

Flexible Protective Solutions

for Pharmaceutical &
Biopharmaceutical Industries



About ILC Dover

Innovators at our core, we develop engineered flexible protective solutions that improve efficiency while safeguarding people, product, and infrastructure in hazardous conditions.

ILC Dover is a world-leader in the innovative design and production of engineered flexible protective solutions, serving a wide range of industries. We provide solutions for life sciences, including pharmaceutical and biopharmaceutical, flood protection, personal protection, bulk packaging, and aerospace. Our customers will attest to our relentless dedication to high value products, advanced technology, and responsive service, as our visionary solutions have improved efficiency while safeguarding people, product, and infrastructure in hazardous conditions since 1947.



Our Mission

To improve efficiency while safeguarding people, product, and infrastructure in hazardous conditions through flexible protective solutions.



Biopharmaceutical Solutions

ILC Dover is a global leader in the innovative design of single-use solutions for biopharmaceutical manufacturing.

Our single-use solutions for biopharmaceutical manufacturing are engineered and manufactured in our ISO 7 Clean Room and designed for the efficient, sterile handling and transport of large volumes of powder. Beyond that, our aseptic solutions provide closed, Grade-A, aseptic environments for fill/finish activities. Explore how our biopharmaceutical solutions support media and buffer transport as well as hydration and aseptic fill/finish processes.





Materials development

Barrier film

Coated/laminated materials

Antistatic films that are FDA, USP and EU regulatory compliant

Engineering Design

Using soft goods to solve life-critical problems

Designing soft goods to replace rigid elements

Designing articulated soft goods pressure vessels



Manufacturing

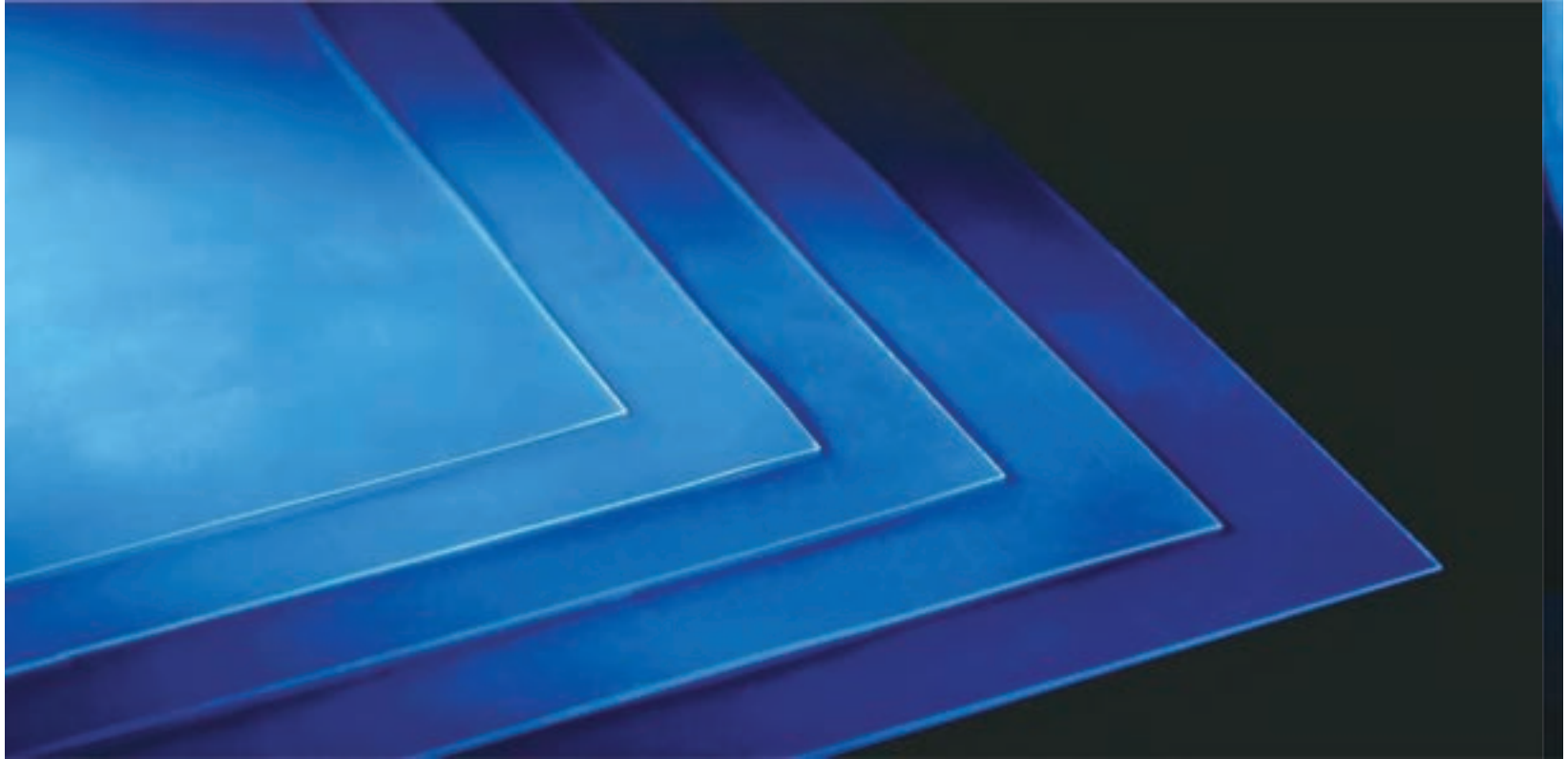
Production, inspection and testing of inflated structures

Precise, reliable sealing for critical applications

Production in ISO Class 7 Clean Room

Armorflex® 114 Film

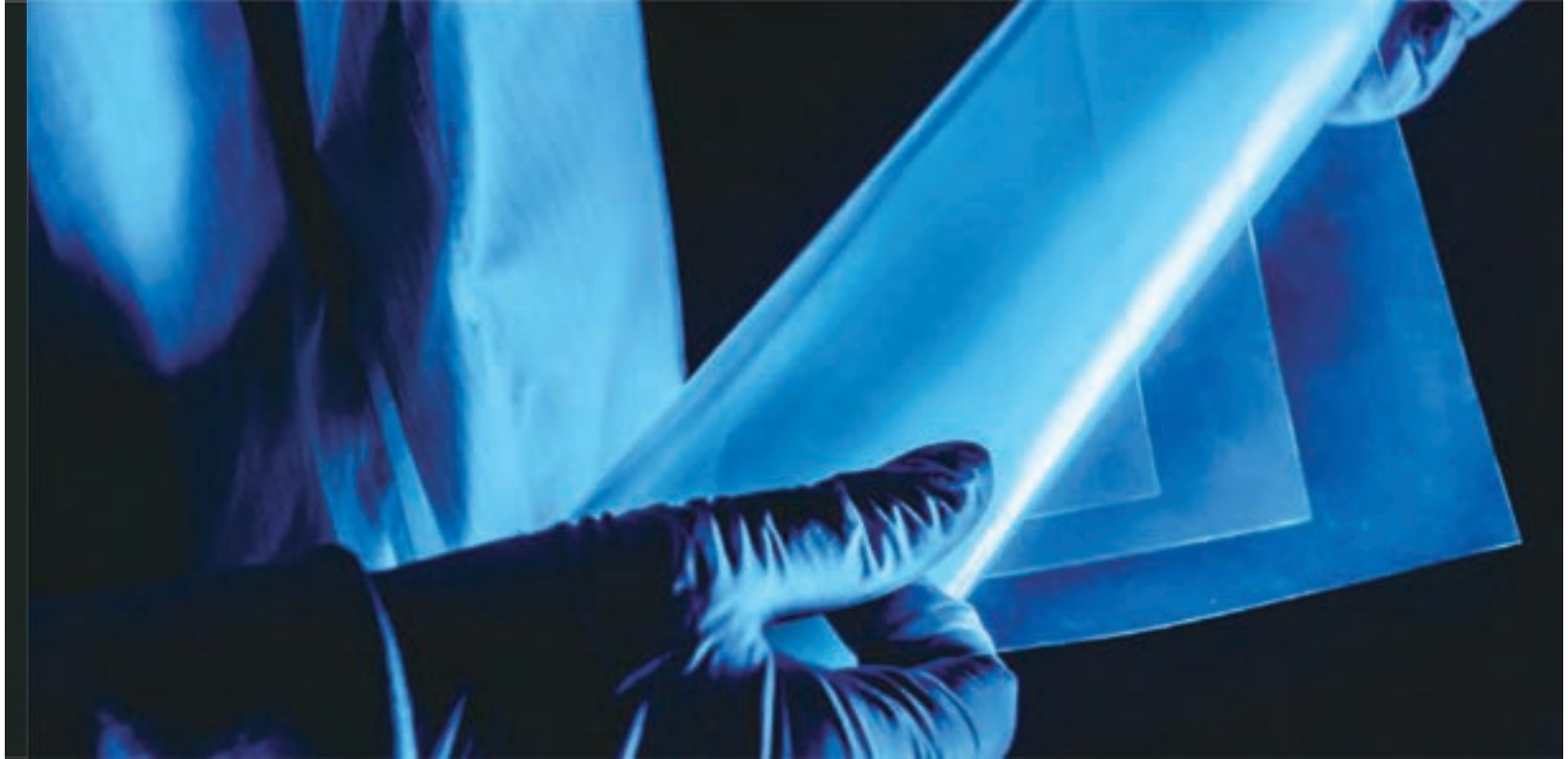
The Latest Addition To The Armorflex® Family



- Complies with FDA 21 CFR
- Fully compliant to EU Regulation 10/2011 and amendments
- Meets test parameters of EP 3.1.3
- Passes USP <661> Physicochemical Tests for Plastics
- Passes USP <88> Class VI (7day implant)
- Passes <87> biological reactivity, in vitro
- Five-year shelf life
- Permanent antistat replaces migrating additives
- Passes Chilworth incendivity tests
- Tested for solvent resistance
- DMF filed with FDA

Armorflex[®] 113 Film

Superior visual clarity, making this the clear film



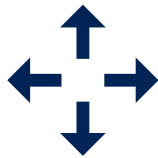
In response to operators' input we've developed an addition to the ArmorFlex[®] family of films - AF113. The clarity of the product makes this the clear film of choice for flexible enclosures and flexible isolators.

- No slip agents
- High strength with antistatic properties
- Strong seals, plus high flex-fatigue resistance
- Abrasion-, solvent-, and puncture-resistant
- Superior clarity
- Gamma irradiation compatible
- Full regulatory compliance
- Five-year shelf life

soloPURE Aseptic Processing Isolator

Grade-A Environment
Quick Turnaround
Maximum Efficiency

Sterile manufacturing isolators for the handling of aseptically manufactured drug products generating highly controlled environments within a closed barrier system.



Transform your
cleanroom into a sterile
manufacturing machine



Achieve more in your
cleanroom without the
added expense



Experience the risk-
reducing power of a
single-use isolator

┐ soloFlex Benchtop Containment Isolator

High Performance Rapid Assembly Fast Delivery



Small & Compact Benchtop Isolator

- Robust stainless steel Support frame
- 3 x H14 HEPA filters
- 3 x fan options
- 300mm(12") Dia. continuous liner x 130 ft liner cassette
- Manual and automatic speed control fans with 120V/60 supply
- Compressed air venturi fan available
- Low friction polyurethane glove sleeves
- Utility sleeves for Utility cables 2" Dia.
- PVC base plates for balance stability

SAFE, EASY, CONVENIENT

Rapid and easy assembly

Modular stainless frame

High containment performance

Contamination-free disposal

Low price and fast delivery

soloADC

Full Lifecycle Safety Isolator

Nanogram containment levels

Fully disposable assembly / Guaranteed integrity



A bridging process between the pharm and biopharm sectors, connecting a toxic small molecule with a monoclonal antibody



Proven SMEPAC and multiple air handling options to match process requirements



Fully disposable assembly with captive filters to allow safe breakdown



Prevent cleaning validation

└ soloLAB Pop-up Benchtop Isolator

Laboratory Containment / Assembles in Minutes
Versatile Applications



Closed-Barrier System for Small Scale Operations

Perfect for providing operator protection from hazardous materials or creating inert gas environments at laboratory scale.

