PALL Biotech

Integrity of Single-Use Systems

New ASTM Standard Practice for Integrity Assurance and Testing of Single-Use Systems

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Introduction

At the beginning of May 2020, a new ASTM International standard practice on integrity of single-use systems (SUS) was published. This document, “E3244 – 20: Standard Practice for Integrity Assurance and Testing of Single-Use Systems”[1], is the outcome of several years of collaboration of about 30 people from the ASTM Committee E55 on Manufacture of Pharmaceutical and Biopharmaceutical Products, gathering SUS suppliers, end users and FDA.

Scope of the ASTM Standard Practice

This standard practice provides useful recommendations on how to manage integrity of SUS, with an approach following quality by design (QbD) and quality risk management (QRM) principles. Integrity assurance is associated in this document to microbial integrity and bioburden control (risk to product quality) as well as liquid product loss (risk to operator and environment).

Content of the ASTM Standard Practice

The ASTM practice recommends performing the risk assessment by following a holistic end-to-end approach, based on the life cycle of the SUS, from the first manufacturing steps of the SUS until its disposal. This end-to-end approach requires close communication and collaboration between the supplier and the end user.

The practice covers the different elements to take into consideration when building and maintaining an adequate integrity assurance of the SUS, defining precise user requirements as a starting point.

It also covers the challenges in setting up the requirements for integrity, explains why a "one-size-fits-all" standard doesn't exist, and why different controls and methods are likely to be applied at different stages of the development (design, qualification, validation, commercial production). In addition, it emphasizes the need for in-depth communication between supplier and end users, when applying a QbD approach in qualification or defining suitable testing parameters to meet the user requirements.

Finally, the document provides an extended overview of the test methods best suited to evaluate the integrity of the SUS, at development, validation, or routine use stages:

- Several microbial ingress test methods, generally used as initial validation test. It is highlighted that relevant challenge conditions should be used to cover the intended application and that overchallenging should be avoided.
- Two categories of physical test methods:
    - Pressure based tests
    - Tracer-gas based tests, in vacuum mode

Main challenges associated with these methods and critical points which should be considered are also covered in the document.

By focusing on SUS, this ASTM standard practice provides an interesting complement to USP <1207>, that explicitly excludes "packaging systems and processing equipment used in the preparation, storage, and manufacture of sterile pharmaceutical products"[2].

References

[1] Can be bought on ASTM International website: https://www.astm.org/Standards/E3244.htm

[2] USP <1207>, Package Integrity Evaluation - Sterile Products

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