aseptic Processing isolator is a soft walled gloved processing isolator. The primary function of the isolator is to provide for the decontamination of the equipment and a grade an environment for microsphere production. The isolator is a uni-directional flow positive pressure isolator. The isolator canopy is designed to be disposable hence reducing cleaning/ cross contamination costs.

Features:
- Unidirectional flow
- Hepa filtered Air
- Rapid Transfer Ports
- VHP generator connections and communication
- Air flow Transmitters
- Pressure Transmitters
- Lighting
- Range of connections
  - Tri-Clover Ports
  - Cable Glands
  - Particle counter Connection

Materials
- 316L Stainless steel for product contact hardware
- CSP Pharmaflex PU disposable (Transparent, Anti-static, Eu compliant, FDA compliant, Good resistance, High Melting point)
- H14 Hepa inlet and outlet filters

Components
- VHP generator connections and communication
- Air flow Transmitters
- Pressure Transmitters
- Lighting
- Range of connections
  - Tri-Clover Ports
  - Cable Glands
  - Particle counter Connection

Applications:
- Decontamination of equipment
- Provide Grade A environment for microsphere Production

Benefits
- Isolated Batch production
- Small footprint
- Mobile
- Range of connections as per users requirements
- Greater Operator and product safety.
Containment Systems

CSP Disconnection Kit

Description
The CSP disconnection kit is a high containment closing system, consisting of a cutting tool, crimping tool, disconnection cable ties and a protective storage case, this device allows flexible liners to be sealed and disconnected in a safe manner of operation.

Features
- The Cutting scissors permits to cut liner bundles (twist & tied) with a diameter of up to 35mm.
- The liner is protected by the blade guide when positioning the cutting tool.
- Rugged technology of the disconnection tools ensures an easy, safe and user friendly handling.

Materials
- The disconnection tools are composed of stainless steel.
- The disconnect crimps are made from nylon.

Components
- The cutting tool consists of a stainless steel blade and a counter piece. This provides a clean and straight cut of the liner with little force needed.
- The blade guide on the Cutting tool protects the liner and allows for safe cutting when positioning the tool for operation.
- The crimp tool is vibration resistant tool that allows to tightly tie off the liner as well as close it permanently with little effort required.

Applications
The use of the CSP disconnection kit can be operated on a variety of expendable liner applications including:
- Sleeve liners or Trash out sleeves
- Sampling liners
- Transfer or packaging liners
- Continuous liners
**Containment Systems**

**CSP Dust Collector**

**Offload Containment System**

**Description**

CSP have designed a high containment offload system with an integrated drum liner which will compliment or upgrade an existing dust collector onsite to reach containment levels of up to OEB 5.

**Features:**

- Integrated drum liner with bag out sleeve.
- Customized pack off head with vent connection.
- Customizable liner size.

**Materials:**

- Fibrekeg drum.
- Stainless Steel, hastelloy or PTFE pack off head.

**Benefits:**

- High containment level achievable.
- Improved CGMP standards.
- Safe disconnect.
- Fully customizable to suit customer requirements.

![Dust Offload 1:](image1) Showing the connection option from an adjacent side offloading.

![Dust Offload 2:](image2) Showing the connection option from directly above offloading.
Accessories for Flexible Isolators
The following are the accessories used with our flexible isolators and containment systems:

**Food Grade Silicone Chord and Nylon Hooks:**
The silicone cord, along with the nylon hooks, are used to support our flexible isolators.

**Polypropylene Canisters:**
Our polypropylene canisters are grooved canisters that can be attached to certain sleeves on the flexible isolators with an o-ring and band clamp. These canisters can be manufactured to the customers’ requirements – diameter, length and number of o-ring grooves.

**O-Rings:**
We supply a range of different size diameter o-rings. These are available in nitrile and food grade silicone.

**Trash Sleeves:**
Our trash sleeves are attached onto our flexible isolators using a polypropylene canister, o-rings and band clamps. These sleeves are available in different diameters and lengths. Each trash sleeve is sealed at one end and has a loose o-ring packed with it.
### Containment Systems

**Stainless Steel Band Clamps:**
We supply a large range of different sized stainless steel band clamps and these clamps are used to seal our flexible isolators and trash sleeves.

**Cutting Tool:**
This cutter is completely metallic with a stainless steel blade and is used for a range of disconnection methods – crimp procedure and twist tie tape and cut procedure.

### Accessories for Flexible Isolators

**Tapes:**
We supply Chemtape, food grade tape and double sided adhesive tape to our customers. Chemtape is a chemical resistant adhesive industrial tape that has many uses.

The food grade tape meets all the food grade standards required in industry and is also used on the twist tie tape and cut disconnection method. The double sided adhesive tape creates a strong bond between our flexible isolators and a stainless steel or smooth surface.

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**NSAI Certified**

I.S. EN ISO 9001:2008
**Containment Systems**

**Containment Belt:**
Our containment belt is manufactured from food grade silicone. This belt provides o-ring grooves on a smooth pipe in order to connect and seal our flexible isolators to the equipment. This belt can be ordered to length or vulcanized to specific diameters.

**Containment Clamp:**
Our containment clamp is also manufactured from food grade silicone. This clamp is used on the connection sleeve of our flexible isolators and can also be used on any flexible material connecting onto a solid canister or pipe. The containment clamp helps to direct the flow of product into the desired canister / pipe and also prevents product from escaping down the outside of the canister and into the working environment.

**Connection Kit:**
Our connection kit consists of Chemtape, double sided adhesive tape, bungee chord and hooks. These kits are used to install our flexible isolators.

**Disconnection Kit:**
Our disconnection kit consists of a stainless steel scissors, a pack of cable ties and food grade tape. These kits are used to disconnect our flexible isolators and sleeves from equipment.
Filters:
We supply a large amount of filters ranging from simple glove box filters to HVAC filters certified to 2C ATEX rating.

Magnahelic Gauges:
We also supply Magnahelic gauges and these are used to measure pressure differentials.

Glove Bag Hanging Kit:
Our Glove bag hanging kit is used on installation of our flexible isolators, this kit supports the isolator in place.

Table to Glove Bag Connection Kit:
The table to Glove bag connection kit is used on installation of naur flexible isolators to SS tables and more SS containment systems.
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Our CSP Global Customers:
Our Containment Systems and Processes are far reaching
and we are proud of the Services we have provided to the Global Community.

CSP Europe: Latvia, Iceland, England, France, Germany, Spain, Belgium, Switzerland,
Italy, Croatia, Romania, Sweden, Malta, Ukraine, Slovenia, Denmark, Austria, Poland,
Worldwide: Puerto Rico, USA, Russia, Australia, Israel, Oman, India, Japan.

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