- Closed pressure tight construction
- Durable
- Cost effective
- Compact & Portable
- Stable working surface
- Large access zipper
- Dexterous interface



Flexible Enclosures

Flexible Containment Technologies



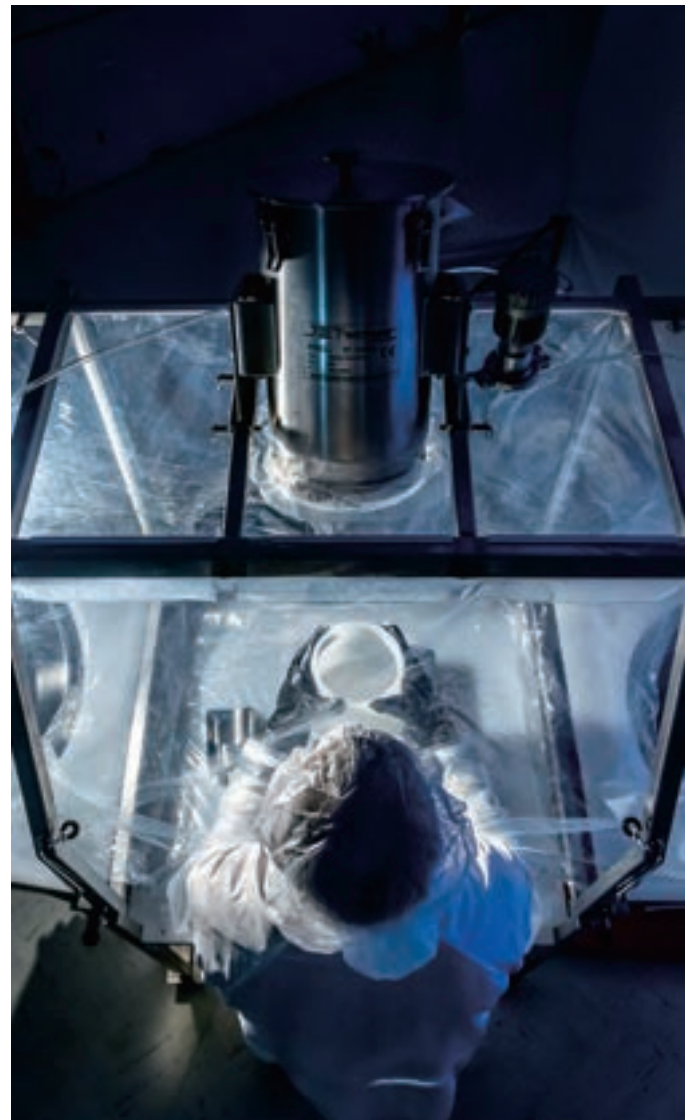
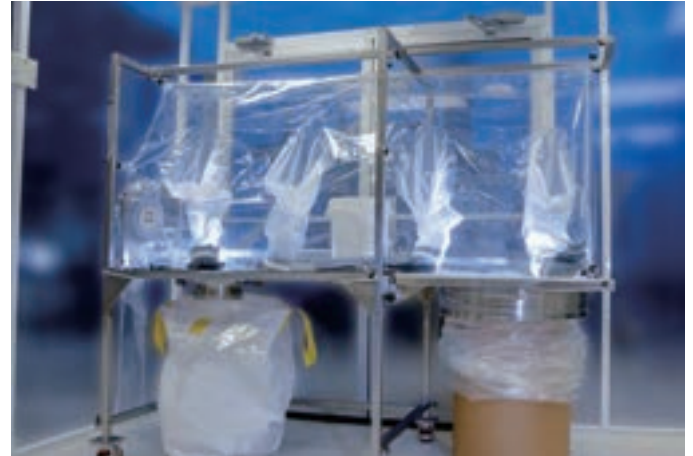
Allows operators to work in shirt sleeve environment - increases efficiency

- 3rd party validated Nanogram containment levels using SMEPAC guidelines
- Economical
- Fast turnaround/installation
- Compatible with a wide range of existing equipment for retrofit
- Design makes use of existing DoverPac® containment details such as crimps, bag/out sleeves, and o-ring interface canisters
- Ergonomics are improved with an increased range of motion
- Designs support separation of process and technical areas
- Where applicable, entire piece of equipment can be contained

ILC Dover's flexible enclosures take the concept of a traditional flexible glove bag to a new level. Using the same reliable fabrication techniques and proven containment design features found on our DoverPac® family of products, we have produced a line of flexible enclosures adaptable to a wide range of existing equipment.

Flexible Enclosure for :

- Lab Scale Analytical Train
- Weighing and Dispensing
- Mill, Blending Process
- Granulator, Tablet Press, Encapsulation
- IBC Transfer



EZ BioPac[®]

ONE SMART SOLUTION

- Powder Single use bag, ready for discharge



Most precise powder containment and transfer bag to handle media and buffer powders.



Complete product
recovery



Easy, convenient
sealing options



Fast fill time

PowderFlo-CB™

PowderFlo-CB™ is a Single opening bag combining a cost-effective 2D bag design with the strength and durability of ArmorFlex® 114



ArmorFlex® 114 Film delivers permanent static dissipative properties while meeting FDA and 2002/72/EC requirements for food contact and EP 3.1.3 test conditions

- Available sizes include 10L, 15L, 25L and 40L
- Option to add-on gamma irradiation
- High tensile and tear strength
- Manufactured in an ISO8 environment
- Spilt butterfly valve available
- 5-year shelf life(2-year shelf life when gamma irradiated)
- Weloc® Clamps and Tri-Clamp Caps/Fabric Covers
- Gamma irradiation available for additional charge
- Sanitary flange with integrated gasket in 2", 4", and 6"



DoverPac® System

Offloading using the individual DoverPac® System



Contained attachment for large scale powder filling, emptying, and sampling during charging and offloading.



Proven to maximize
productivity



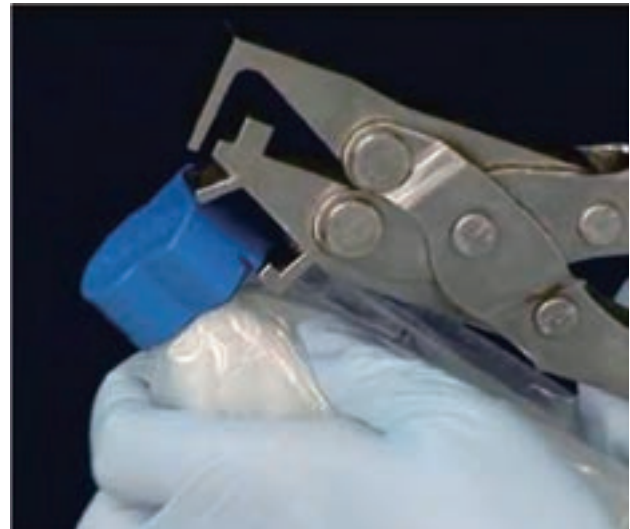
Eliminate cleaning costs
ensure safety



100%
pressure tested

Unique Doverpac[®] crimping system

ILC Dover crimps have been designed and tested



Easy-to-use system for containing active pharmaceutical ingredients and other hazardous compounds to minimize powder contamination risks, and protect people, plant, and product

- Contained processing to protect the operators
- cGMP processing in a completely closed operation to protect the product
- Single person operations
- Pre-loaded liner material minimizes processing time
- Significant reduction in cleaning time, waste, and validation expenses

D100

Contained transfer for pharmaceutical intermediates

System of single-use containers and accessories designed for handling pharmaceutical intermediate and excipient powders with moderate potency.

Benefits

- Protects operators from industry-validated containment levels of 100 $\mu\text{g}/\text{m}^3$ to 5,000 $\mu\text{g}/\text{m}^3$
- Eliminates cross-contamination risk without the need for cleaning or cleaning validation
- Increases facility storage space with flexible 3D containers that lie flat until needed
- Reduces risk of external contamination with cGMP-compliant, inert, and rugged ArmorFlex® films
- Accelerates process development and validation with expert service, guidance, and data from ILC Dover



Key Features

Containment down to 100 $\mu\text{g}/\text{m}^3$

Available in 6 different volumes:
110L, 185L, 300L, 500L, 700L, 850L

Bag-out sleeve on both the inlet neck and the outlet neck to facilitate contained exchange out of bags during filling and discharging processes

Certain configurations available in compliance with IEC 61340-4-4 Ed 3

GuardianPac

Closed Transfer System for Non-Potent Powder Handling

Engineered flexible intermediate bulk container (FIBC) system for handling non-hazardous powders used in pharmaceutical processes.

Benefits

- Eliminates the need for cleaning and cleaning validation
- Liners are manufactured under cGMPs from FDA-compliant films
- Maximizes storage capacity and discharge yields with form-fitted liners
- Mitigation of environmental dust reduces safety hazards, machine maintenance, and cross-contamination risks

Typical Applications

- excipients
- binders
- buffers
- sugars
- salts
- nutraceuticals
- food-grade powders



Key Features

Available in 6 different volumes:
110L, 185L, 300L, 500L, 700L, 850L

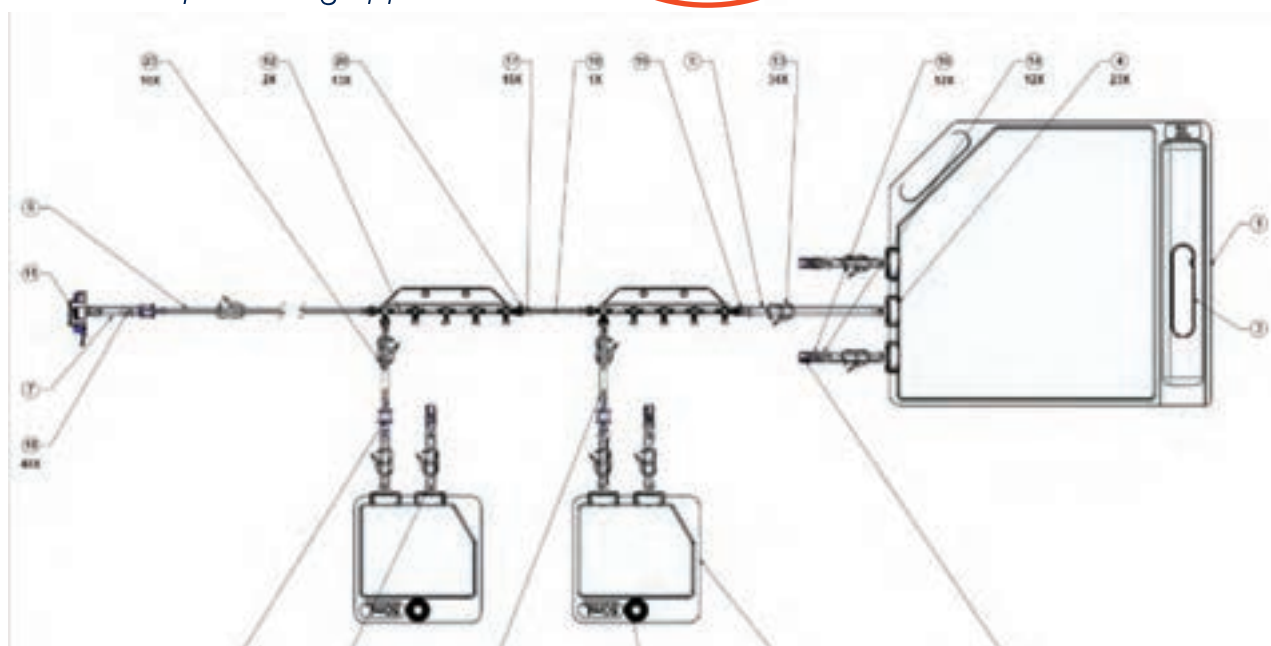
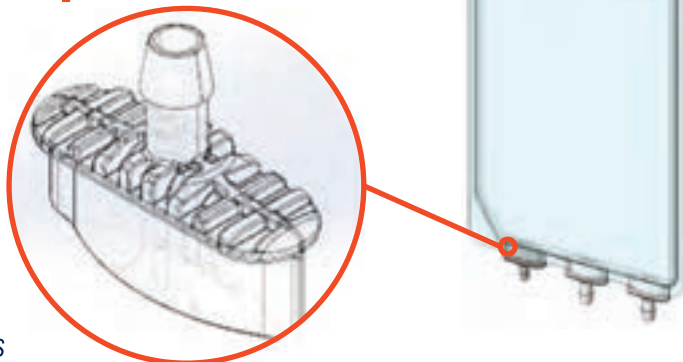
Encapsulated O-rings in the inlet and outlet spouts facilitate a dust-free connection when charging or discharging powders

