
ChargePoint
AsoptiSafe®
CONTAINED ASEPTIC
TRANSFER VALVES
10°c
ChargePoint
TECHNOLOGY

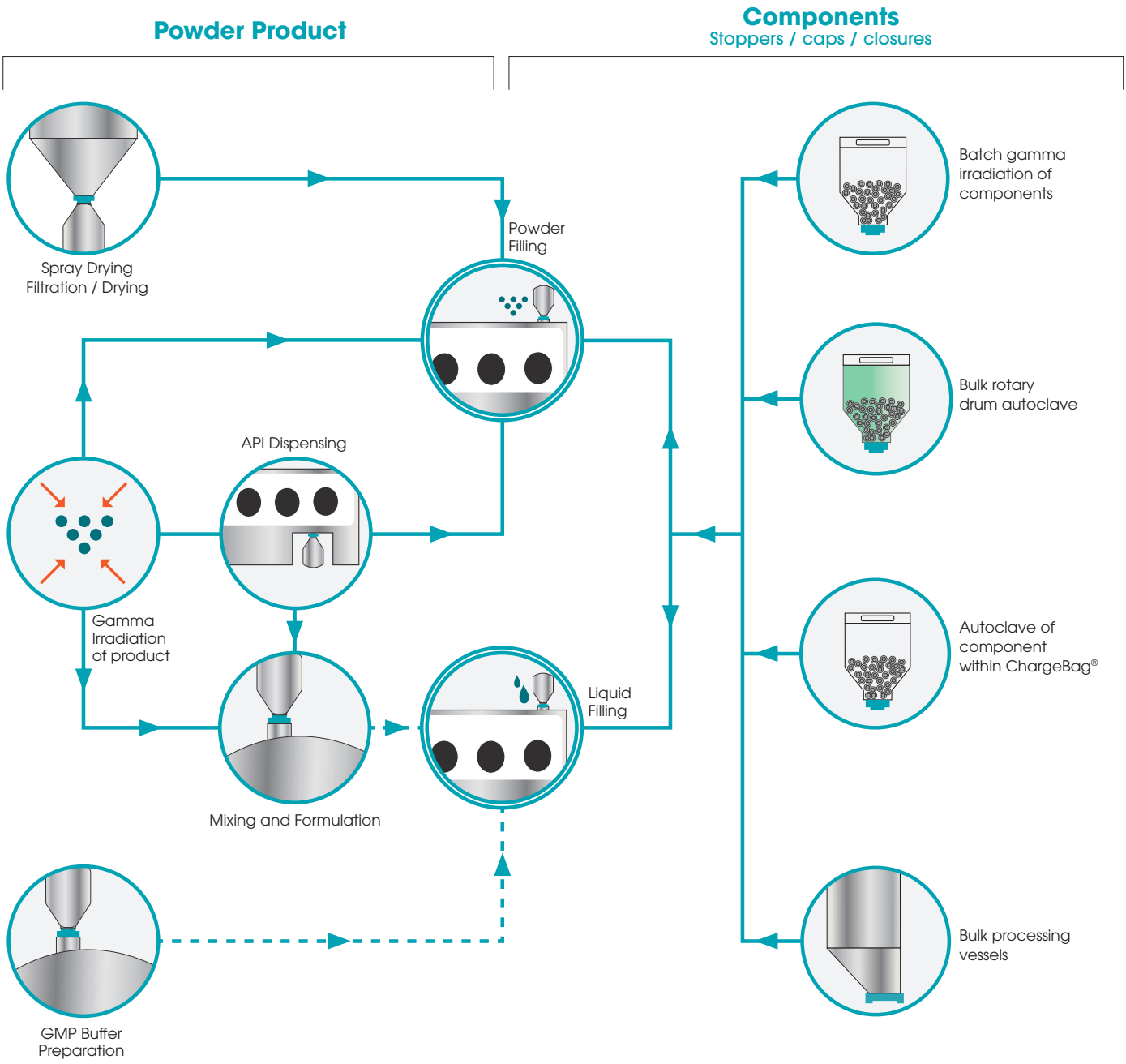
ChargePoint AseptiSafe®

- Perform aseptic transfers that **maintain critical area integrity.**
- **Reduce risk of cross contamination** with closed transfers that limit manual intervention.
- Meet **GMP and product quality** requirements.
- **Remove high air class control areas and cumbersome PPE.**
- Process toxic powders, ensuring the **safety of your personnel** and a **dust free environment.**
- **Maximize yield** transferring poorly flowing and high value product.

