Achieving a Greater Assurance of Integrity of Single-Use Systems

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As single-use technologies are maturing and as they are more and more implemented in GMP manufacturing processes, there is an increasing need for integrity assurance of single-use systems (SUS). This presentation will provide an overview of the latest issued guidance, the recommended approaches, and the available solutions to mitigate the risk of losing the integrity of SUS.

We will develop a case study around the life cycle of a SUS for a biopharmaceutical critical application. Based on the risk assessment of the different steps of this life cycle, we will present the mitigation strategy consisting of a very sensitive helium integrity test at the SUS supplier and a true *in-situ* point-of-use leak testing of the SUS at the drug manufacturer. The sensitivity levels, applicability and benefits of this two-step approach for integrity assurance will be detailed.