

STEMart Launches Disinfection Efficacy Studies Services for Medical Devices

STEMart has announced the launch of its Disinfection Efficacy Studies Services in various standards to ensure the safety of medical devices.

SHIRLEY, NEW YORK, UNITED STATES, October 26, 2023 /EINPresswire.com/ -- <u>STEMart</u>, a US-based provider of comprehensive services for all phases of medical device development, has announced the launch of its <u>Disinfection Efficacy Studies</u> Services in various standards to ensure the safety of medical devices. The services can be performed to evaluate the effectiveness of disinfectants against a wide range of microorganisms, including bacteria, yeast, viruses, and fungi.

Good Manufacturing Practices (GMP) regulations and FDA guidelines require biologic/pharmaceutical manufacturers to demonstrate that hazardous residues or organisms have been adequately removed during cleaning to a predetermined level of safety, thereby eliminating contamination of equipment.

Disinfectant testing is used to prove that cleaning and disinfecting procedures are effective enough to remove or inactivate microorganisms such as bacteria, yeast, fungi, viruses, molds and mycoplasmas. Before a new disinfectant can be introduced to the market, its disinfectant efficacy must be determined. Typical test materials include household and industrial disinfectants, sporicides, fungicides, and hand sanitizers. Meanwhile, deficiencies in cleaning and disinfection validation can result in the issuance of 183 warning letters by the FDA due to the potential release of unsafe products.

STEMart now offers comprehensive Disinfection Efficacy Studies Services to help medical device manufacturers to evaluate the efficacy of disinfectants against a wide range of microorganisms, including bacteria, yeast, fungi, and viruses. These services are guided by the AOAC Chapter 6 and USP <1072> to evaluate a disinfectant against a panel of clinically significant microorganisms and spores.

Disinfectant efficacy testing includes three main test parameters: chemical agent, test microorganisms, and typical facility surfaces. In addition, disinfectant regimens for cleanrooms, isolators, and other controlled areas must be validated against the manufacturing process. Customers may participate in STEMart's Disinfectant Efficacy Program when environmental monitoring data indicates a change in the common environmental flora or an organism has

developed resistance to current chemical disinfectants, in addition to the emergence of a new chemical agent, or when there are changes in the facility that may increase bioburden challenges above normal operating levels.

STEMart's services include three components: study protocol development, standard disinfection procedure implementation, and comprehensive evaluation studies. With extensive experience in designing and conducting disinfectant studies with a wide range of organisms, surfaces, and disinfectants, STEMart offers customized study protocols and specific methods depending on the client's project needs. STEMart can also streamline test combinations to meet client budgets, timelines, and regulatory requirements.

STEMart offers comprehensive Disinfection Efficacy Studies Services in various standards. If you have additional questions or would like to learn more about medical device testing services, please visit https://www.ste-mart.com/disinfection-efficacy-studies.htm.

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.

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