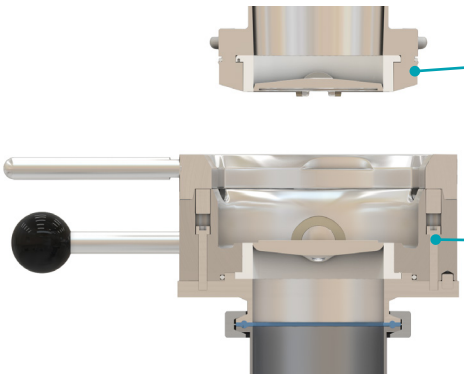
Applications

Contained filling and dispensing for all production processes.

AseptiSafe® aseptic transfer valves can be integrated into the production of both powder and liquid formulations from API production to fill/finish processes, transferring either powder or components.



Products



Passive (beta)

Attached to mobile product/ component container

Active (alpha)

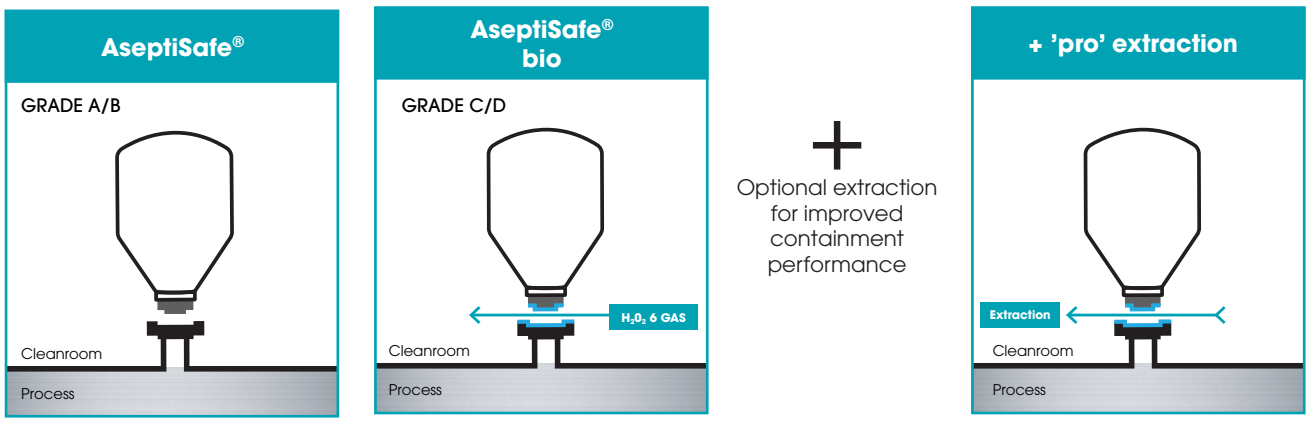
Attached to process vessel/ filling line

- Prior to the transfer process the Passive unit/ container is pre-sterilized outside of the process.
- This is normally completed in an Autoclave and the critical interface that will be later exposed to the production area can be sealed with a GMP Cover.
- Each half of the valve contains one half of a butterfly valve disc. Each unit is sealed and cannot be opened unless they are docked together.

Solutions to meet critical area set up and required sterility assurance

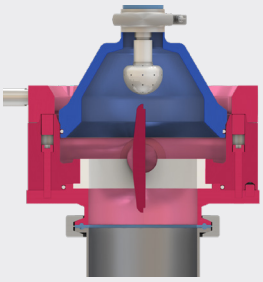
Two alternative methods of sterilizing the product contact and sealing faces of the valve are available to meet the critical area and process set up. In both cases, patented split-valve technology will ensure a closed environment at the point of transfer and throughout the handling and storage process.

