

CASE STUDY: DEVELOPMENT OF A HELIUM-BASED SUPPLIER INTEGRITY TESTING METHOD FOR SINGLE-USE SYSTEMS (SUS) INTEGRATED INTO A GLOBAL CONTAINER CLOSURE INTEGRITY (CCI) STRATEGY

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With the adoption of SUS in more critical process steps of cGMP commercial production, bag integrity failures can affect patient and operator safety and process economics. As a result, there is a growing regulatory scrutiny and industry requirement for integrity testing at both the supplier and end-user.

The presentation introduces an integrated CCI strategy for SUS based on Quality by Design (QbD), Quality Risk Management (QRM), process validation, in-process controls, supplier integrity testing and end-user point-of-use leak testing.

The author will outline a case study on the development of a highly sensitive helium integrity test capable of detecting 2µm pinholes in final single-use bag, tubing and connector assemblies after production. The sensitivity, reproducibility and accuracy of this method are detailed as well as the relevance of the detection limit to the required level of closure integrity. The results of a bacterial challenge test study that can be correlated to the detection of the helium test will also be presented.