



ChargePoint® AseptiSafe®

CONTAINED ASEPTIC
TRANSFER VALVES

ChargePoint®
TECHNOLOGY

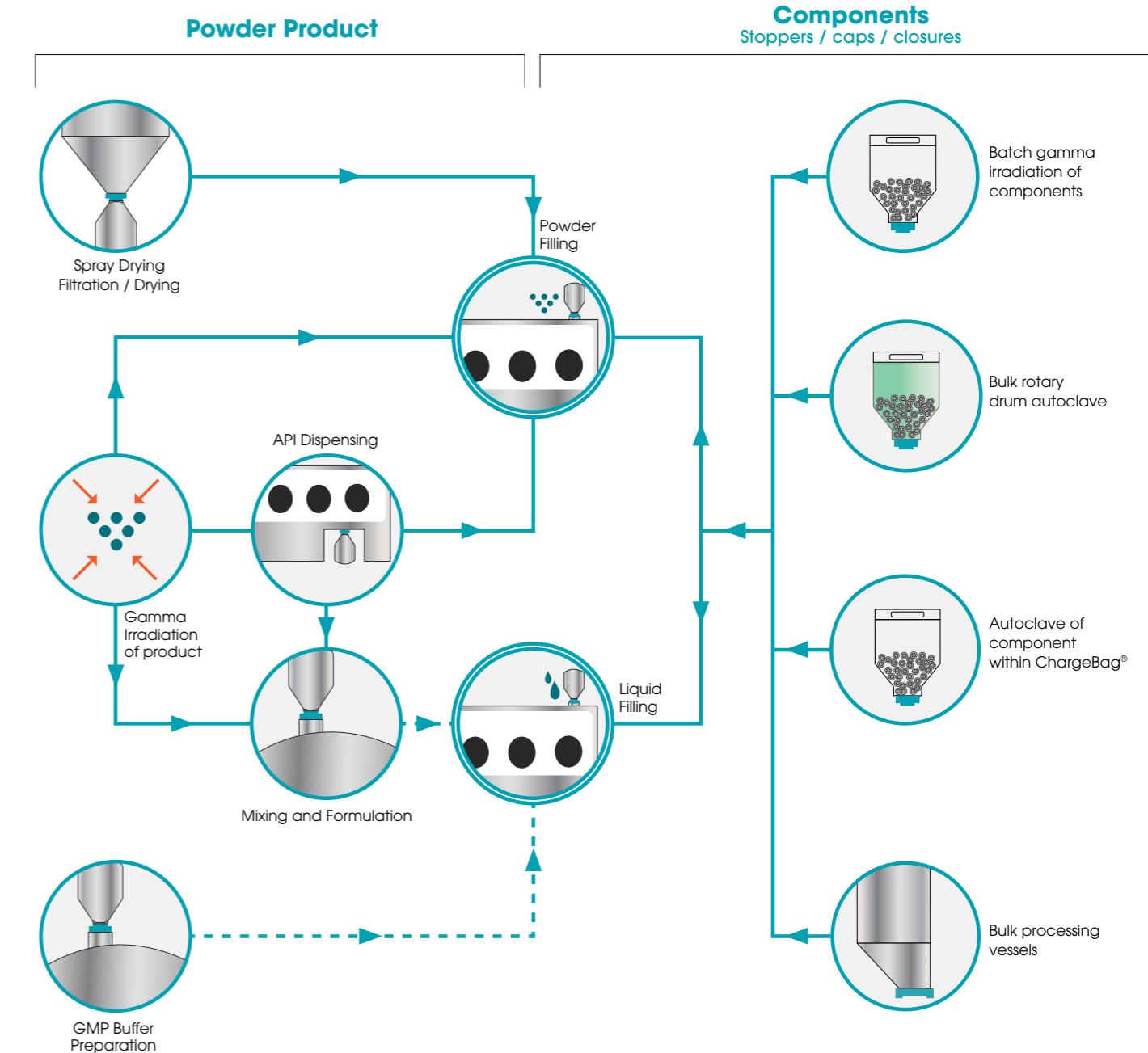
- Perform aseptic transfers that **maintain critical area integrity**.
- **Reduce risk of cross contamination** with closed transfers that limit manual intervention.
- Meet **GMP and product quality** requirements.
- **Remove high air class control areas and cumbersome PPE**.
- Process toxic powders,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