		AseptiSafe®	AseptiSafe® bio
Sterilisation / Classification method	Autoclave	•	•
	Gamma	•	•
	SIP	•	•
	H_2O_2		•
Materials	Powders	•	•
	Components	•	•
Containment Performance	Without Extraction	<10 µg/m³ (OEB4)	
	With Extraction	<1 µg/m³ (OEB5)	
Cleanroom / Process Set-Up		High grade areas (e.g. Grade A/B/ISO 5)	Low grade areas (e.g. Grade D/ISO 8)

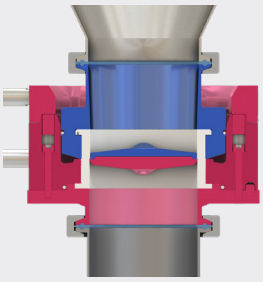


Operation Sequence

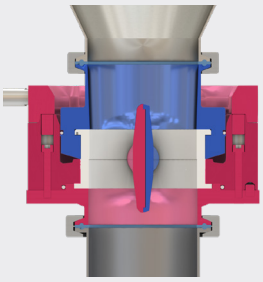
ChargePoint AseptiSafe®



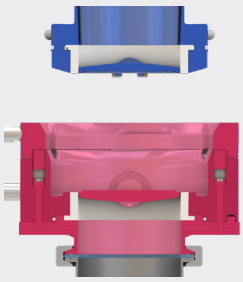
1 OPTIONAL:
The Active unit is sterilized in place (SIP) with the use of an SIP Passive unit. This step may not be required in processes that simply require a high level GMP contained transfer.



2 Two disc halves are locked in place to form a single sealed unit.
The previously exposed interfaces are now sealed together to form a single butterfly valve disc.



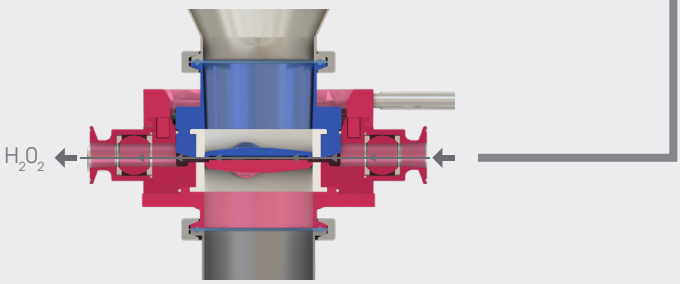
3 The Active unit is the driving half of the valve. Once operated the disc will open to allow the transfer of material through the valve. The active and Passive interface is sealed to ensure no material can penetrate the critical area. Once the transfer has taken place the valve is closed.



4 The Active and Passive units are then unlocked and undocked revealing the previously closed interfaces ensuring a clean transfer.

ChargePoint AseptiSafe® bio

The disc faces are exposed to decontamination gases within a sealed chamber prior to the product transfer to ensure decontamination of all critical areas, providing a validated 6 log reduction.

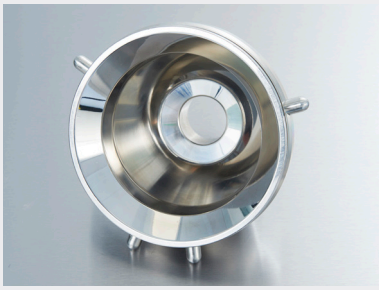


Accessories

Passive Opener

Opening device for sterilization of Passive valve within an autoclave.

SIP Passive



Local SIP (Steam In Place) sterilization of the Active unit.

GMP Cover / Plug

Protect and maintain containment of the AseptiSafe® valve.

Features & Benefits

Enhanced sterility Assurance	• Mechanical interlocks guarantee safety prior to, during and after material transfer • Possible to store product/component container under sterile conditions. • Microbiologically qualified (MBQ) • H_20_2 6 log reduction
Economic processing	• Remove requirement for large high grade control areas by maintaining critical area within valve • Possible to perform multiple, repeated transfer without the need for continuous SIP steps or re-validation. • Single use bag system eliminates cleaning and sterilization associated with rigid containers.
Easy to operate and maintain	• Simple manual or automatic operation. • Optimised sterilization cycles. • Minimum parts design for quicker maintenance.
Safer handling of potent or hazardous ingredients	• Nanogram level / OEB5 performance possible. • Independently validated according to ISPE containment performance measurement (SMEPAC) guidelines. • Maintains RABS and isolator containment integrity.
Process Versatility	Scalable technology for multiple process functions • Powder filling and dispensing • Component handling • SIP / WIP • Sampling • Process inspection (Sightglass)
Key validation features	• All materials are suitable for SIP and WFI. • All materials are suitable for use with H_2O_2 decontamination. • The system kills organisms effectively and quickly. • The decontamination phase is optimised. • The product is protected from the decontamination gases.