Certain configurations available in compliance with IEC 61340-4-4 Ed 3

Liquid Single-use Bags (LSB)

Liquid Storage & Transport

TruFLO ports are specially engineered to offer high-integrity and improved flow for critical bioprocessing applications



Fluid transfer and storage products offering optimized reliability, throughput, and quality assurance for critical bioprocessing, DoverFlo bags are highly configurable from 50mL to 20L with custom designs up to 200L.



Design ensures minimal product holdup to maximize product recovery

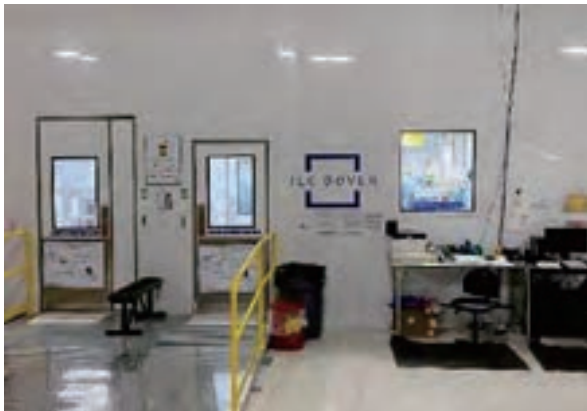


Configurable with a numerous BPOG-compliant components



48-hr drawing turnaround for transfer assemblies and manifolds

Liquid Single-use Bags (LSB) Standard Quality



Single Use Liquid Bags are qualified in accordance with BPSA and BPOG guidance for use in biotherapeutic cGMP manufacturing, including:

- Sterility validation
- Performance and Integrity Testing
- USP<85> Endotoxins
- USP<87> and <88> Biological Reactivity Tests
- USP<788> Particulate Testing
- Film Extractables and Leachables Data



Audit ready and
operational



ISO 7 Certified Clean
Room



Full validation in
accordance with BPOG
and BPSA

WFI - Water For Injection



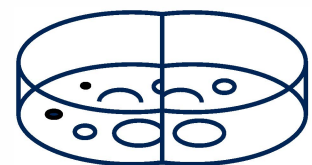
Reverse Osmosis Purified Water for Injection(WFI) is used for the preparation of media, buffers, and other ingredients for biopharmaceuticals, medical devices, and other life sciences.



Reverse osmosis purified WFI is the feed water for our processes



Our upcoming distilled WFI expansion will provide further benefits



2-ISO 8 Certified Rooms
3-ISO 7 Certified Rooms

Aseptic Liquid Handling and Filling



Liquid products are handled 1 of 5 cleanroom manufacturing suites and aseptically filled in ISO 5 certified hoods. We combine sterile filtration with our unique packaging solutions to ensure product quality.



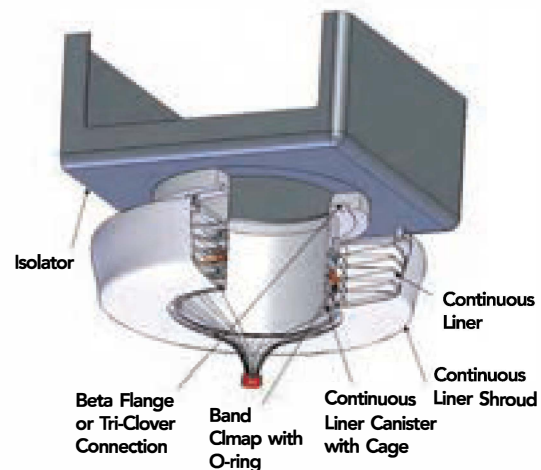
Variety of packaging solutions including ILC Liquid Bags



cGMP to FDA21 CFR 820
ISO 13485 Certified
ISO 9001 Certified

Continuous liners

Safe and effective transfer of powders



Easy-to-use system for containing active pharmaceutical ingredients and other hazardous compounds to minimize powder contamination risks, and protect people, plant, and product

- Contained processing to protect the operators
- cGMP processing in a completely closed operation to protect the product
- Single person operations
- Pre-loaded liner material minimizes processing time
- Significant reduction in cleaning time, waste, and validation expenses

BIBO System

Multiple size Bag In / Bag Out(BIBO) System

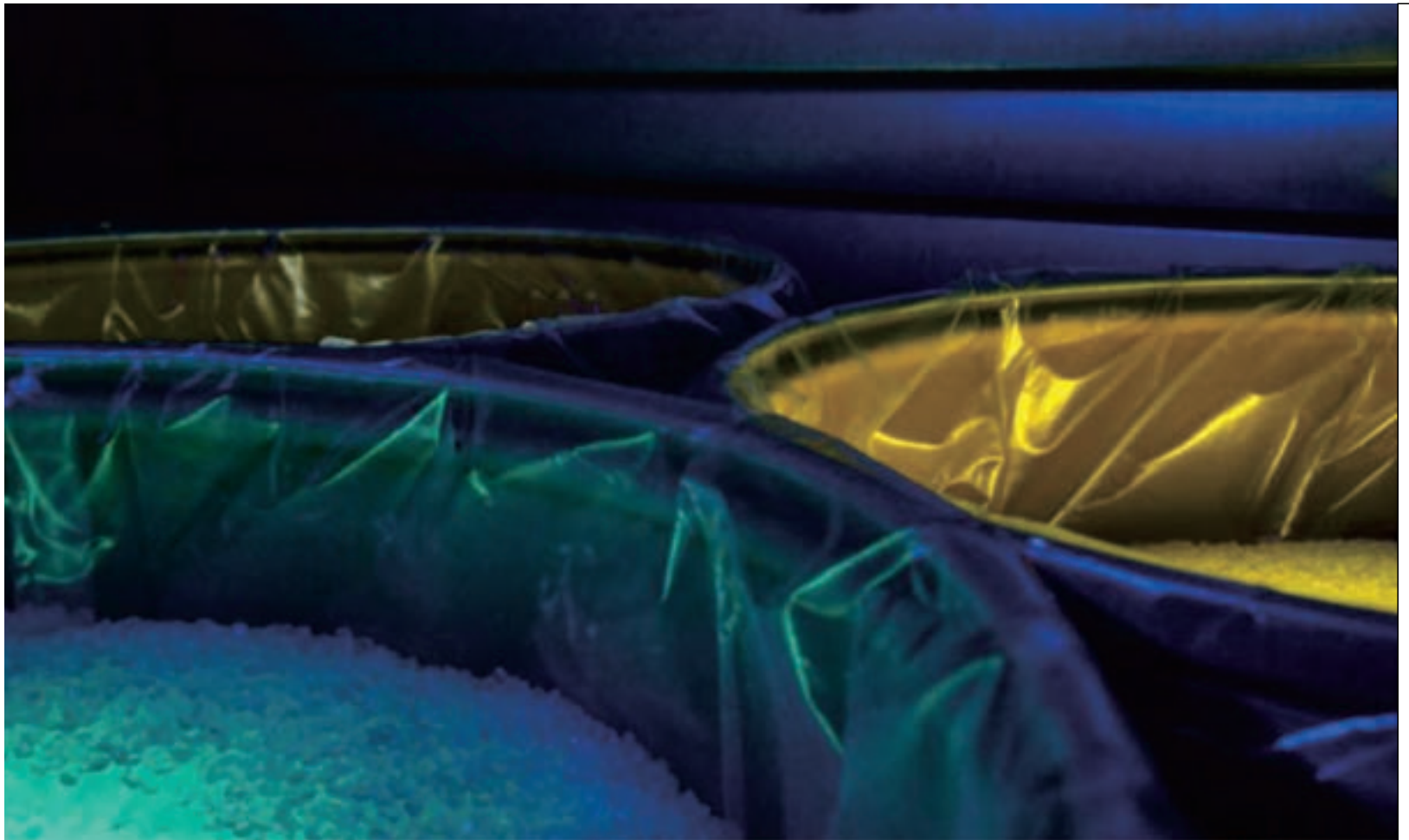


The use of multiple size canisters allow a broad range of needs to be met, system can be retrofitted to existing assets, and the BIBO system requires a low capital outlay

- Minimizes risk during operation
- ArmorFlex® film are regulatory compliant
- Eliminates concern of cross contamination due to "pneumatic" effect of low end films leaking
- Reduced cleaning and cleaning validation costs
- Reduced process time and cost by eliminating multiple RTP canisters
- Eliminates RTP seal maintenance