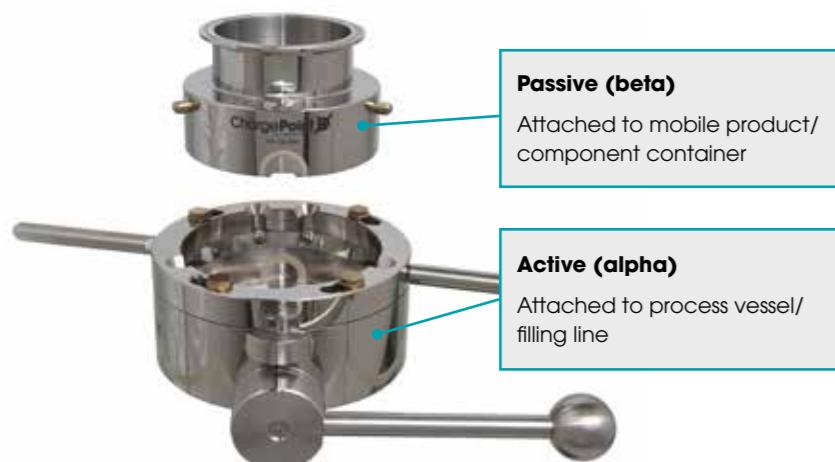
Applications

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)

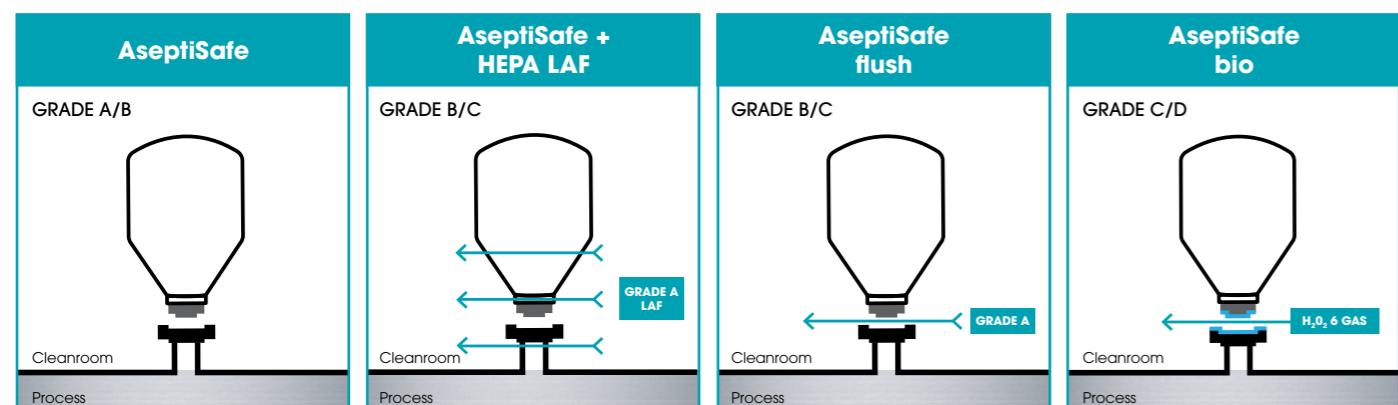
Attached to process vessel/filling line

- 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.

