

Cold Storage / Transport

The Challenge

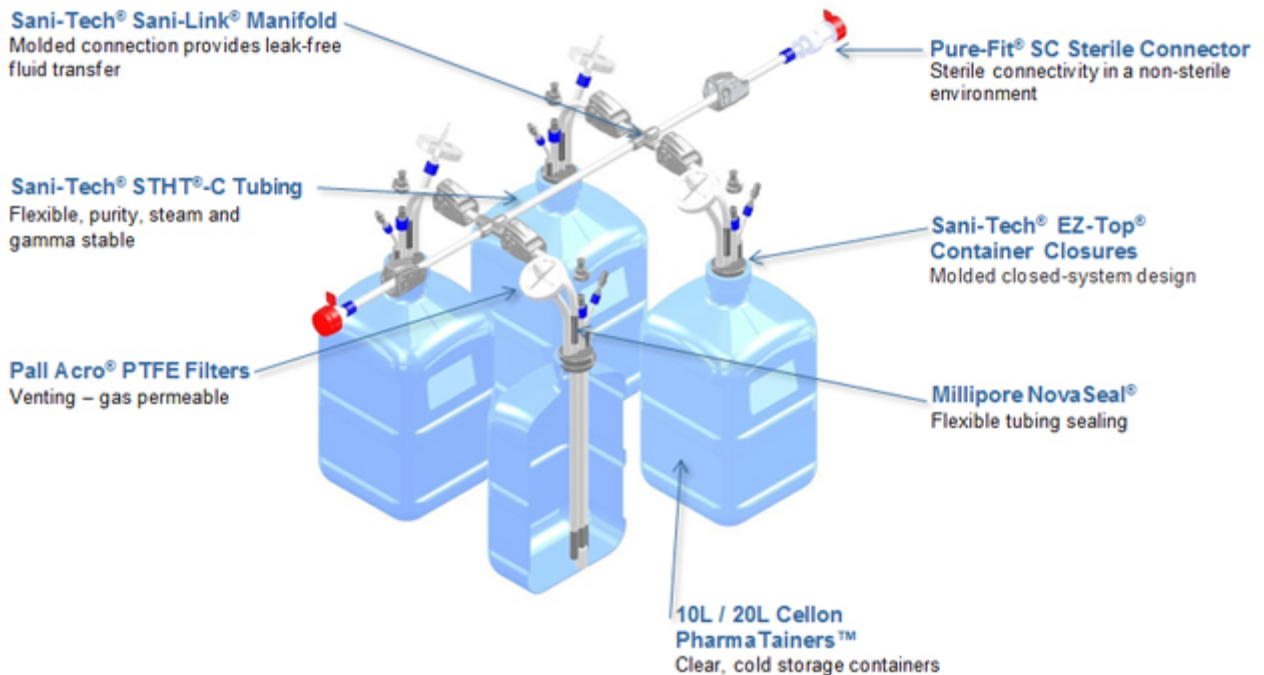
A monoclonal antibody developer was systematically collecting bulk drug substance (BDS) in an open top polycarbonate (PC) carboy prior to delivery to drug product site. Upon initial receipt of the new containers, the developer would clean in-house to remove all visible loose particulates and then autoclave before collection. Their BDS containment task force realized the potential risk associated with using their existing open-system design and sought out a supplier to develop a fully integrated closed-system. This system would be subjected to a low of -70°C at initial freeze/transport and then thawed to a 22°C. The desired single-use system materials must be suitable for gamma irradiation and delivered to the customer for aseptic BDS collection. The customer implied risk was extremely high during this BDS storage and transport phase of bioprocess. The single-use system must provide the very best in product integrity assurance.

The Saint-Gobain Collaborative Design Services' Solution

Saint-Gobain Design Services met with this developer to create a closed single-use system that was most appropriate for their application. Several container materials and suppliers were proposed in consideration of the BDS storage and transport requirements. The developer selected their desired materials of construction based on their planned cold storage and transport conditions. The new sterile single-use system met this criteria in addition to no visible particulate matter per USP <788> along with a low endotoxin level following USP <85> guidelines.

Customer Experience

Customer engagement was excellent during this development and built on our business relationship at all levels within their organization. Saint-Gobain has since been recognized as a key supplier for their organization that spans the globe.



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