Static Dissipative Drum Liners

Economical solution for safe transport and storage



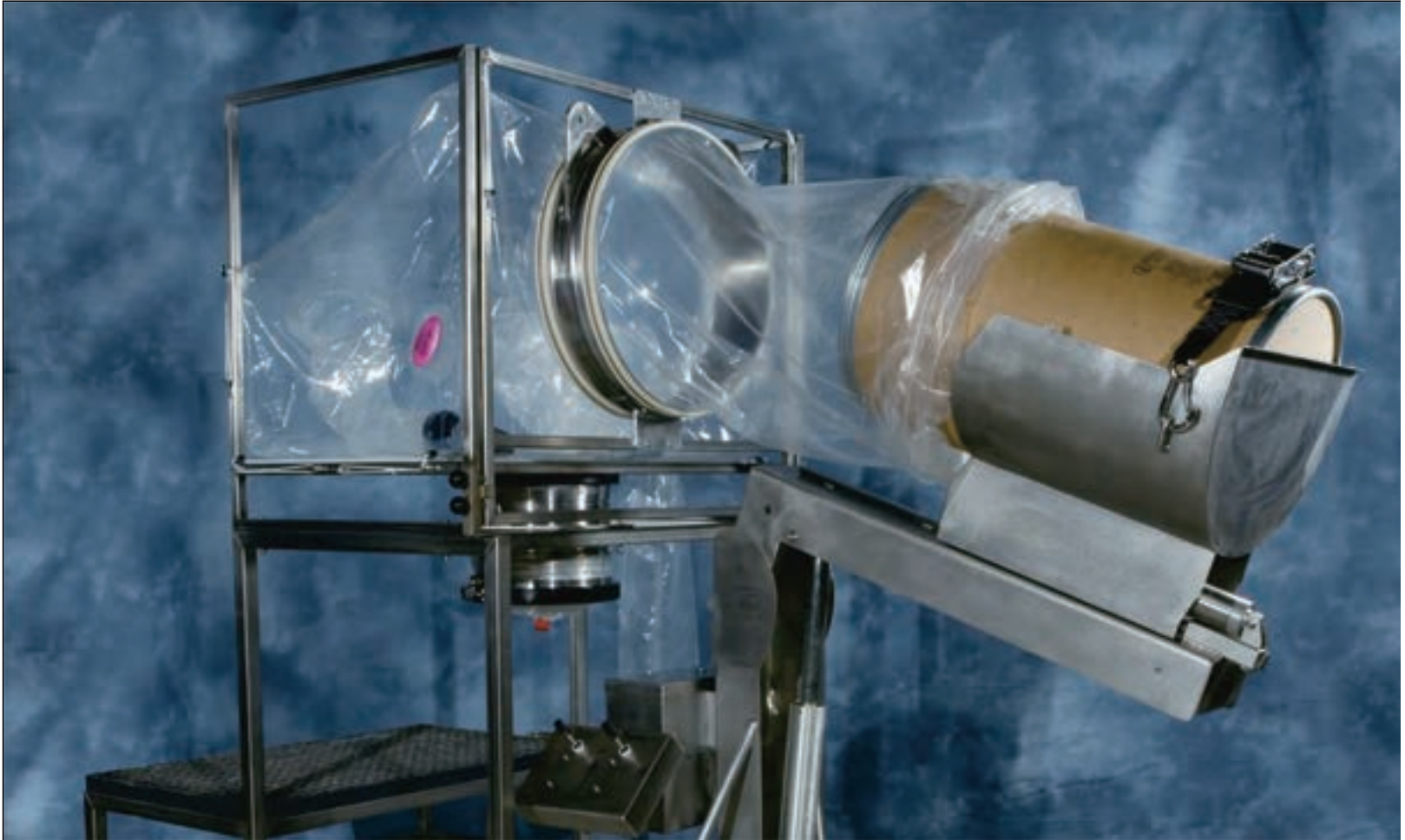
ILC Dover static dissipative drum liners provide you with the confidence to safely transfer and store a wide range of APIs and other powders

- Protect your powder with our clear, durable, and regulatory friendly ArmorFlex film
- Passes Chilworth incendivity test ensuring the safety of your product when used in certain hazardous environments
- Up to 5-year shelf life unless gamma irradiated



Drum Transfer System

Drummed materials using a closed system

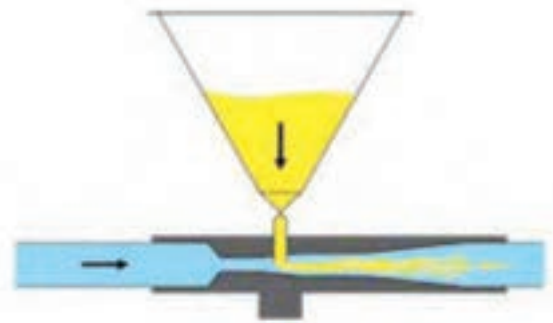


ILC Dovers' Drum Transfer System can be used for contained transfer of active pharmaceutical ingredients(APIs), intermediates, and excipients in applications such as: milling, subdividing, charging and repackaging.

- Shortens time to manufacturing readiness
- Improved operator ergonomics
- Lightweight, mobile system
- Less complex than rigid isolators
- cGMP system - no cross contaminations
- Protects operator and product
- Minimizes product loss
- OEL's to 1.0ug/m³ achieved
- Low capital cost
- Validated in customer applications
- Disposables reduce cleanup and cleaning validation

JET MIXER

The Smartest way to mix powder



The patented nozzle system creates an accelerated jet, which draws in a significant amount of powder

- Rapid mixing
- Complete dissolution of the powder
- No clumping of powder
- No moving parts = no maintenance
- Low footprint
- GMP design
- No introduction of shearing forces on the powder, thus preserving all their properties for solids suspension

The smartest way to mix powder

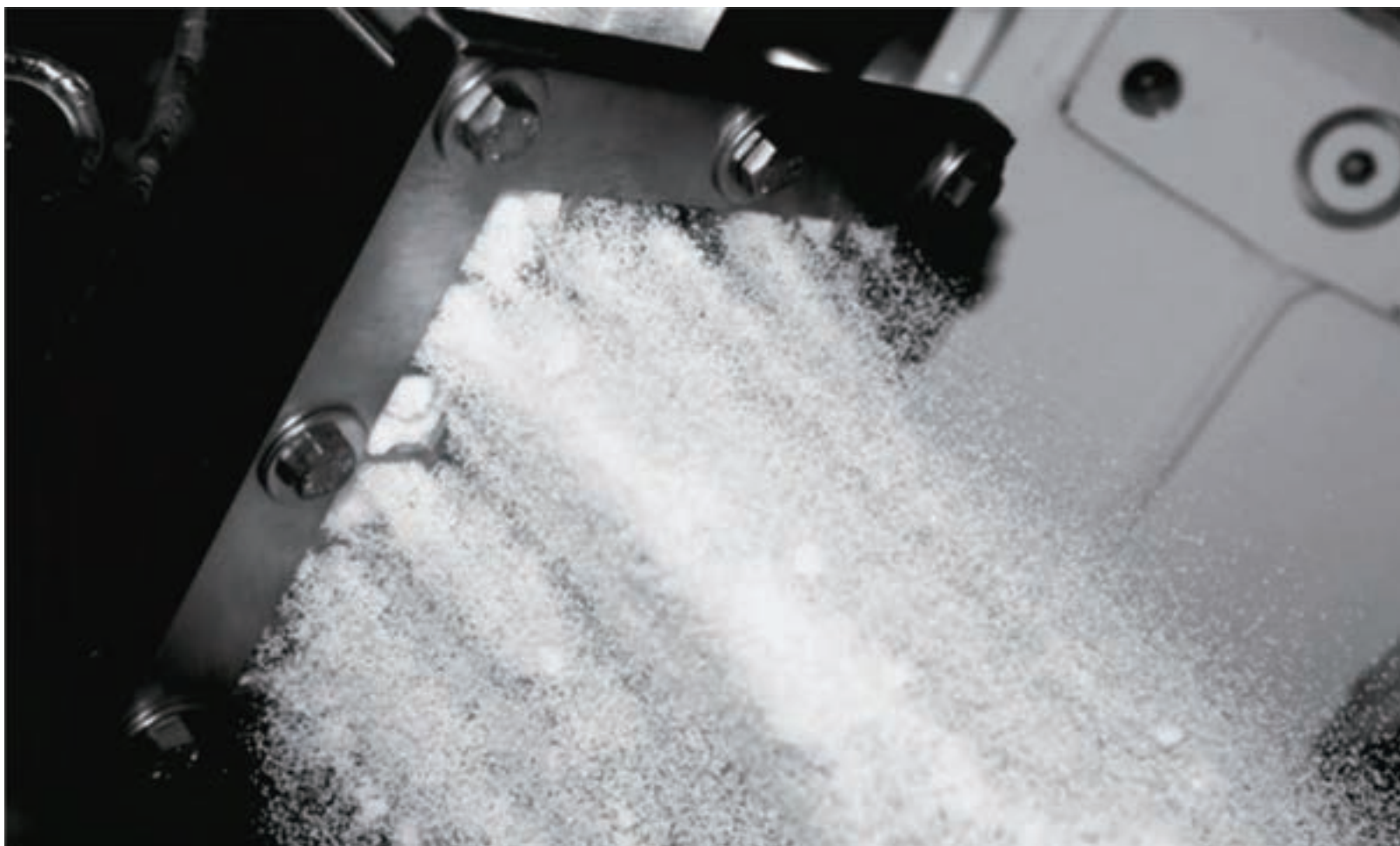
Powder dissolution,
even for high viscosity liquid

Solid suspension into liquid

Liquid / liquid mixture

JETBREAKER

Reducing agglomerated bulk material



The raw material coming from FIBC, bag, barrel, equipment such as dryers, etc. is fed by gravity into the Jetbreaker. The agglomerate is sheared between the stator and the rotor until resulting particles are smaller than the grid.

- Single block up 0.5m reduced to few mm grains in one step
- Low footprint
- GMP design
- High yield
- In-line or stand-alone unit
- Available in ATEX execution



Powder Delumping system

FIBC discharge station

Bag dump station

Barrel discharge station

Various sizes

SPT SAMPLE TAKER

Taking powder sample on a production line



The carved piston/screw is advanced into the product stream to retrieve the powder sample. The control of the motion/speed of the piston/screw allows perfect control of the amount and time of collection.

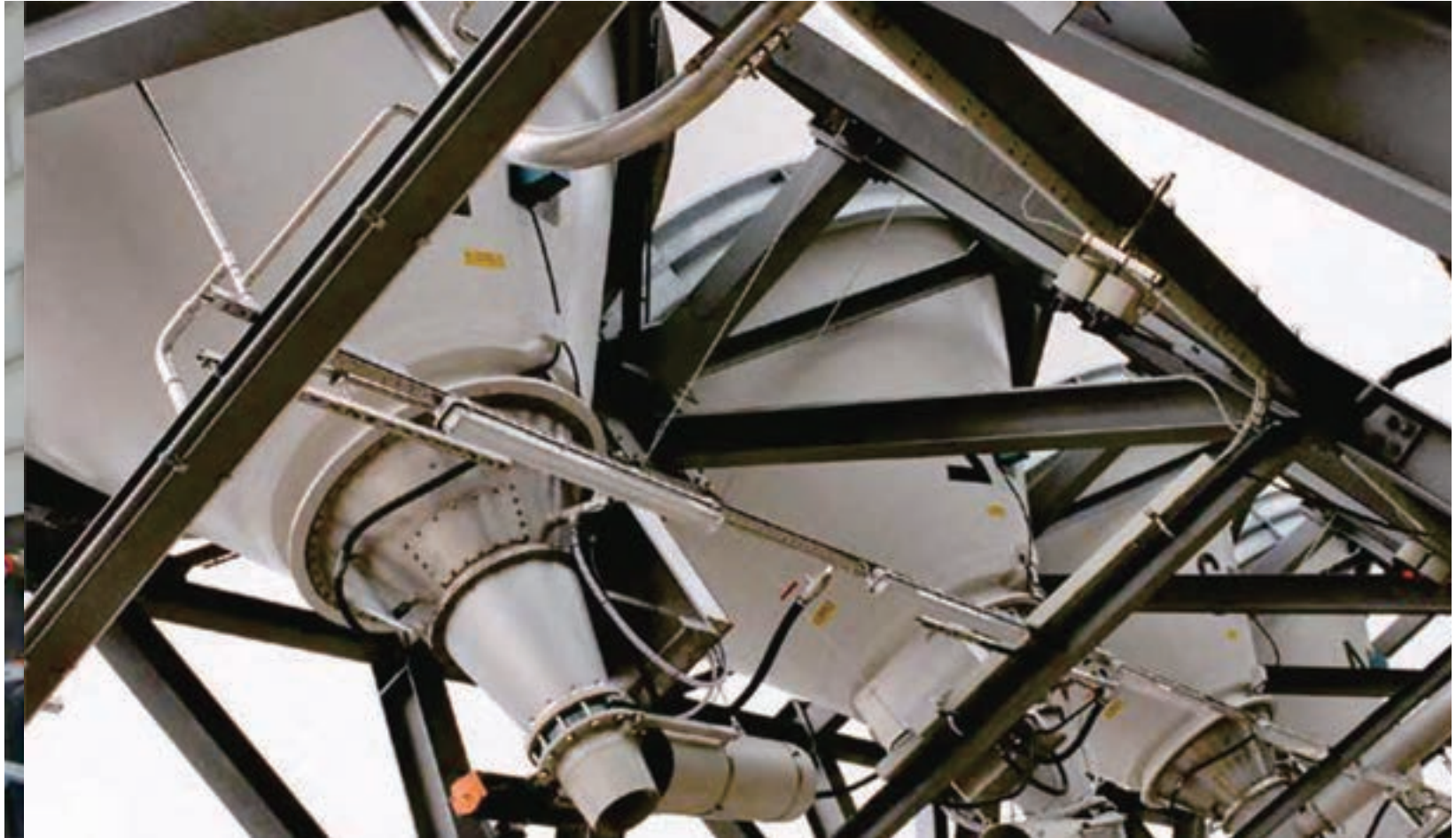
- Available in high containment version(OEB 5)
- Available in ATEX execution
- Customized connection to specific vessel
- No friction parts in the product stream
- GMP design / In process Sampling
- Continuous sampling
- Sampling during the unloading of the raw material
- Sampling finished product up stream of final packaging



