as medical devices become more advanced and innovative, so do the regulations that surround them. This includes guidance for cleaning validations. Historically, AAMI TIR30 and other similar documents have offered guidance for this process; however, the creation of AAMI ST98 offers a standard for cleaning validations. Where AAMI TIR30:2011 states what considerations should be made during a cleaning validation, AAMI ST98 provides more details on those considerations, including, but not limited to, validation of extraction methods, extraction efficiency requirements, TOC acceptance criteria, and justification of sample size.
Validation of Extraction Methods

One of the new requirements in AAMI ST98 is that cleaning extraction methods should be validated. AAMI TIR30:2011 presents different methods for performing an extraction; however, it does not mention that the methods need to be validated or how to perform the validation. Per the new standard, ST98, two possible approaches for validating an extraction method are spike recovery and exhaustive extraction.

The use of spike recovery for validating an extraction method involves soil ing a medical device with a known amount of soil. The soils used for spiking are the same soils that are tested in the endpoint testing. Using this method, the extraction efficiency is a comparison between the amounts of soil recovered to the amount of soil added.

The use of exhaustive extraction for validating an extraction method involves performing extractions several times on the same soiled device. The amount of
Medical Device Cleaning Validations

A team of scientists that have a myriad of experience performing cleaning validations on all types and categories of medical devices will help keep the validation on track and completed in an efficient manner. A global network of resources is advantageous when performing cleaning validations on any categories of devices, but it is also beneficial if the device will be used in different countries.

When planning a cleaning validation study, the testing laboratory chosen to perform the study should be knowledgeable in the regulations surrounding the study. It is important that the lab understands all current and upcoming regulations, so that the device being validated is tested appropriately. Additionally, the lab should have testing equipment similar to what is used in a clinical or hospital setting. The end users of the device must be able to replicate the cleaning process when using the device.

Finally, the lab should be agile and competent to troubleshoot any obstacles as they arise. A team of scientists that have a myriad of experience performing cleaning validations on all types and categories of medical devices will help keep the validation on track and completed in an efficient manner. A global network of resources is advantageous when performing cleaning validations on any categories of devices, but it is also beneficial if the device will be used in different countries.

The upcoming AAMI ST98 standard will help medical device manufacturers and scientists in developing and testing devices that will undergo cleaning validations. The detail provided in ST98 on validation of extraction methods, extraction efficiency requirements, TOC acceptance criteria, and justification of sample size helps to ensure that the cleaning validation meets regulatory requirements. AAMI ST98, along with the aforementioned considerations for test labs, will help the continuity of the cleaning validation against any setbacks and ensure that it is completed successfully. The considerations detailed in ST98 are critical to a successful cleaning validation and confirm the cleaning protocols on medical devices to help ensure patient safety.

Reference

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