

Case Study – Aseptic Transfer and Material Handling Application

Dynamic Design Pharma (DDP) has successfully completed a complex aseptic transfer and material handling isolator project for a major pharmaceutical manufacturer. The project's objectives were to resolve a number of operational issues with their current isolator system.

Process Flow

The customer's process flow requires the aseptic transfer of delicate components, including glass vials, from a Biological Safety Cabinet (BSC) to a VHP decontaminated isolator. While inside the BSC, the VHP decontaminated RTP canister is opened and the steam sterilized components placed inside. Once resealed, the RTP canister is moved from the BSC to the isolator where it is docked to a standard RTP alpha port. The parts are then transferred from the RTP canister to the isolator chamber for further processing.

Challenges with the existing equipment

The primary concern with the operations described above were the inevitable tumbling of the process components and vials inside the RTP canister upon docking to the RTP port.

Additional concerns were the limited safety of physically moving the sealed canister from the BSC to the isolator system and the difficulties experienced by the operator in removing the beta door while the canister is positioned inside the BSC.

DDP's solution to the challenges

Dynamic Design Pharma (DDP) resolved the parts tumbling issue by integrating its proprietary Non-Rotating Canister (NRC) technology into the process.

The NRC allows docking to the RTP port of the isolator or RABS system without rotating the canister body. A tray, securely attached to the canister body via a shuttle mechanism, holds the parts securely within the canister thus preventing unwanted movement during canister docking. The VHP compatible shuttle mechanism design is such that all outer surfaces are exposed to the VHP gas during the decontamination process.







The concern with the safe movement of the canister within the filling room was addressed by providing a custom lift and transport device to support the NRC at all times during the process. The lift positions the NRC into precise alignment to the RTP port of the isolator during the docking sequence and supports the NRC while inside the BSC. To accommodate the elevation difference between the isolator and the BSC, the lift includes a vertical position adjustment. In addition, the NRC is attached to the lift via a horizontal swivel to accommodate NRC orientation requirements during the two phases of the process.

Having the NRC rigidly mounted to a lift while inside the BSC also permitted the implementation of a beta door removal system that permits a single operator to reliably and safely remove the beta door of the NRC while inside the BSC.

Conclusion

The NRC technology was at the heart of the technical solutions described above. This versatile technology enables to resolve the difficulties encountered with the aseptic transfer of delicate components and even more so especially when combined with the custom development capabilities of Dynamic Design Pharma,

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	<p>←</p> <p>NRC, permanently attached to the Lift, in the orientation required for docking to the isolator system.</p>	
	<p>→</p> <p>NRC, pivoted to the orientation that permits insertion into the BSC and for operator access to contents</p>	
	<p>→</p> <p>NRC, inside the BSC, with the beta door removed and self supported by the removal tool.</p> <p>Tray is shown inside the NRC and self supported by the shuttle mechanism.</p>	
	<p>←</p> <p>NRC shown with the tray extended and available for easy load/unload of components.</p>	
	<p>→</p> <p>VHP compatible shuttle mechanism, shown with tray disconnected (for visualization purposes only).</p>	