Secured vial with depressurization for the sampling

SAK-EXTRACTION CONE VALVE

Conical extraction valve for bulk products



Circular product extraction ensures mass flow from the silos, thus avoid demixing

- First-in First-out
- Avoid the segregation of mixture
- Adjustable unloading speed
- GMP design
- Allows the extraction of poor flowing powders
- Available in different sizes from Ø480 to 1800mm
- Available in ATEX execution
- Rapid silo unloading
- Dosing directly from the silo



SAK closed and open position

- Unloading of poor flowing powders
- Unloading with speed regulation

LIQUEFYER

Powder extraction system



The blade continuously rotates around the entire discharging hopper, Breaking the friction between the product and the wall, allowing a continuous discharge of the powder with low flowability

- No moving parts in contact with the product thanks to the Dynaform™ Membrane
- GMP design
- Low footprint allows easy integration
- Available in different sizes from Ø100 to 200mm
- Available in ATEX execution
- Fast, accurate dosing when combined with the Dosimat™ dosing valve™
- Ensuring product flow through process scale reductions

VTR HOMOGENIZER

Add shear to your mixing process to speed mixing



The liquid containing suspended particles is pumped to the homogeniser and successively through the follow zones

- Homogeneous size reduction
- Guaranteed repeatability
- Continuously adjustable homogenising chamber (even during the production)
- No moving parts
- GMP design
- Homogenous mixing line in combination with the PST injector



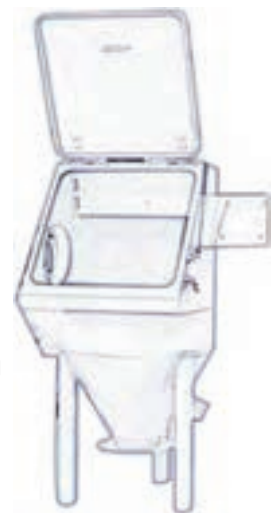
BAG DUMP STATION

Station to unload solids in clean and safe way



Depending on the size, weight, pace and level of containment, the product can be fed by front door and semi-continuous loading the side airlock

- Various configurations depending on containment constraints (from OEB1 to OEB5)
- Custom manufacturing with various handling assistance
- System outlet adapted to your downstream equipment or process
- Feed pneumatic conveying line
- In combination with JetBreaker, delumping of agglomerated 25kg bag
- In combination with Jet-Injector, hydration and mixing of raw materials



PCS(Pneumatic Conveying System)

Move powder safely and pneumatically with either a push or pull action depending on your application



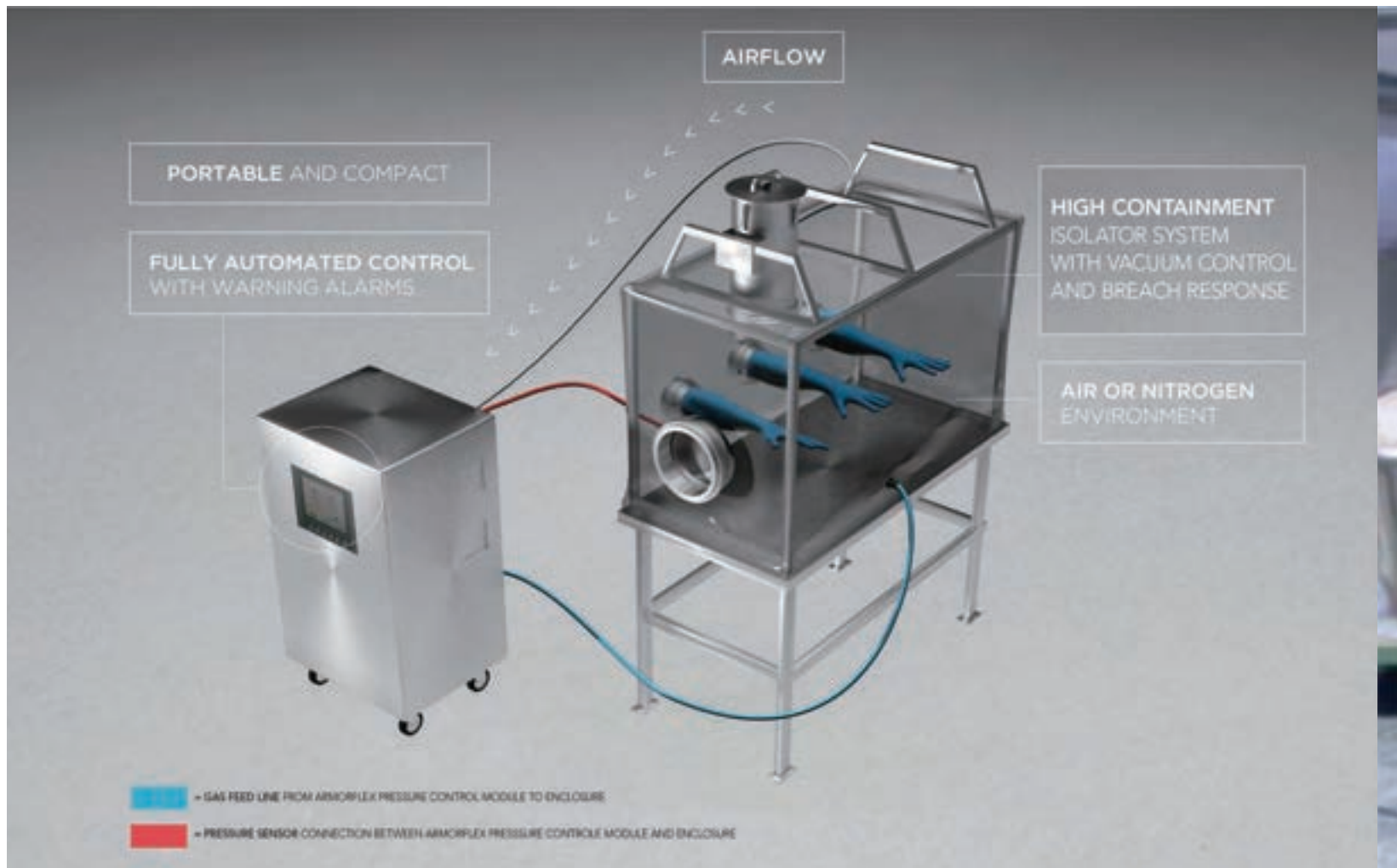
Depending on the mode of conveying, the powder is pushed or pulled through the piping by gas(Air or Nitrogen)

- Wide range of product able to convey from few kg to several tons per hour
- Capability to determine the filtering surface and pump required for each application
- GMP design
- Available in explosion proof and ATEX approved executions
- Easy access and cleaning
- Transfer of raw material(IBC / FIBC / Silo / Bags / Drums / etc.) to the process
- Transfer of the finished product to the final container



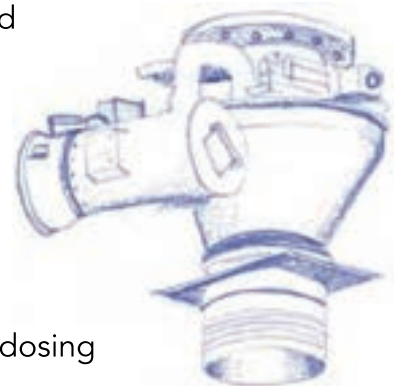
ACM(Atmospheric Controle Module)

Reducing the risk of worker exposure



The ACM can also deliver positive air pressure for applications requiring sterility, or to help in controlling relative humidity when containment is not necessary

- Ventilation unit can be installed in a separate room as the contained compartment
- Holding a negative or positive pressure inside a contained compartment during all the process
- Fixture or mobile unit
- Available in ATEX execution
- Dedusting of flexible isolators
- Clear the influence of the pressure for confined accurate dosing
- Maintain a constant negative or positive pressure in a flexible isolator



FIBC DOCKING

Dust-free connection of the FIBC to be discharged



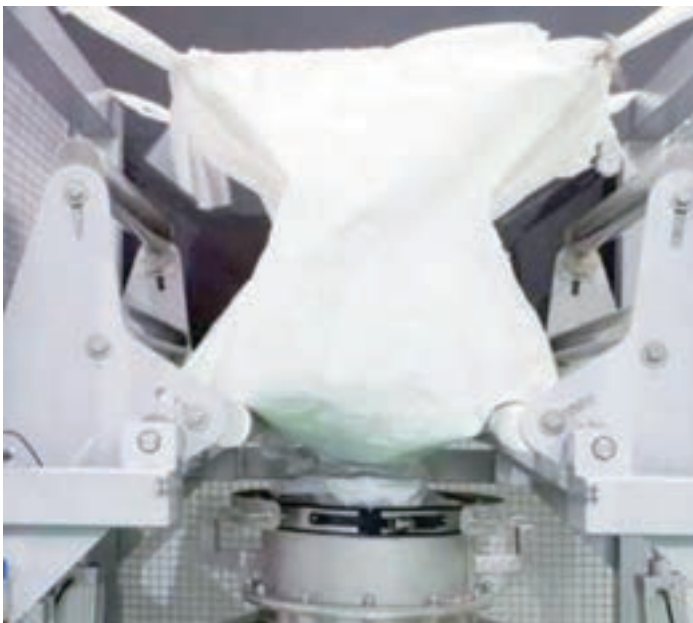
The outlet liner of the FIBC is pinched between the top-plate seal and the discharging pipe

- Easy to use
- ATEX approved
- Improved discharge flow
- GMP design
- FIBC discharge station
- Direct mounting on the manhole of the reactor
- Optional dedusting system allows clean disconnection of empty FIBC



FIBC DISCHARGE STATION

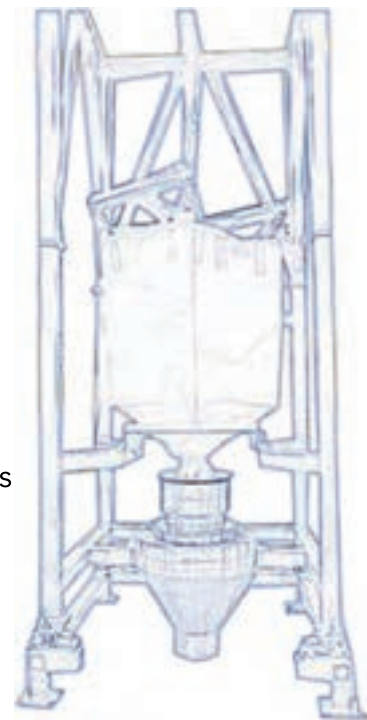
Powder handling



FIBC station with tilting table, lumpbreaker and Jet-Mixer

Custom made installation to meet the most stringent requirements in terms of finishing and containment

- Designed to meet the regulatory and performance demands of your industry
- Facilitate unloading of systems to agglomerated powders
- Direct integration of the unloading station to your process
- When conventional unloading stations are not sufficient



MULTI-DOSIMAT

Multi-purpose unit for fluidizing, dosing and weighing of powders



Multi-Dosimat mounted on the lifting column to dose into IBC

The combination of the extraction unit(Liquefyer) and the metering unit(Dosimat) allows to perform a fast and accurate dosing.

