ChargePoint AseptiSafe® Case Study

GMP Upgrade for Sterile Stopper Handling

CUSTOMER: CSPC Pharmaceutical Group Limited

LOCATION: China

INDUSTRY: Pharmaceutical

DATE: 2011

PROJECT REF: 75765

PARTNER: Austar

PRODUCTS:

ChargePoint AseptiSafe® - Aseptic Transfer Valve

SIZE: DN150 / 6"

ACCESSORIES: SIP

BACKGROUND:

In 2011 the State Food and Drug Administration of China (SFDA) published a revised version of the GMP regulation. Hence, all new and upgraded manufacturing facilities will need to comply with these requirements with strict deadlines for existing manufacturers of sterile products.

The client needed to upgrade their facility to meet GMP requirements for closed handling of vial stopper components from an autoclave to a filling line. The room background classification was a Grade B which means the critical area handling must be maintained under sealed conditions once sterilised.

Due to the confined space available, it was deemed unfeasable to introduce additional RABS and air handling systems.

THE CHARGEPOINT SOLUTION:

Requirements	Solution
Fully sealed system to maintain critical area integrity with Grade B background.	ChargePoint AseptiSafe® valve is pressure rated capable of maintaining seal under SIP processes. The valve will maintain a dust tight seal prior to, during and after the transfer.
The system can be cleaned in-line via SIP, and must be suitably pressure resistant.	The valve and IBC product contact surfaces can be cleaned in-line via CIP and / or SIP processes.
The transfer system should not damage the stoppers and produce loose particulate.	The area for product flow is maximized via a thin disc profile. All surface finishes are ≤0.4µm.
Easy operation.	Manually operated valves were specified which keeps the handling process simple. For the lifting a hoist was implemented to assist the docking of the IBC to the Active valve.
Reduce the amount of transfer batches by increasing the volume of the batch transfer without compromising flow of components.	The customer utilizes a 140L IBC, which can fill 10,000 stoppers. The 150mm bore valve is capable of transferring these stoppers successfully.
Compact, space efficient solution to minimize impact on small production space.	The small space required to install the ChargePoint AseptiSafe® solution ensured a simple space efficient retrofit.

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CUSTOMER BENEFITS:

- Reduce the manual intervention compared to the former technology, hence lower the contamination risk.
- Increase the volume of each batch, and therefore reduce the frequency of each transfer. This in turn lowers the contamination risk and complications of handling.
- Use limited space.
- The equipment can be cleaned and sterilized in-line.
- Compared to RABS, the system has lower risk, and offers easy validation.

Transfered stoppers

ChargePoint AseptiSafe® Valve

Stopper discharge from autoclave

Stopper feeding into filling line

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