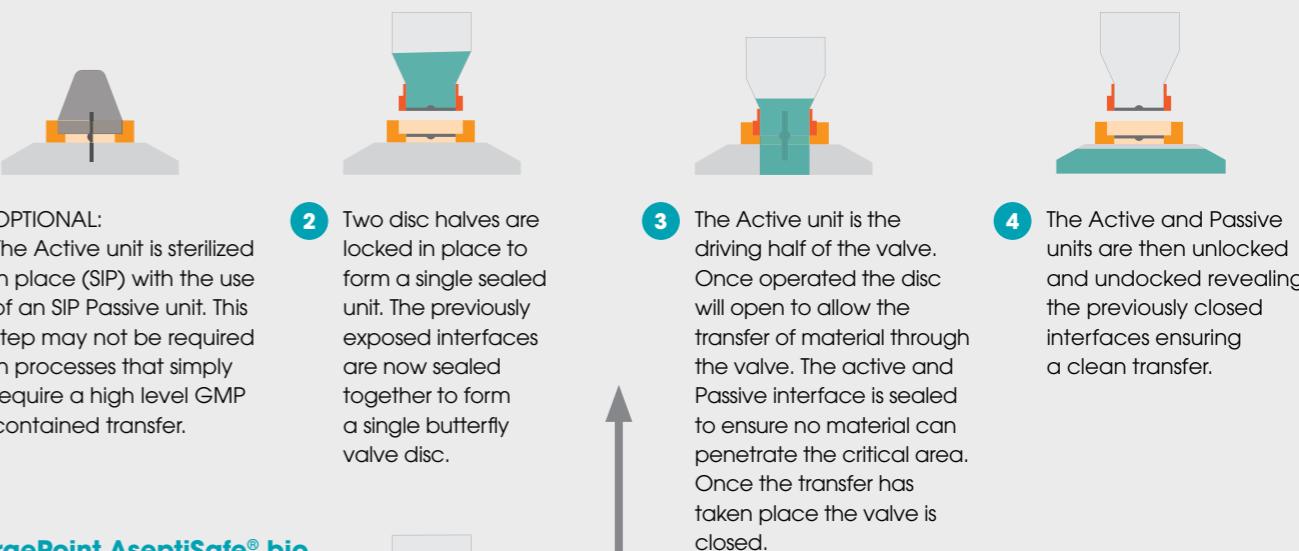
	AseptiSafe	AseptiSafe + HEPA LAF	AseptiSafe flush	AseptiSafe bio
Sterilisation / Classification method	•	•	•	•
	•	•	•	•
	•	•	•	•
		•	•	
				•
Materials	•	•	•	•
	•	•	•	•
Containment Performance (with additional extraction)	OEB5 (<1ug/m ³)	•	•	•
Cleanroom / Process Set-Up	High grade areas (e.g. Grade A/B/ISO 5)	High grade areas (e.g. Grade C/ISO 7)	Low grade areas (e.g. Grade D/ISO 8)	



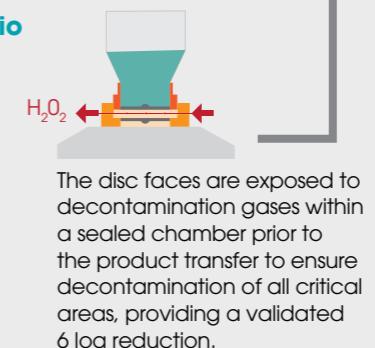
IMPROVED STERILITY

Operation Sequence

ChargePoint AseptiSafe®



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.

ChargeBag®



High integrity single use transfer bags

ChargeBag® PE

- FDA approved high performance LDPE film packed within a sealed sleeve and gamma irradiated.
- Anti-static film assists poorly flowing materials to maximize product recovery.
- Ideal for powders, RTU (Ready To Use) components and gamma irradiation sterilisation processes.

ChargeBag® RTS

- Tyvek and HDPE materials of construction for sterilisation of RTS (Ready to Sterilise) components within autoclave.
- Double packed within easy to tear sealed liners.



