Over the past decade the adoption of single-use technologies has moved beyond upstream processes to bulk and filling applications. One example of integrating single-use systems in a final fill operation is to simplify connections to mobile stainless steel transfer tanks. These tanks are designed to transfer product from formulation suites to storage areas and ultimately to filling suites. To allow sterile connection to and from these vessels, designers traditionally add three-way valve assemblies to fill and drain ports to facilitate SIP operations, but the design of these valve assemblies makes it difficult to validate cleaning procedures. Replacing these heavy assemblies with single-use tube sets and connectors will eliminate cleaning validation and maintenance.

Single-use tubing assemblies can either be attached to the mobile tanks prior to equipment sterilization with single-use SIP connectors, or steamed separately, just prior to fluid transfer. For vessel outlet, combining a number of single-use components into the transfer line can create a robust system to ensure product safety. For example, outlet transfer lines can incorporate a single-use SIP connector to attach to the sterile holding tank. Then, a “through-the-wall” fluid transfer system is used to bring a portion of the transfer line into the filling suite. Next, a sterile connector is used to attach the transfer line to a separate portion of the transfer line that has already been steamed onto the filling machine with a single-use SIP connector. Finally, a quick disconnect coupling validated as an aseptic disconnect enables the processor to confidently make an aseptic disconnection of the transfer line from the storage vessel when the process is completed. Integrating single-use technologies into the bulk and final filling operations eliminates expensive cleaning validation, facilitating faster product changeover and providing greater manufacturing efficiencies.

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