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Container Closure Integrity (CCI) for single-use systems (SUS): Regulatory trends, challenges and technology transfer of test methods

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CONTAINER CLOSURE INTEGRITY (CCI) for SINGLE-USE SYSTEMS (SUS): REGULATORY TRENDS, CHALLENGES AND TEST METHODS

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Single-use fluid management solutions are being applied in critical downstream and final filling applications including applications requiring container closure integrity testing. Single-use bags are increasingly used for the storage, mixing, shipping, freezing of drug substances and drug products. Since single use bags are migrating towards more critical process steps and applications, there is a growing regulatory scrutiny and industry requirement for testing the containers in order to guarantee their integrity and their sterility before their use in commercial production processes.

This presentation will consider the regulatory trends for Container Closure Integrity of single-use systems with a focus on the proposed revision to USP<1207> *Sterile Product Packaging – Integrity Evaluation* and the challenges for vendors and users in the implementation of single-use systems in critical applications subject to container closure integrity testing.

The presentation will show a case study of the development of two different non-destructive test methods, one being a Helium test method at supplier, the second one being a point-of-use pressure decay leak test method. The sensitivity, reproducibility and accuracy of each method are explored as well as the relevance to the required level of closure integrity.

All through the presentation, the emphasis will be given on container closure integrity as a concern throughout the product life cycle from its development, validation and manufacturing phase at supplier to its intended final use.

An analysis of the defect type expected at each step of the life cycle of a flexible bulk container is presented as well as a proposed implementation strategy for these test methods to manage the risks of defects.

Figure 1 – System for Point-of-Use Leak Test