- Fast and accurate dosing
- ATEX approved
- Improved discharge flow
- GMP design
- Subdivision and packing of finished product
- Power flow control

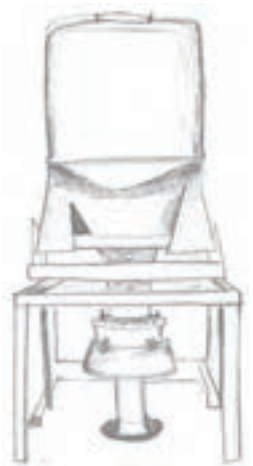
DOSICON

IBC with conical closing valve allowing dust-free filling and discharging of bad-flowing powders



«Dosicon» is used to receive, mix, store and discharge powders for formulation preparation. The closing cone valve enters and vibrates in the heart of the product thus allowing controlled discharge of any type of powder.

- Dust-free container filling and emptying
- Discharging of poor-flowing powders
- Discharging of mixed powders while maintaining product consistence
- Speed controlled discharge
- Folmulation of different ingredients to be mixed directly into the container
- Dust-free discharging of IBC
- Fully-automated production line(AGV for the taxi between differents places)
- Tablet press supply without segregation(Direct compression)



CONTAINED PACK-OFF SYSTEM



Pack-Off station with conical sieve mill vacuum conveyor and sample taker.

The Pack-Off System consists of a set of modules and custom adaptations allowing to unload of your equipment (typically dryer and mixer) containing the end-product, to dose and to pack under high level of containment

- Reproducible dosing accuracy up to 0.1%
- Pressure regulation system cancelling the influence of the pressure on the scale
- OEB 5 (<1g/m³) level containment
- GMP design & CIP / ATEX and UL approved
- Dosing software covering all types of powder
- Pressure regulation system ensuring the smooth flow of the powder into the final container
- Contained subdivision and packing of finished product
- Dryer (or Mixer) discharge and packing

Sentinel XT Clear PAPR System

WELL-SUITED FOR SAFETY



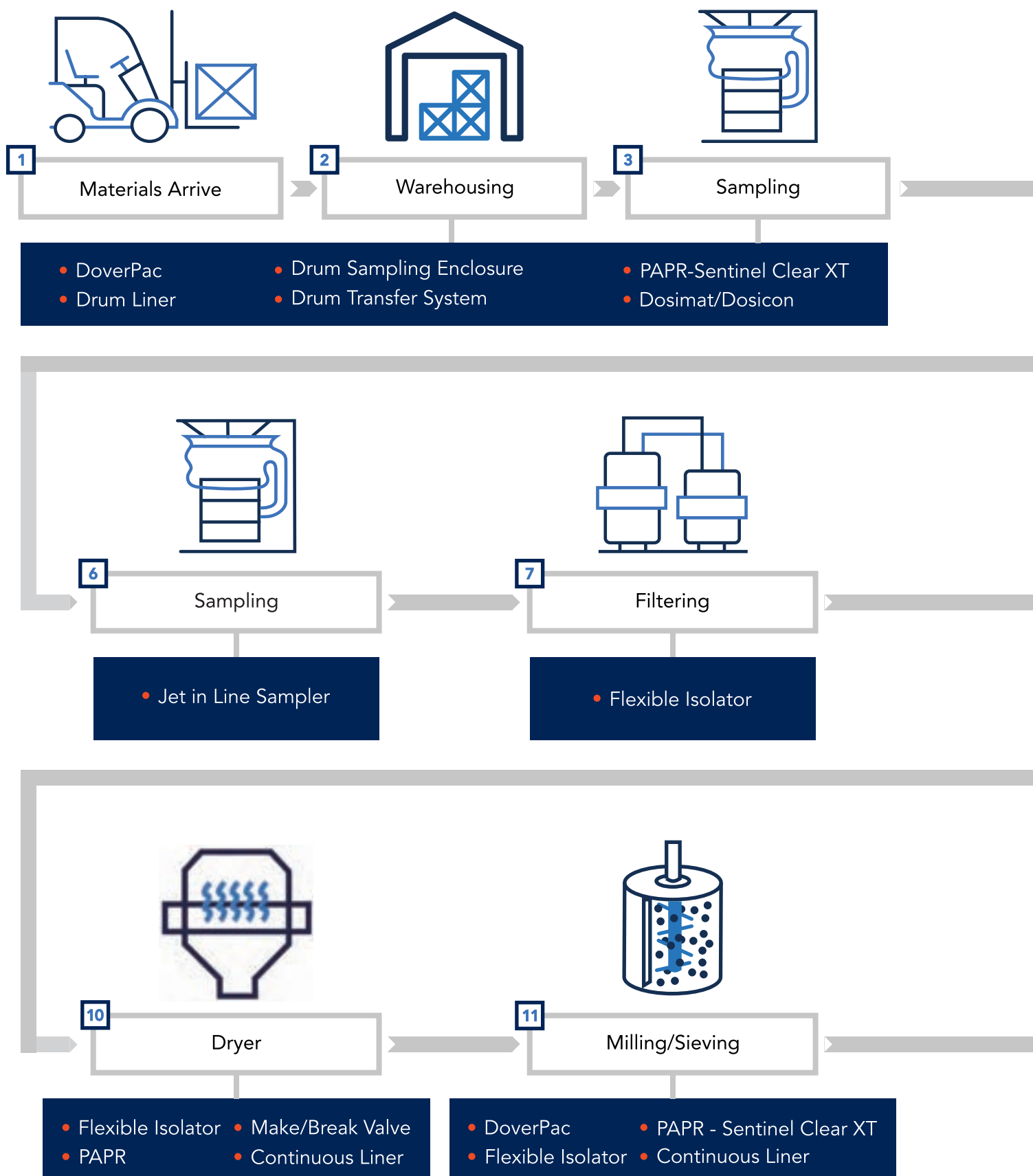


Improved workforce productivity & engagement for companies with fresh air feeling for operators

- 8.3CFM standard airflow
- More fresh air feeling for operators
- Ergonomically designed
- 20% lower weight blower/ battery(2.2 lbs)
- No-headband design
- Easy to don
- 320 degree field of view
- Reduces neck strain, claustrophobic feeling
- Improves operator safety
- Easy to read battery life meter(12 hour battery life)
- Serialized batteries allow tracking and improve accountability



Chemical Synthesis Workflow





4

Repackaging



5

Reactor Charging

- JETBREAKER
- Jet Mixer
- DoverPac



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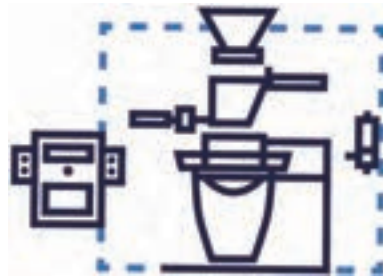
Slurry to Centrifuge



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Reactor Charging
with Wet Cake

- DoverPac
- PAPR - Sentinel Clear XT
- Flexible Isolator
- Make Break Valve
- Continuous Liner

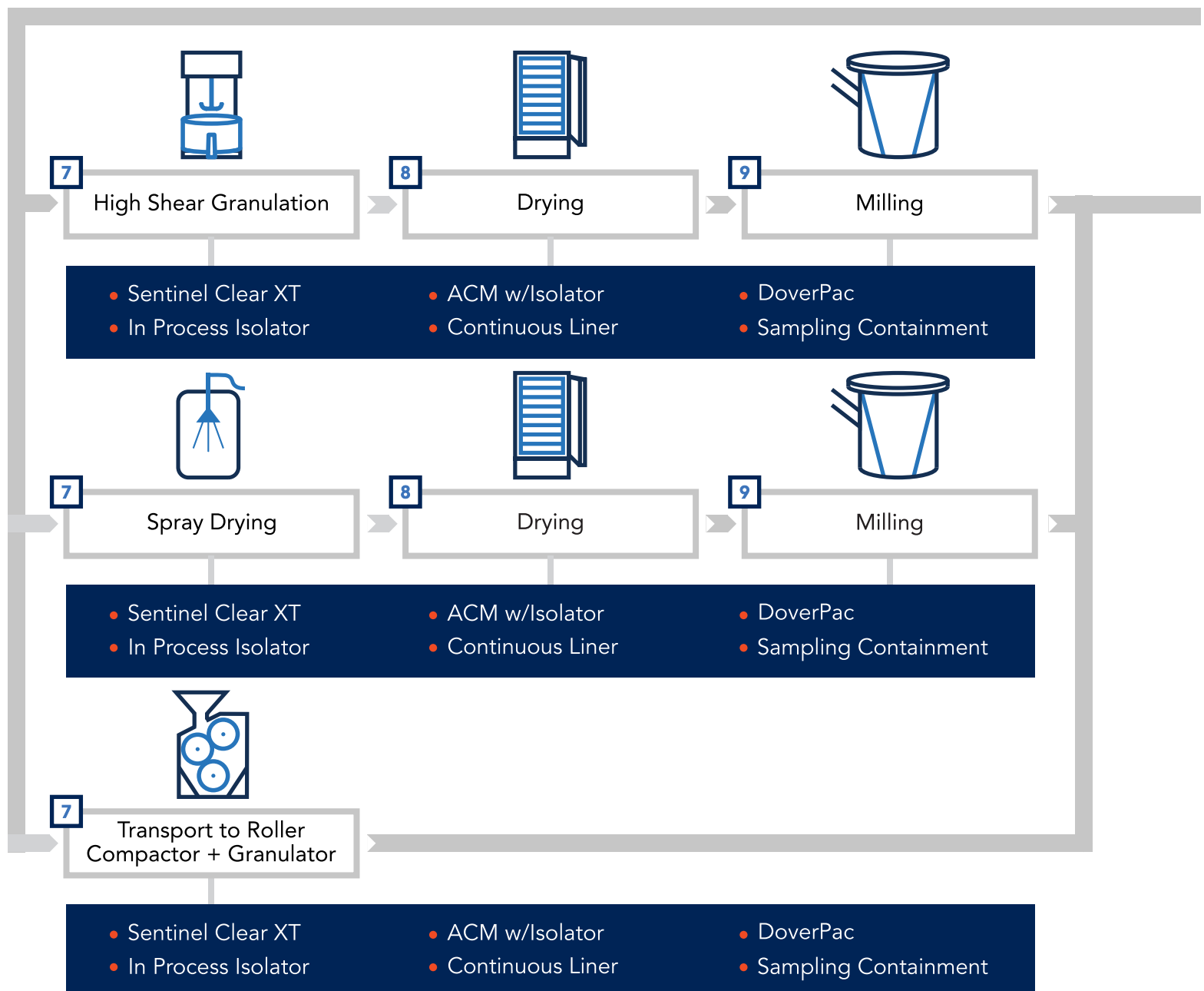
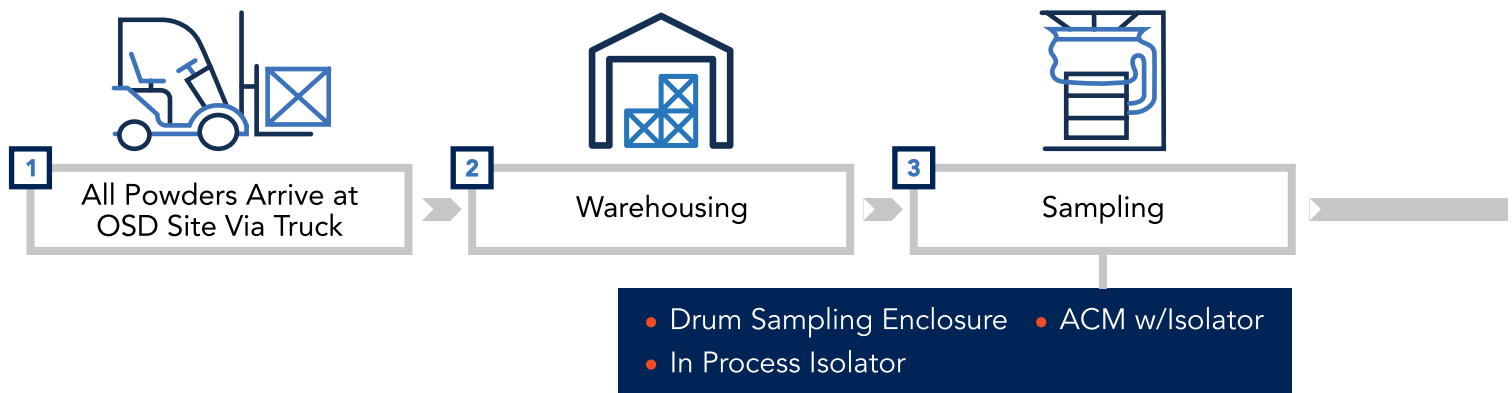