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)
- H₂O₂ 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 H₂O₂ decontamination.
- The system kills organisms effectively and quickly.
- The decontamination phase is optimised.
- The product is protected from the decontamination gases.

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.



Specifications

	AP50	AP100	AP150	AP200
ChargePoint AseptiSafe®	•	•	•	•
ChargePoint AseptiSafe® + HEPA LAF	Terminal HEPA plenum	•	•	•
ChargePoint AseptiSafe® flush	Integral HEPA flush		•	•
ChargePoint AseptiSafe® bio	H ₂ O ₂ Biodecontamination		•	•
Size	DN50 (2")	DN100 (4")	DN150 (6")	DN200 (8")
Containment Performance	Available from <1 µg/m ³ / 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	•	•	•
Passivation (product contact parts)	•	•	•	•
Connection Interface	Tri-Clamp (BS/ISO/DIN/JIS)	•	•	•
	Aseptic Tri-Clamp / ASME BPE	•	•	•
	Other	Available to suite process / container		

¹Pressure/vacuum Rated only when fitted with a suitable pressure/vacuum rated component or accessory.

¹Check for process material compatibility with sterilisation / decontamination methods.

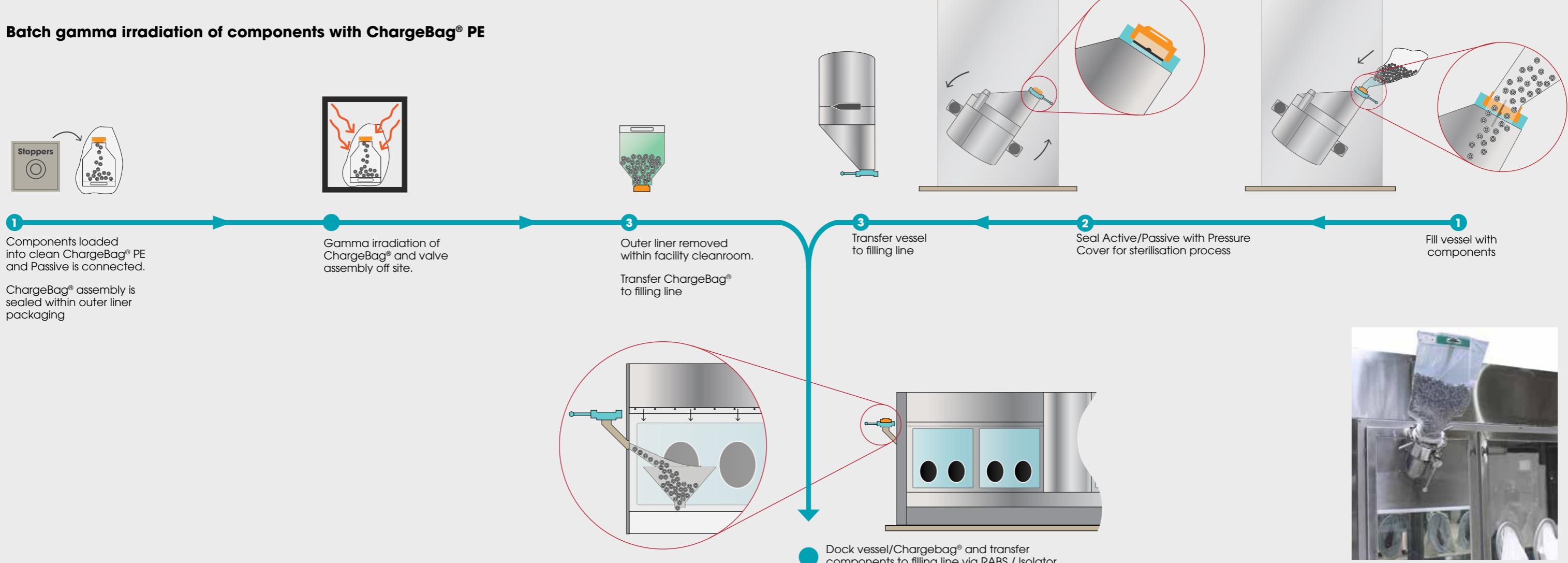
Compliance & Quality Assurance

- 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

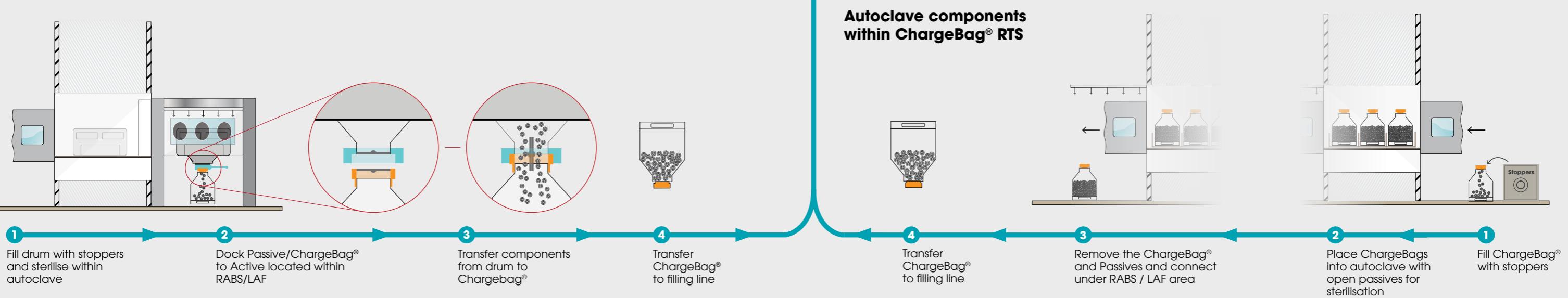
Process Applications

Aseptic Handling of Components

Batch gamma irradiation of components with ChargeBag® PE

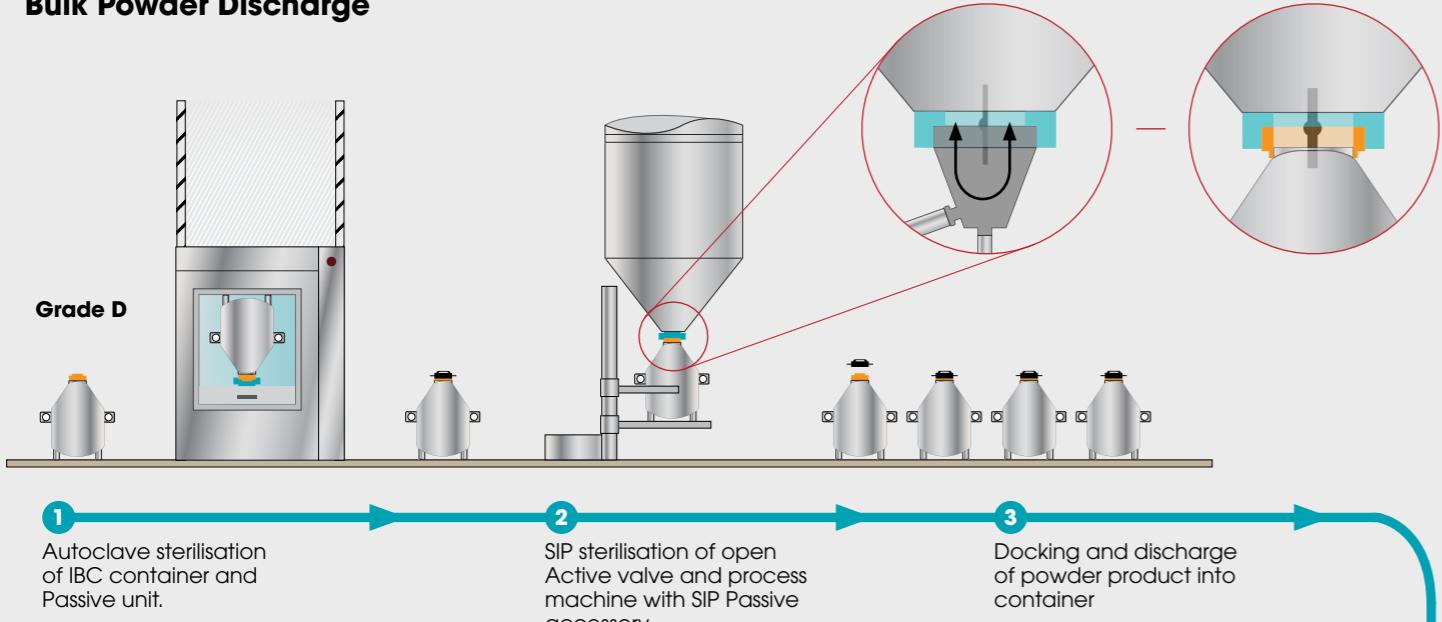