Specifications

			AS50	AS100	AS150	AS200
ChargePoint AseptiSafe®			•	•	•	•
ChargePoint AseptiSafe® bio	H_2O_2 Biodecontamination			•	•	
Size			DN50 (2″)	DN100 (4″)	DN150 (6″)	DN200 (8″)
Containment Performance	Without Extraction		<10 µg/m³ (OEB4)			
	With Extraction		<1 µg/m³ (OEB5)			
Autoclavable			•	•	•	•
SIP (Steam In Place)*			Up to 2.5 Bar (36 psi)			
Pressure Rating*			Up to 6 Bar (87psi)			Up to 3.5 Bar (50 psi)
Vacuum Rating*			Full vacuum			
Operation	**Manual**		•	•	•	•
	Semi Automatic			•	•	•
	Fully Automatic			•	•	•
Product Contact Material	**Body**	**316L**	•	•	•	•
	Seals	**EPDM**[1]	•	•	•	•
		FKM	•	•	•	•
		FFKM	•	•	•	•
Passivation (product contact parts)			•	•	•	•
Connection Interface	**Tri-Clamp (BS/ISO/DIN/JIS)**		•	•	•	•
	Aseptic Tri-Clamp / ASME BPE		•	•	•	•
	Other		Available to suite process / container			

*Pressure/vacuum Rated only when fitted with a suitable pressure/vacuum rated component or accessory.
[1]Check for process material compatibility with sterilisation / decontamination methods.

ChargeBag®

ChargeBag® PE-S | PE-SBV

- ChargeBag® is a cost effective and convenient single use container for the handling, storage and transfer of bio-pharmaceutical powders.
- Manufactured from HiPure ULP7, a proprietary LLDPE film from ChargePoint Technology, with extremely high levels of integrity with optimised purity.
- The statically dissipative film means ChargeBag® is also suited for use in hazardous areas.
- 100% pressure tested to verify the integrity of each bag.
- Manufactured within an ISO6 cleanroom for high levels of quality control, can be gamma sterilised ready to use in aseptic processes

ChargeBottle®

Robust rigid powder handling containers

ChargeBottle® P | P2

- 0.5L to 20L robust powder transfer containers.
- FDA compliant, Polypropylene and HDPE construction options.
- Maximise product flow and yield with optional flush port (10/20L only)

ChargeBottle® M | MX

- 1L to 20L Stainless steel containers with optional pressure rating.
- Maximise flow and yield with optional wet/dry purge port.
- Optional sightglass viewing ports.

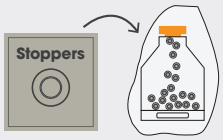
Compliance & Quality Assurance

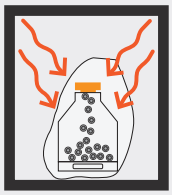
- ✓ **Designed to GMP standards**
- ✓ **FDA compliant materials**
- ✓ **Conforms to European Hazardous Area directive (ATEX)**
- ✓ **Conforms to European Pressure Equipment Directive (PED)**
- ✓ **European Machinery Directive**
- ✓ **Manufactured in ISO9001 accredited facilities**
- ✓ **Full material certification and batch traceability**
- ✓ **Independently validated according to ISPE containment performance measurement (SMEPAC) guidelines**

