STEMart Announces Medical Device Reprocessing Validation Services

STEMart has recently introduced a series of Reprocessing Validation services to verify reprocessing instructions for reusable devices.

SHIRLEY, NEW YORK, UNITED STATES, April 21, 2023 /EINPresswire.com/ -- STEMart, a U.S.-based provider of comprehensive services for all phases of medical device development, has recently introduced a series of Reprocessing Validation services based on ISO, AAMI and ASTM standards to verify reprocessing instructions for reusable devices, including Cleaning Validation, Disinfection Validation, and Sterilization Validation.

It is necessary to ensure that healthcare products and devices are sterile and safe for each intended contact with a patient or user. Manufacturers of reusable medical devices are responsible for providing clear and understandable reprocessing instructions for their products. In addition, these procedures must be evaluated to demonstrate that reprocessing is performed safely and effectively in accordance with regulatory standards. Generally, reprocessing includes cleaning, disinfection and sterilization, depending on the risks associated with the use of the device.

"Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling" is a guide for industry and FDA staff that identifies general factors to consider when validating reprocessing instructions for reusable medical devices. Manufacturers of 510(k)-exempt devices should follow the recommendations in this guide unless, for example, the device is specifically exempted by regulation from certain QA requirements.

STEMart now offers Reprocessing Validations services in accordance with ISO, AAMI and ASTM standards to validate reprocessing instructions for reusable devices. The full range of medical device cleaning, disinfection and sterilization validation services help customers prove the functionality and safety of reusable medical devices through repeated exposure and clinical simulation.

Cleaning validation services, for example, must be performed on reusable instruments, trays, surgical kits and similar products. Typically, cleaning validation includes an assessment of the effects of contamination, cleaning and reprocessing. While simulated-use testing methods that mimic surgical procedures rather than direct inoculation methods, validation or customized test soils to create clinically relevant conditions may also be used for this testing.

Another example is the Sterilization Validation services, which confirm the appropriate Sterility Assurance Level of medical devices. The manufacturer will be able to provide validated sterilization parameters based on the parameters obtained from the test. Validation can be performed using steam, ethylene oxide, or dry heat. For some devices, liquid chemical sterilization or thermal sterilization may be acceptable alternatives.

STEMart offers comprehensive aseptic testing for sterile, non-pyrogenic products. With extensive expertise in microbiology and sterility testing, STEMart can provide comprehensive services to help manufacturers achieve regulatory goals and minimize compliance risks.

If you have additional questions regarding these Reprocessing Validation services for medical devices or would like to know more about STEMart's medical device development service, please visit https://www.ste-mart.com/.

About STEMart

STEMart is an industry-leading eCommerce platform incorporated with an extensive global footprint and a broad portfolio of more than 10,000 products. It aims to provide better lab materials, medical instruments and consumables, excellent technologies, and high-quality services to global customers in the fields of science, technology, and engineering, from the discovery stage upward to the manufacturing process. STEMart is dedicated to enhancing research and biotech production with simpler and safer protocols in order to access better health worldwide.

Staci Horme
STEMart
email us here