Rotary drum autoclave filling gamma sterilised ChargeBag® PE

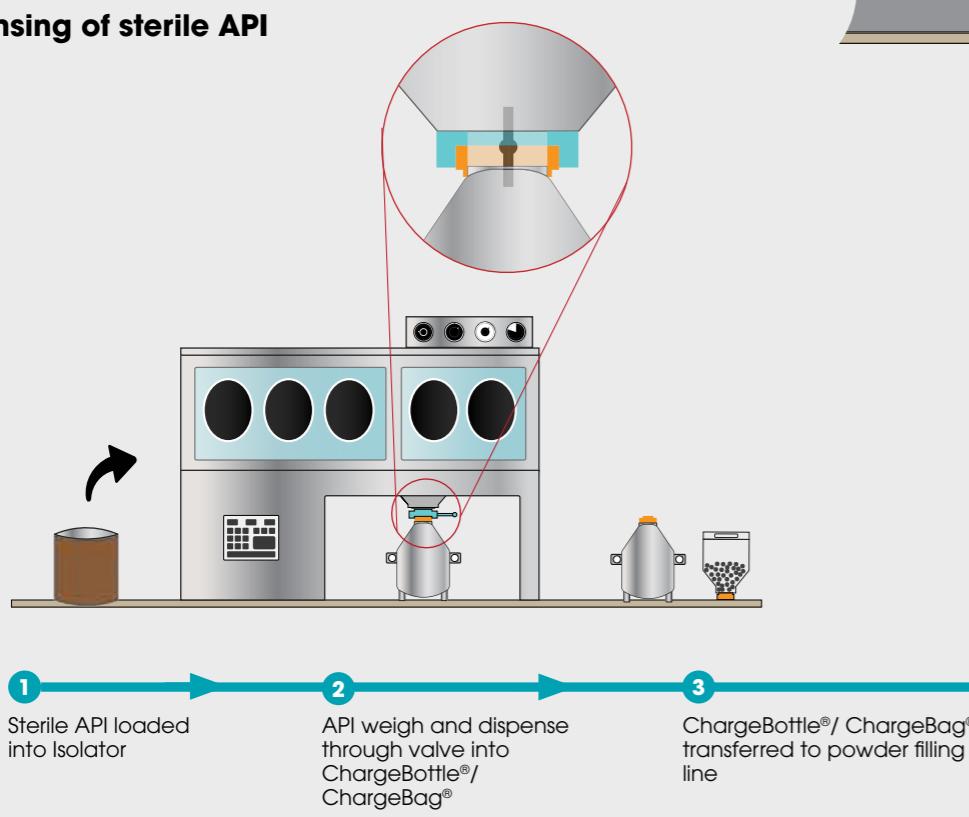


Aseptic Processing of Bulk API/Powders

Bulk Powder Discharge

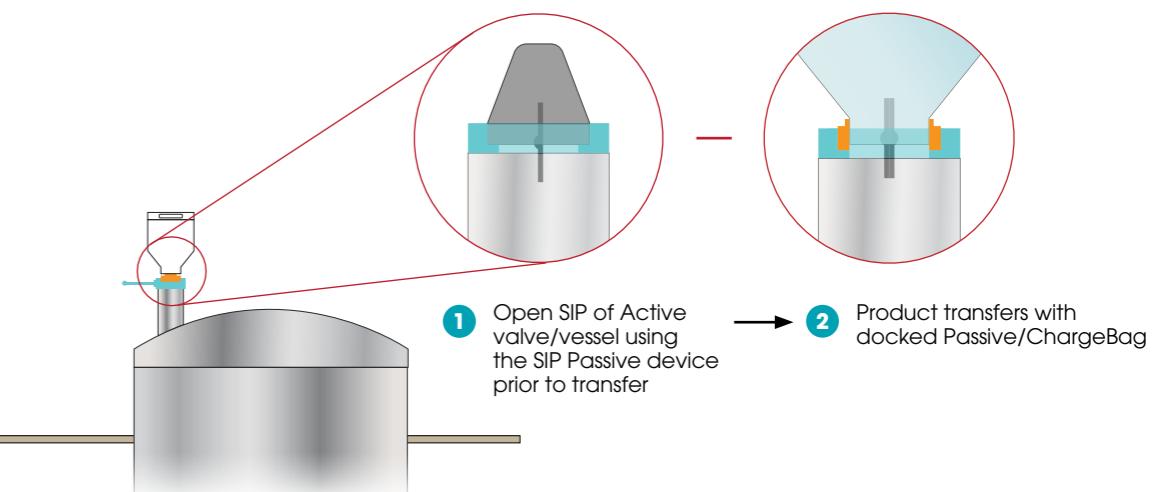


Dispensing of sterile API

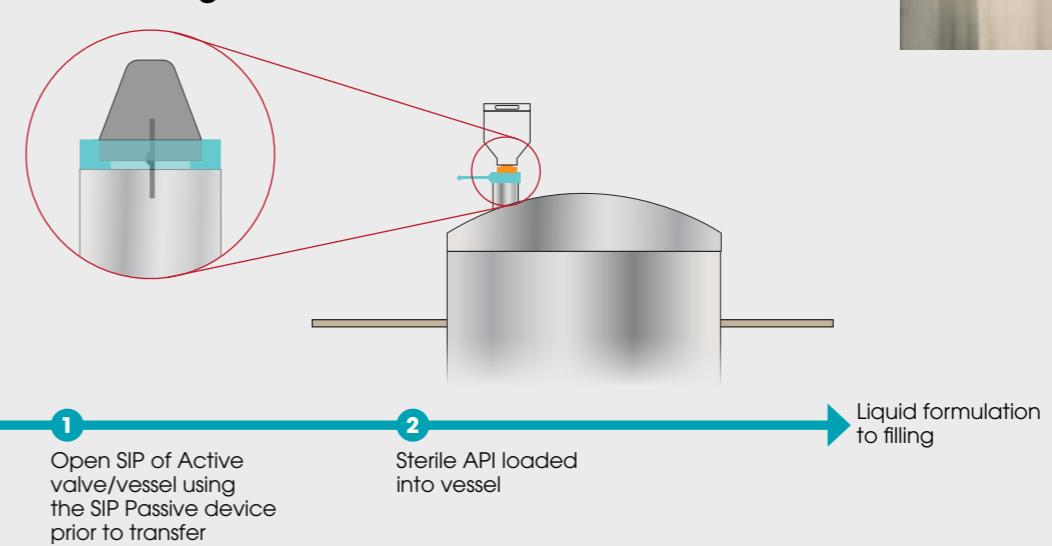


Buffer / Media Preparation

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



Transfer to mixing/ formulation vessel





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.

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