ChargePoint

PharmaSafe™

POWDER TRANSFER CONTAINMENT VALVES

- Safer handling of non-sterile bio/pharma and chemical ingredients
- Nanogram level containment performance
- R&D to pilot and production scale formulation

ChargePoint TECHNOLOGY

www.thechargepoint.com

ChargePoint PharmaSafe™

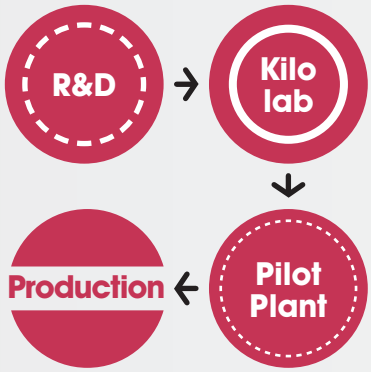
- Ensure **industry regulatory compliance.**
- Process toxic powders, ensuring the **safety of your personnel** and a **dust free environment.**
- **Reduce risk of cross contamination** with closed transfers that limit manual intervention.
- Meet **GMP and product quality** requirements .
- **Maximize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

Applications

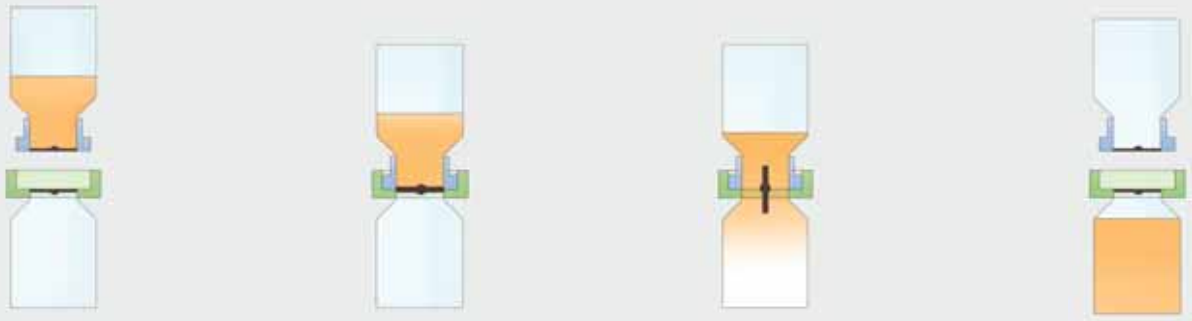
Contained filling and dispensing for all production processes.

Processes		Ingredients	Materials
Dispensing	Blending / Mixing	API	Powder
Vessel Charging	Milling	Reagents	Semi-solid
Filtration / Separation	Sieving	Intermediates	Granular
Centrifugation	Compression	Excipients	Suspension
Drying	Filling	Formulated blends	Tablets / Capsules
Sampling	Coating	Raw materials	Liquid
Mixing			
Wet/Dry Granulation			

…from R&D to full scale production.



Operation Sequence



1. The Active and Passive units are docked together. Each half of the valve consists of one half of the butterfly valve disc. Each unit is sealed and cannot be opened unless they are docked together.
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 dust free transfer.

Containment Performance

Independently validated according to ISPE containment performance measurement (SMEPAC) guidelines.

ChargePoint® PharmaSafe™

<10 µg/m³ / OEB4

High containment performance with no additional seals, vacuum or extraction required.

The entry level ChargePoint® PharmaSafe™ offers a simple, cost effective upgrade to facilitate the required GMP and containment requirements in manufacturing. The minimum part design is easy to operate, clean and maintain whilst providing outstanding entry level performance.

ChargePoint® PharmaSafe™ plus

<1 µg/m³ / OEB5

An economic upgrade to higher performance as a retrofit to existing installations or as a modular unit in facilities with multiple ChargePoint® valves.

The ChargePoint® PharmaSafe™ plus extraction ring comprises of a circular plenum arrangement which couples to the active unit and is connected to an extraction source. During the operation process the extraction process is run to ensure that any airborne particulate is safely taken into the extracted air stream.

ChargePoint® PharmaSafe™ excel

<0.7 µg/m³ / OEB5

Advanced performance to low nanogram levels in a compact efficient split valve.