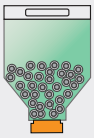
Process Applications

Aseptic Handling of Components

Batch gamma irradiation of components with ChargeBag® PE





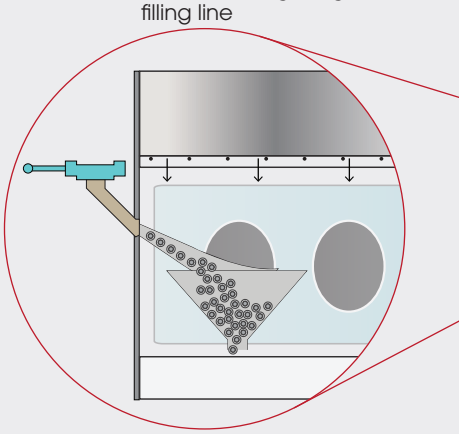


1. Components loaded into clean ChargeBag® PE and Passive is connected.

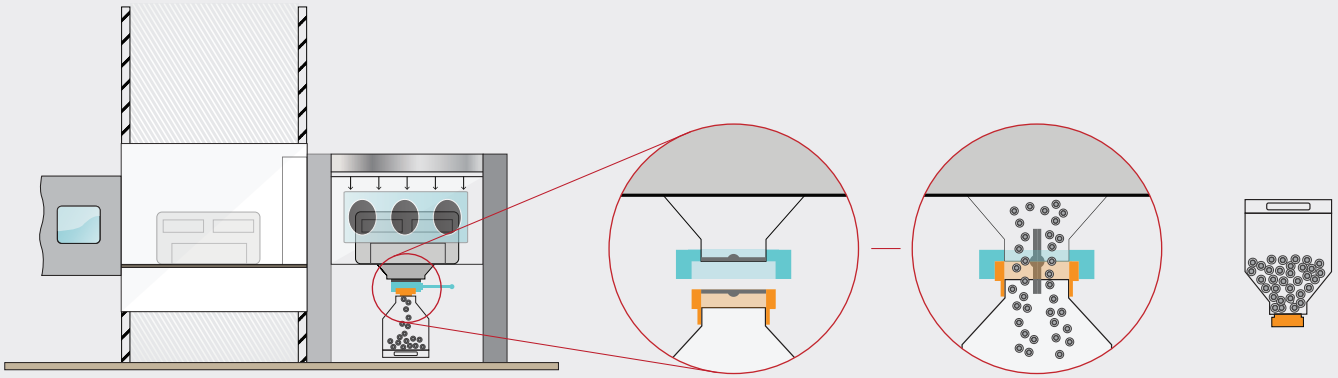
   ChargeBag® assembly is sealed within outer liner packaging

2. Gamma irradiation of ChargeBag® and valve assembly off site.

3. Outer liner removed within facility cleanroom. Transfer ChargeBag® to filling line

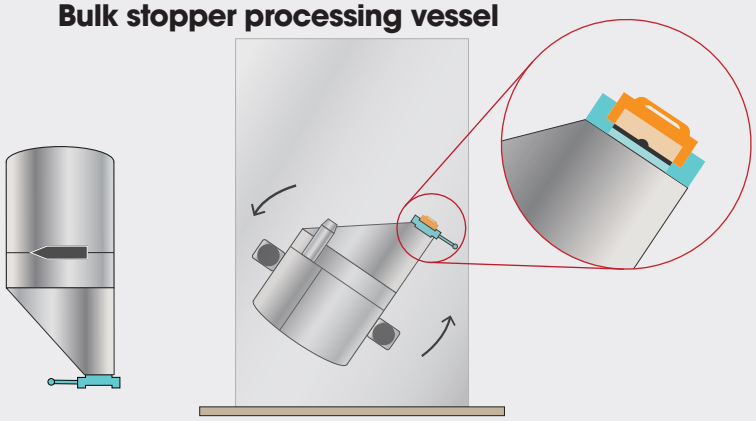


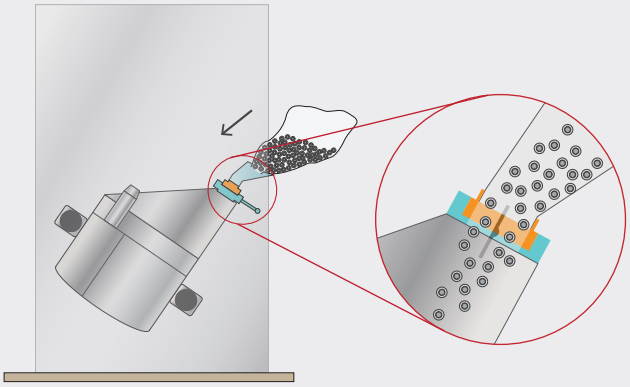
Rotary drum autoclave filling gamma sterilised ChargeBag® PE-S



1. Fill drum with stoppers and sterilise within autoclave
2. Dock Passive/ChargeBag® to Active located within RABS/LAF
3. Transfer components from drum to Chargebag®
4. Transfer ChargeBag® to filling line

Bulk stopper processing vessel

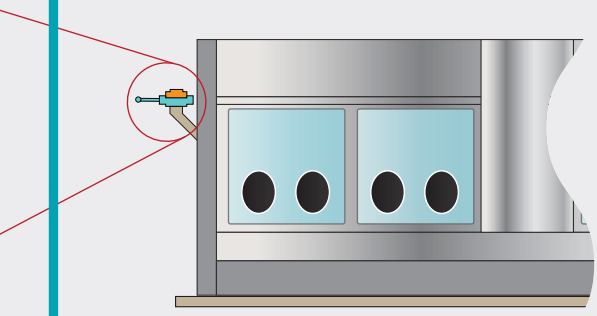




1 Fill vessel with components

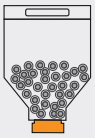
2 Seal Active/Passive with Pressure Cover for sterilisation process

