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Challenges in implementing validation testing of the sealing process

Introduction:

In recent years the Central Sterile Supply Department (CSSD) in Brazil, presented a breakthrough in the technology park. Since 2012, ANVISA, a local regulatory agency, published the RDC 15, which addresses the requirements of good practice for the processing of health products, in order to guide and standardize the activities in CSSD. The attention of staff who works in CSSD was aimed at challenging articles, difficult to clean, and performance of the steam sterilization in which the daily qualification tests and the annual thermal validation are performed. With the new standards, the need arises to perform qualification testing and validation of cleaning equipment, such as washers, in addition to assess cleaning efficacy tests in articles and in sealing machines. Aim: Describe the challenges after the implementation of sealing process validation with Seal Check, based on experience report and ISO11607-2 standard for meet Seal Check validation test requirements.

Method

It was used the Seal Check, that was standardized as an eventual monitoring test, and all information about installation, operation and performance of sealing machine was used in order to validate the equipment.

Results

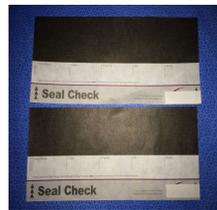
Once the tests have been performed, the staff noticed that, visually, the sealing area of surgical package was apparently perfect, but using the test, the result was unsatisfactory. After evaluation of technical service of sealing machine, it was proved that the sealing had a problem with temperature system and the problem was promptly solved.



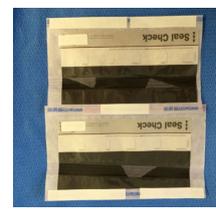
Benchmark



Equipment to perform the test (sealing)



Seal Check, used to perform the test



Test fail



Test in accordance

Conclusion:

Based on this experience and meeting the legal requirements, the test is now performed weekly. Another change was made in the preventive maintenance schedule, which went from semi-annual to quarterly, supplemented by annual validation.