The ChargePoint® PharmaSafe™ excel incorporates purge and extract connections on the Active Unit. During the undocking step a sealed gap is created between the Active and Passive interface. A purge and extraction process is run to remove traces of particles that can potentially become airborne once the valve is fully undocked.

ChargePoint PharmaSafe™

Features & Benefits

Optimum seat design	Each ChargePoint® seat is manufactured within a precise tolerance to ensure an optimum level of performance: • Repeatable performance over lifetime of equipment • Guaranteed interchangeability of seats between Active and Passive units. • Easy manual operation even with larger valve diameters
Metal to metal disc seal	No additional solid or inflatable seals ensure a simple GMP design • Reduced risk of damage or product trap that could compromise containment integrity • Minimal parts for easier and lower cost maintenance
Single body design	A single piece robust design with minimal parts • Easier maintenance • Longer lifetime trouble free performance • Passive seat can be removed manually in seconds.
Secure pressure / vacuum rated system	A unique method of achieving a pressure seal • Charge/dispense under pressure or vacuum with the valve open. • Additional benefits for powder flow, a reduction in seal wear and ease of operation even at larger valve dimensions when compared to other split valves.
Safety Interlocks	Safety for the process and personnel • The Active and Passive units cannot be opened when they are not docked together. • The Passive unit cannot be accidently removed from the Active unit when the valve is open.
Process Versatility	Can be utilized for multiple process functions • Product charging / dispensing • WIP / CIP • Sampling • Process inspection (Sightglass)
Small Footprint	The ChargePoint® valve retains a compact footprint throughout the size ranges with no need for an extended handle to operate the valve manually.

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**

ChargePoint TECHNOLOGY

Specifications

			PS50	PS100	PS150	PS200	PS250	PS300
ChargePoint® PharmaSafe™	< 10 µg/m³		•	•	•	•	•	•
ChargePoint® PharmaSafe™ plus	< 1 µg/m³		•	•	•	•		
ChargePoint® PharmaSafe™ excel	< 0.7 µg/m³		•	•	•	•		
Size			DN50 (2″)	DN100 (4″)	DN150 (6″)	DN200 (8″)	DN250 (10″)	DN300 (12″)
Pressure Rating*			Up to 6 Bar (87psi) Option for 10 Bar (145 psi)		Up to 6 Bar (87psi)	Up to 3.5 Bar (50 psi)	None	
Vacuum Rating*			Full vacuum					
Operation	**Manual**		•	•	•	•	•	•
	Semi Automatic			•	•	•		
	Fully Automatic			•	•	•	•	•
Product Contact Material	**Body**	**316L**	•	•	•	•	•	•
		Alloy 22	•	•	•	•	•	•
		POM (Passive only)		•	•	•		
	Seals	**EPDM**	•	•	•	•	•	•
		FKM	•	•	•	•	•	•
		FFKM	•	•	•	•	•	•
Connection Interface	**Tri-Clamp (BS/ISO/DIN/JIS)**		•	•	•	•	•	•
	PN6/10/16		•	•	•	•	•	•
	ANSI		•	•	•	•	•	•
	Other		Available to suite process / container					

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

Cleaning & Washing

The ability to effectively clean or wash the product contact and sealing areas of a ChargePoint® valve is assured with the use of our specifically designed Wash In Place (WIP) devices.

- Suitable for cleaning within an autoclave.
- GMP design specifically considered for effective cleaning.
- Local WIP of the Active valve product contact and sealing surfaces in place.
- Remote WIP of the Passive valve and connected containers including IBC wash stations.
- ATEX rated designs.

Handling & Automation

Systems to ensure safe operation in hazardous or inaccessible areas or where the production scale does not permit manual handling:

- Manual or automated valve operation and docking.
- Proximity sensors
- Control systems
- Repeatable and safe alignment of equipment in conjunction with lifting hoists and docking systems.
- Reduced weight versions.
- GMP covers to protect the valve while not in use.

Also available - our range of high integrity single use transfer bags and robust containers.

ChargeBag® & ChargeBottle®

ChargePoint TECHNOLOGY

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.

Europe, Middle East, Africa & Asia
ChargePoint® Technology Ltd
80 Venture Point West, 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 08721
United States
+1 609 549 6165
USAsales@thechargepoint.com

Find your local representative online:
www.thechargepoint.com

THE QUEEN'S AWARDS FOR ENTERPRISE: INTERNATIONAL TRADE 2012