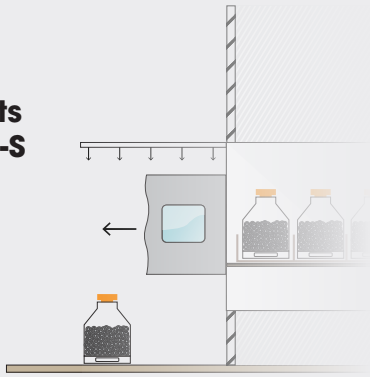
3 Transfer vessel to filling line

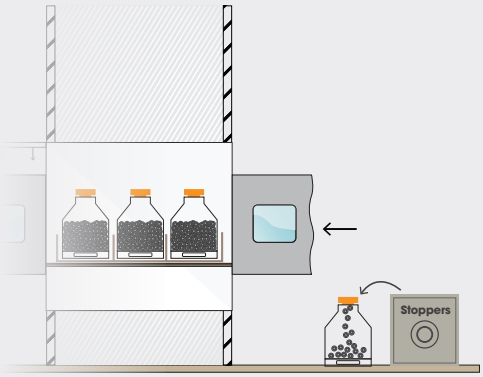


Dock vessel/Chargebag® and transfer components to filling line via RABS / Isolator

Autoclave components within ChargeBag® PE-S







1 Fill ChargeBag® with stoppers

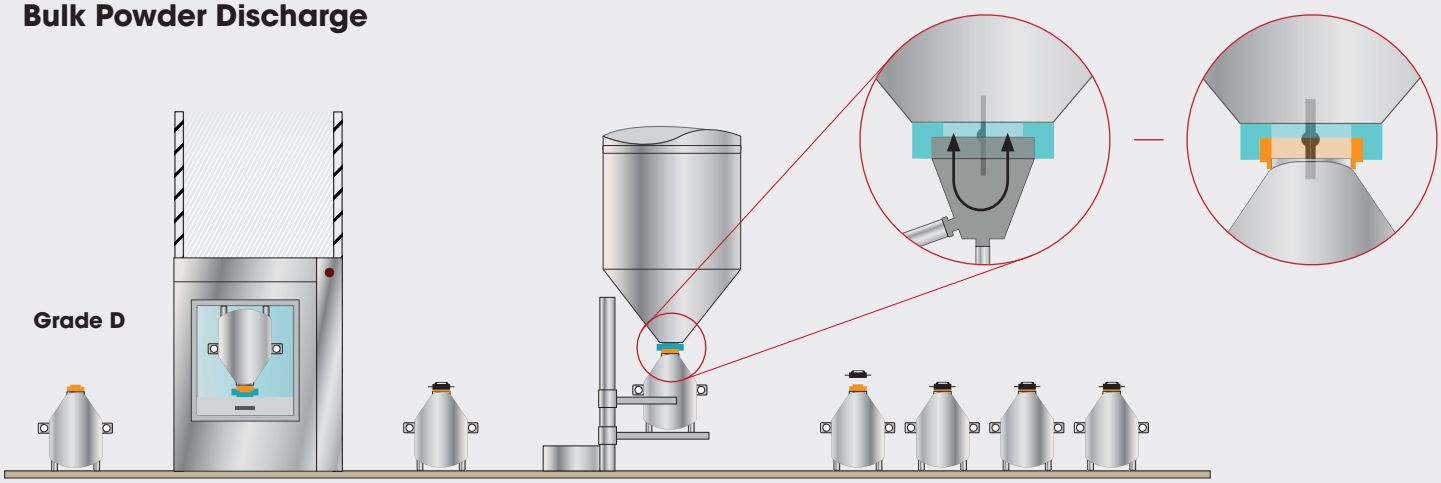
2 Place ChargeBags into autoclave with open passives for sterilisation

