A DEEP DIVE INTO THE PROCESS OF DESIGNING AND DEVELOPING A SINGLE-USE ASEPTIC CONNECTOR

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With the rapid adoption of single-use products over the past decade, connections have become more and more critical to biopharmaceutical applications especially as the applications move into commercial applications. As a result, there have been a drastic increase in opportunities to close the process with the utilization of aseptic connectors. Currently, there are a lot of connector options in the market and each have their own promoted benefits that end users can evaluate. But what is seen in the market is just the finished product and does not tell the story of the process it takes to develop a high quality connector that fits the end user needs.

Though connectors can seem minor when compared to a large single-use bioreactor bag or a pleated, sterile filter capsule there is still a lot of work that is needed to develop a robust, aseptic connector. Several of the items that can go into the design of the connector can be:

- Design functionality of the connector
- Materials selection
- Injection molding design and process optimization
- Prototyping
- Effects of sterilization
- Risk assessments (FMEA's)
- Process validation
- Functional testing

This presentation will dig deeper into the process of designing and developing a connector. Though this presentation will use aseptic connectors as a case study, most of this information should apply to any single-use component that involves molding and assembly. This will not be a commercial presentation to try and lean the audience to a certain company's technology, rather its goal will be to help educate the audience into what goes into developing a connector and considerations and obstacles that a manufacturer will encounter.