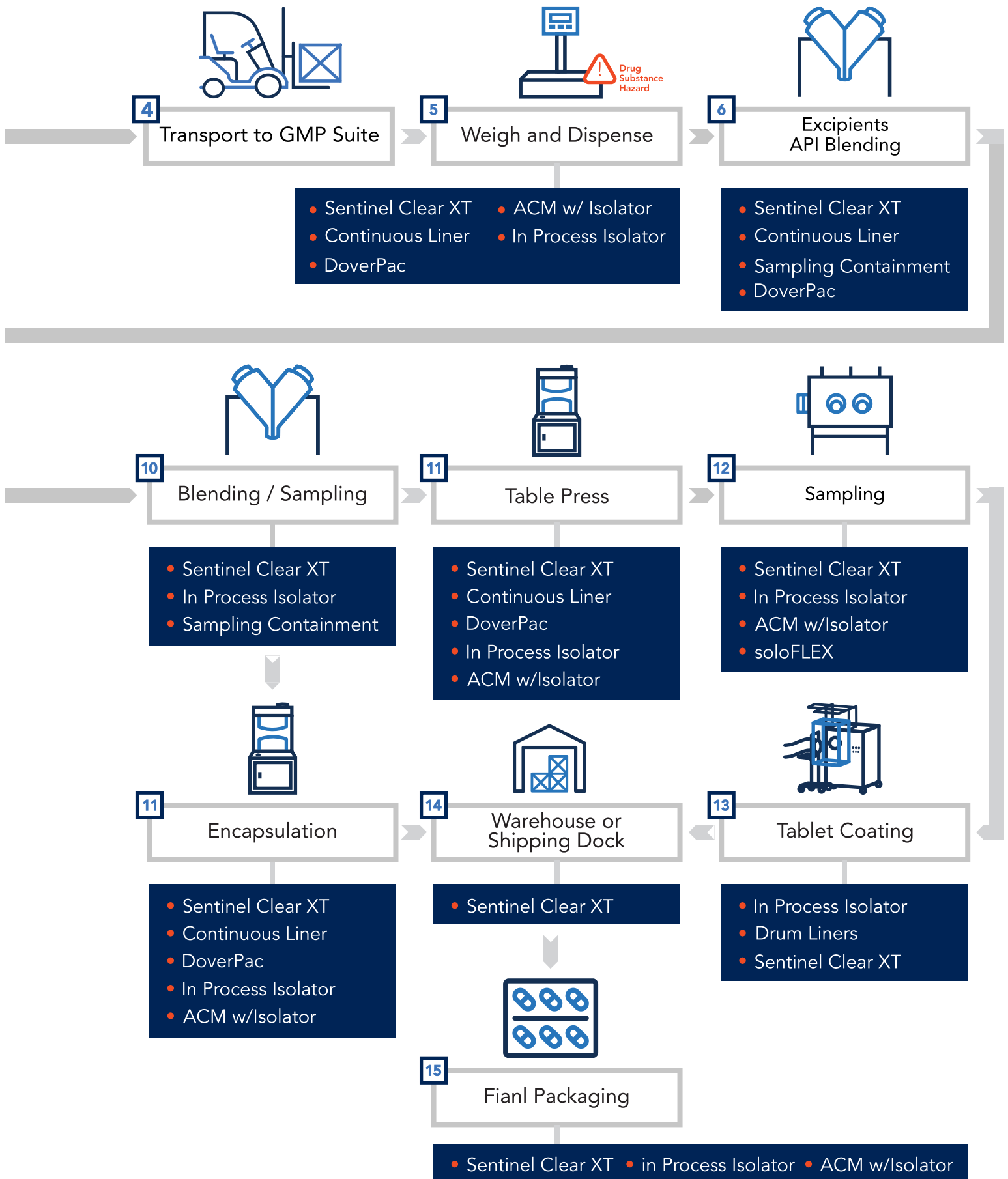
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Pack off to Oral Solid Dosage Process

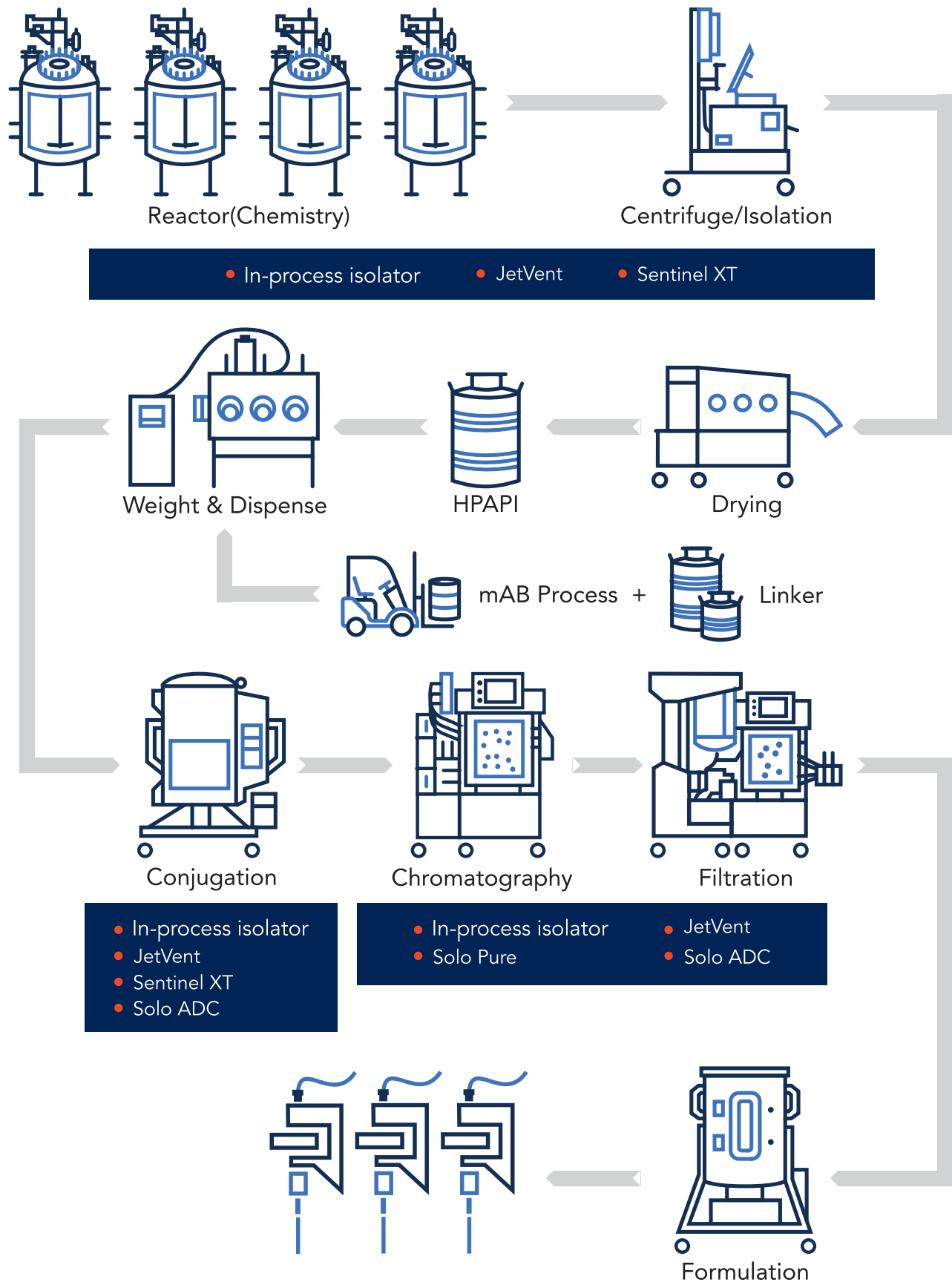
- DoverPac
- Continuous Liner
- Drum Liners
- Flexible Isolator

Oral Solid Dosage Workflow

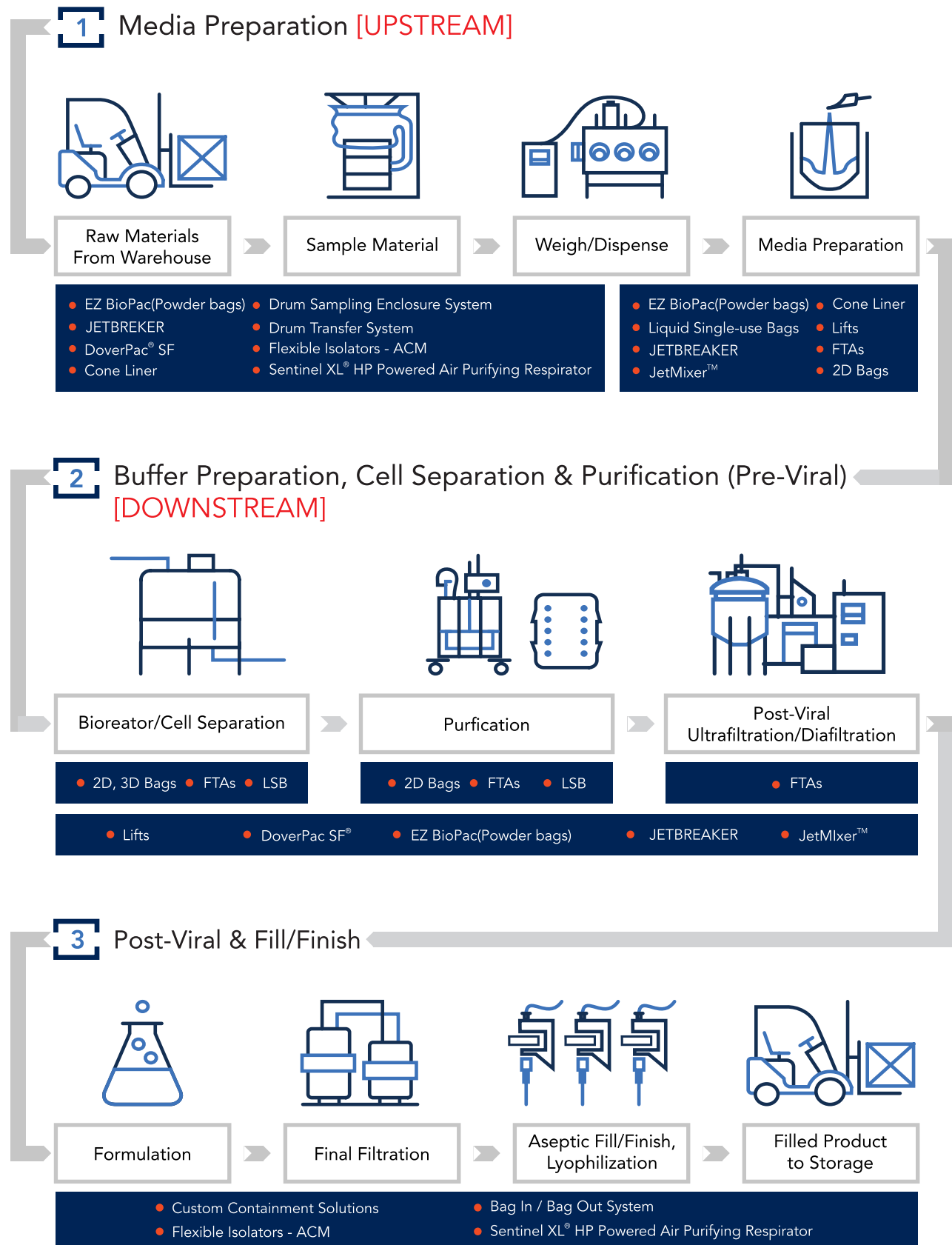




ADC Workflow



mAb Workflow



Biologics (Large Molecules)