3 Remove the ChargeBag® and Passives and connect under RABS / LAF area

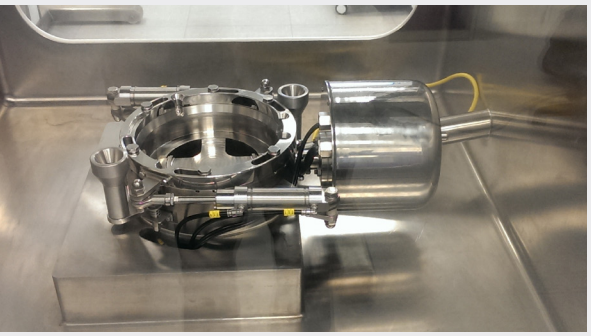
4 Transfer ChargeBag® to filling line

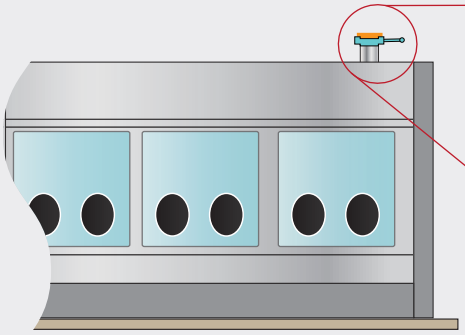
Aseptic Processing of Bulk API/Powders

Bulk Powder Discharge



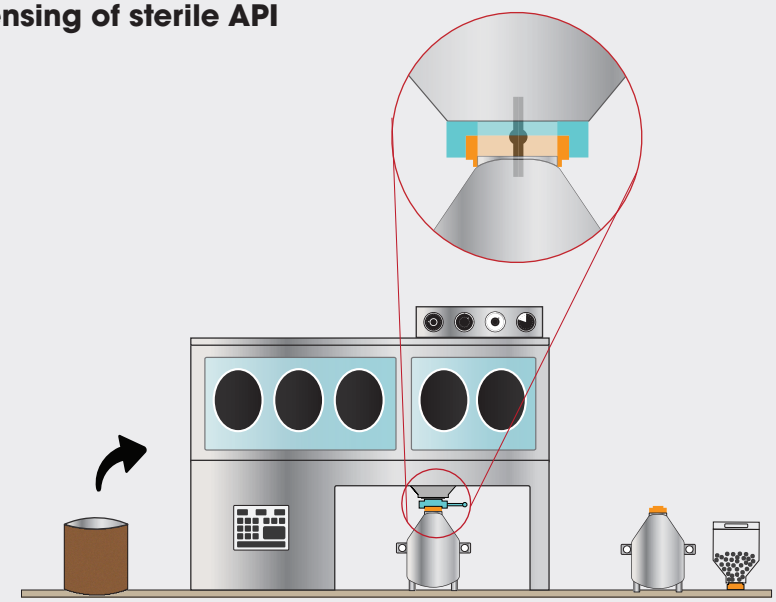
1. Autoclave sterilisation of IBC container and Passive unit.
2. SIP sterilisation of open Active valve and process machine with SIP Passive accessory.
3. Docking and discharge of powder product into container