1 Media Prep [UPSTREAM]



Raw Materials
From Warehouse

- EZ BioPac(Powder bags)
- DoverPac
- Crimploc
- Drum Transfer System



Sample Material

- Drum Sampling Enclosure
- JETBREAKER
- Cone Liner
- Bag In/Bag Out System



Weigh/Dispense

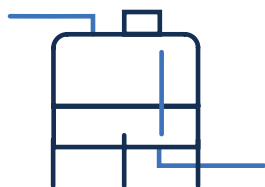
- Continuous Liners
- Flexible Isolators
- Sentinel XT



Media Preparation

- EZ BioPac(Powder bags)
- Lifts
- DoverPac
- LSB / FTAs

2 Pre-vial [DOWNSTREAM]



Bioreactor/Cell Separation

- Lifts



Purification

- DoverPac SF®
- EZ BioPac(Powder bags)



Post-Viral
Ultrafiltration/Diafiltration

- JETBREAKER
- JetMixer™

3 Post-Viral & Fill/Finish



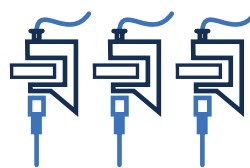
Formulation

- Customized Containment Solutions
- Bag In / Bag Out Systems
- Crimploc



Final Filtration

- Continuous Liners
- Sentinel XL
- Flexible Isolators



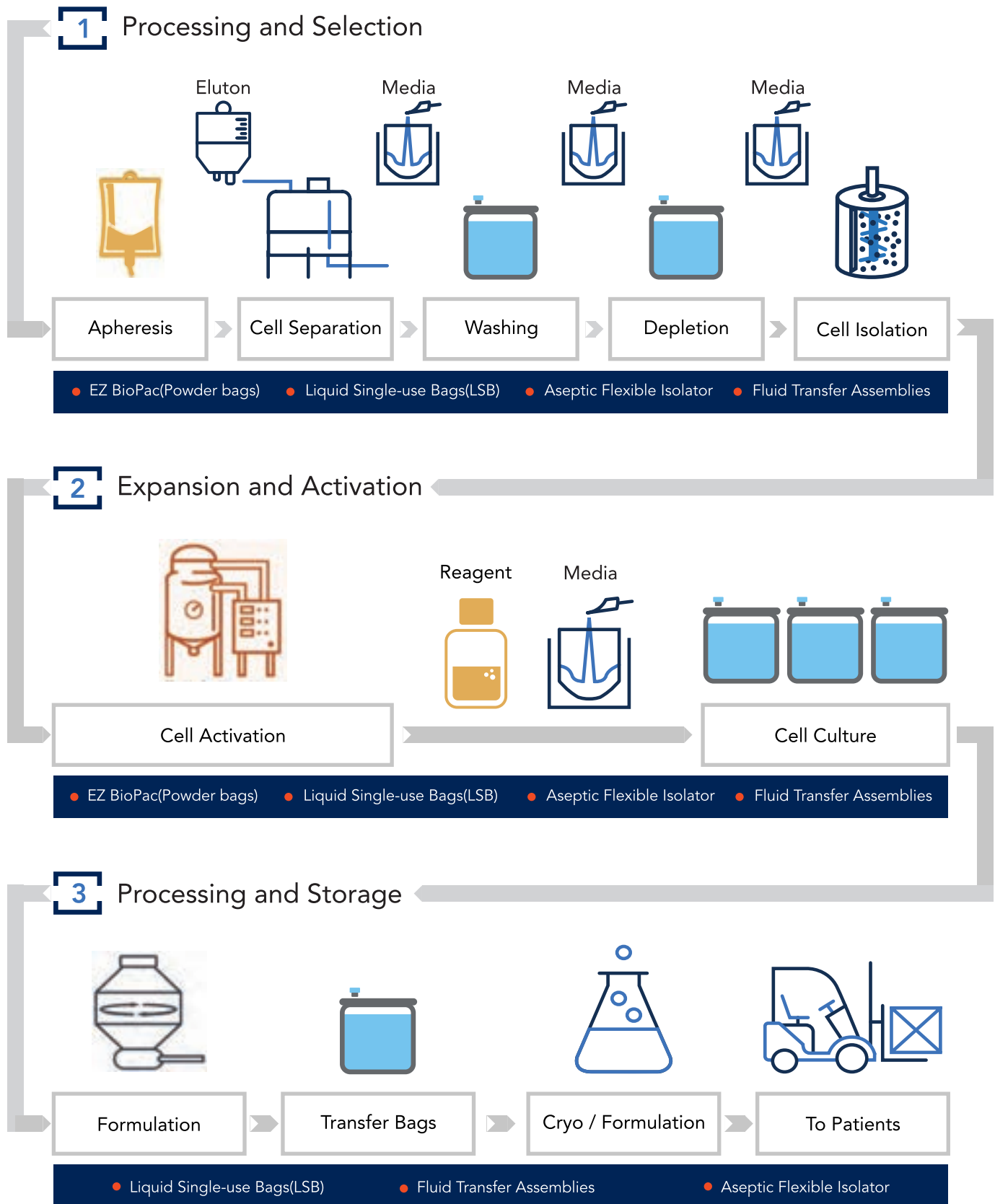
Aseptic Fill/Finish,
Lyophilization

- Atmospheric Control Modules
- Liquid Single-use Bags(LSB)

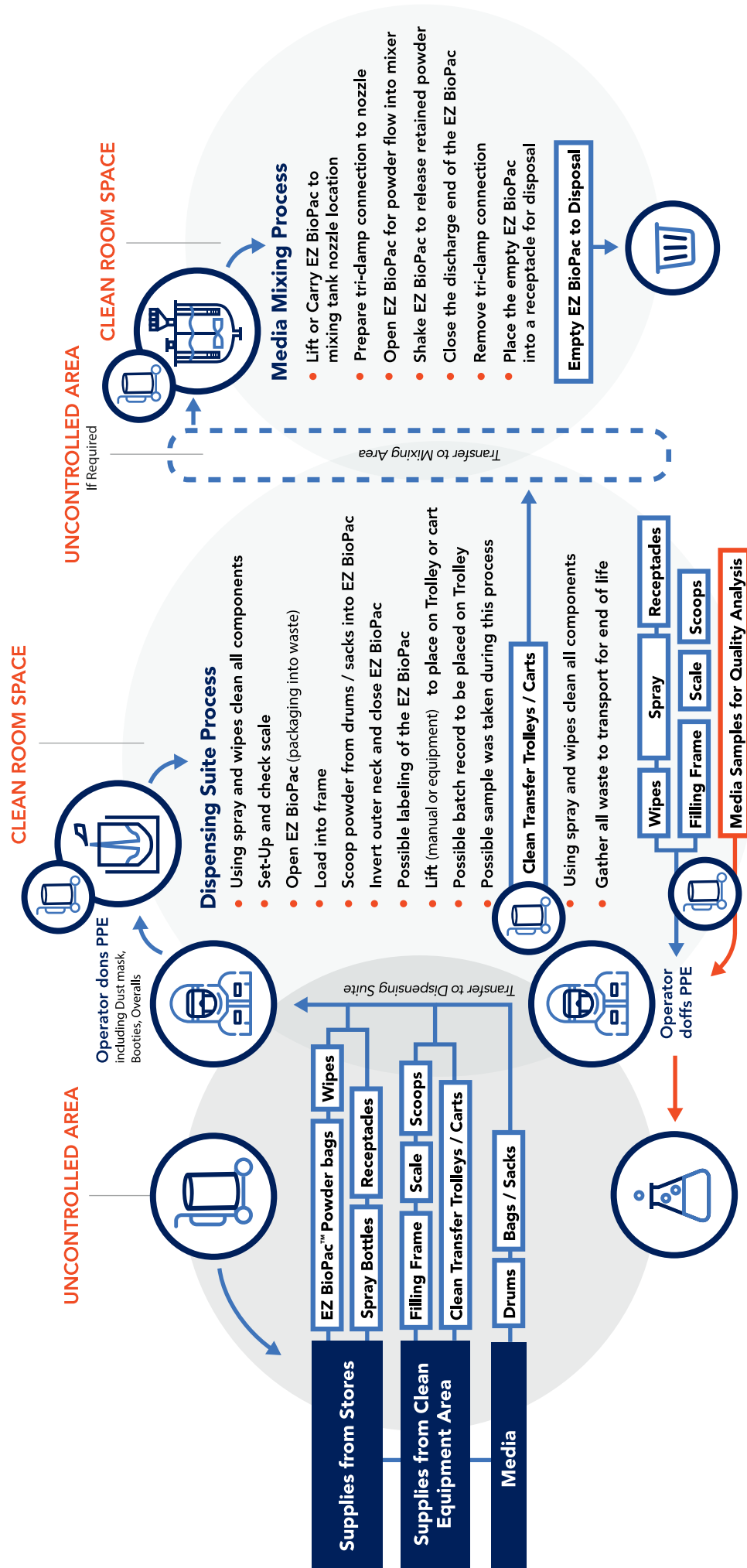


Filled Product
to Storage

Cell & Gene Therapy



Media Preparation

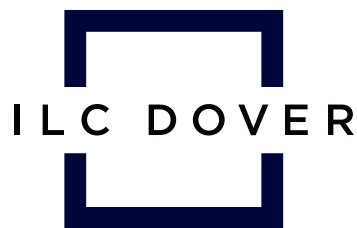




BEYOND BOUNDARIES™

Our ILC Dover Family





BEYOND BOUNDARIES®

ILC Dover is a world-leader in the innovative design and production of engineered flexible protective solutions for pharmaceutical and biopharmaceutical, flood protection, personal protection, bulk packaging, and aerospace industries. Our customers will attest to our relentless dedication to high value products, advanced technology, and responsive service, as our visionary flexible protective solutions have improved efficiency while safeguarding people, product, and infrastructure in hazardous conditions since 1947.




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Frederica, DE, USA
Seaford, DE, USA
Rossens, Switzerland (Jet Solution 2014)
Juarez, Mexico (Grayling 2013)
Blarney, Ireland
Stockport, United Kingdom (solo 2020)
El Paso, TX, USA - warehouse

 **ILC Dover Offices**
Newark, DE, USA - Head Quarters
Houston, TX, USA
Clarke Quay, Singapore
Haryana, India
Shanghai, China
Seoul, Korea

 **Flexan (acquired 2021)**
Lincolnshire, IL, USA
Chicago, IL, USA
Salt Lake City, UT, USA
Suzhou, China

 **KSE Scientific (acquired 2021)**
Durham, NC, USA
Sanford, NC, USA - warehouse
Denver, CO, USA - warehouse

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