Dock vessel/ChargeBag® and transfer powder to filling line via RABS / Isolator

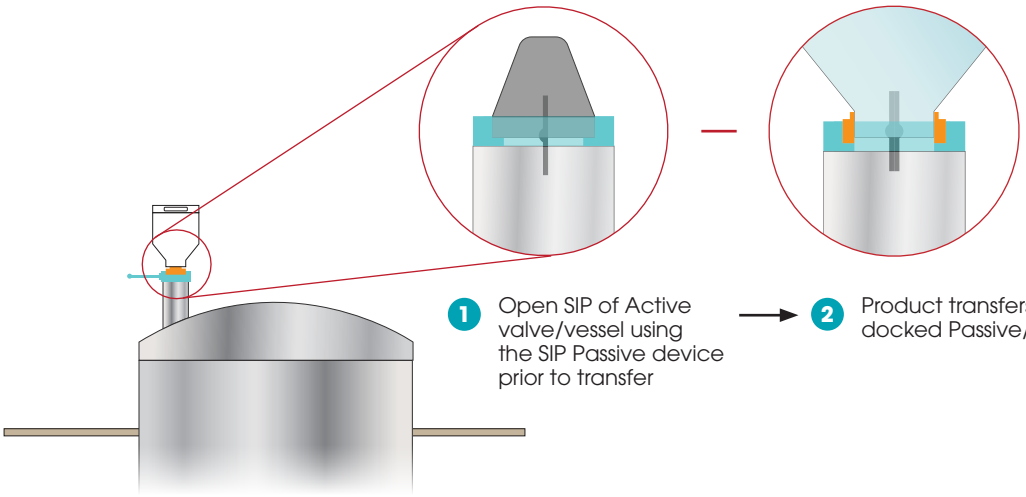
Dispensing of sterile API

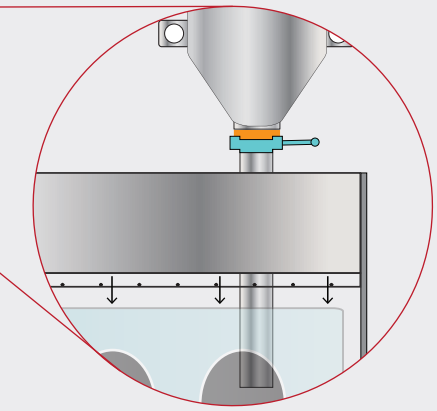


1. Sterile API loaded into Isolator
2. API weigh and dispense through valve into ChargeBottle®/ ChargeBag®
3. ChargeBottle®/ ChargeBag® transferred to powder filling line

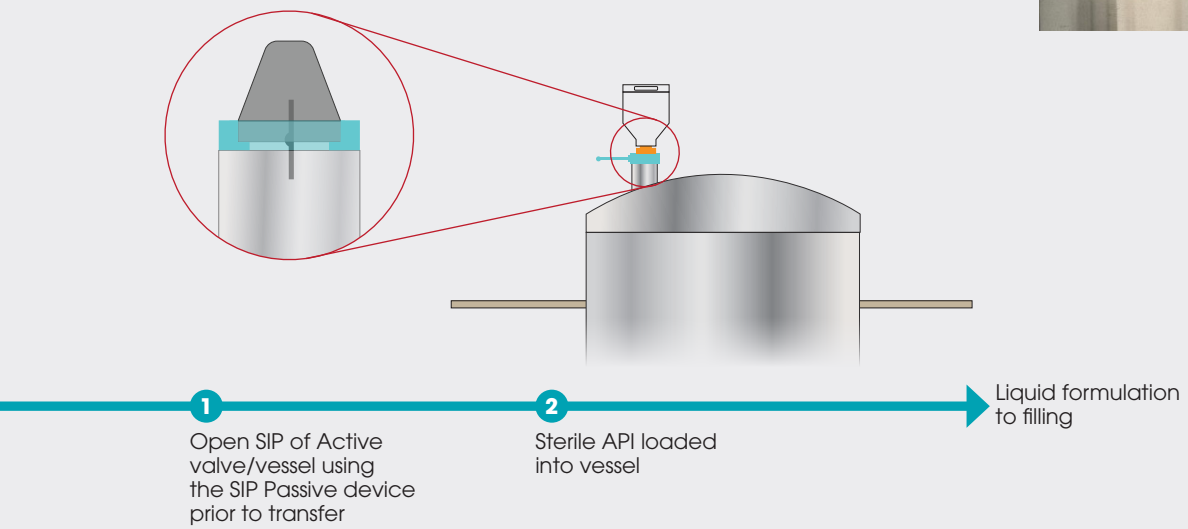
Buffer / Media Preparation

- Powder transfer to formulation and mixing tanks
- Disposable transfer ChargeBag® (gamma irradiated)
- Dust free and aseptic connection





Transfer to mixing/ formulation vessel



ChargePoint AfterCare™

Assisting you throughout the warranty period and continuing to offer our responsive support to ensure continuity of production with Onsite Service Packages, Spare Parts, Consumables and Training delivered via our dedicated support centres in Europe, North America and Asia.

株式会社 奈良機械製作所

〒143-0002 東京都大田区城南島2－5－7
TEL（03）3790－8011 FAX（03）3790－8055
https://www.nara-m.co.jp

事業所／奈良機械販売株式会社 〒532-0011 大阪市淀川区西中島3-23-15-606
TEL(06)6307-2371 FAX(06)6307-2370

Europe, Middle East, Africa & Asia

ChargePoint Technology Ltd
Venture Point Business Park
58 Evans Road, Liverpool, L24 9PB
United Kingdom
+44 151 728 4500
sales@thechargepoint.com

Americas

ChargePoint Technology Inc.
120 North Main Street, Suite 11
Forked River, NJ 08731
United States
+1 609 549 6165
USAsales@thechargepoint.com

ChargePoint TECHNOLOGY

Find your local representative online:
www.thechargepoint.com

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