BIOBURDEN AND STERILITY TESTING OF MEDICAL DEVICES

CMDC BIOCOMPATIBILITY TESTING

Do you have a hands-on role in the manufacturing of medical devices? You've probably heard of bioburden testing. Following the completion of all procedures prior to sterilization, you must undergo this test to remain in compliance with the FDA's rules for medical device testing.

Safety of end users is a top priority for manufacturers of medical devices. Patient safety and your business could be in danger from incidents like sterility failures, regulatory interference (483s), and contaminated raw materials. Use of a qualified microbiological testing facility is a straightforward way to avoid these situations.

CMDC Labs may assist if you want to lessen the discomfort associated with regulatory compliance through bioburden testing. Don't let the performance of your medical equipment decrease. Receive the testing services you require from a skilled and experienced group of microbiologists.

BIOBURDEN TESTING OF MEDICAL DEVICES

How many microorganisms are present on the medical device is determined by a bioburden test. A suitability exam must be conducted first, then the test. The goal of the bioburden appropriateness test, also known as method validation, is to make sure that the bioburden test technique will be successful in removing microorganisms from the device and to demonstrate that the test method will support the development of the device microorganisms. A known low concentration of bacteria is placed on a sterile device and then removed using the same procedure that would be utilized for the actual bioburden test in order to accomplish the method validation. The percentage of microbes that could not be eliminated from the device is taken into consideration using a recovery factor that is established based on the results of the technique validation.

The device will go through bioburden testing to establish its microbiological load after an approved technique validation is finished. This device bioburden level is frequently employed in sterilization validations to determine the potential verification or sterilization dose required for a given device. Additionally, quarterly bioburden monitoring is carried out as part of quality control to check whether the microbial load on a device has changed.

STERILITY TESTING OF MEDICAL DEVICES

When conducting a sterility test, it is crucial that the lab ensures the instrument is truly sterile rather than releasing substances that can impede or even kill microbe growth. Therefore, sterility testing has a suitability test much like bioburden testing does. Bacteriostasis and fungistasis testing refer to the sterility appropriateness test. Whether a device prevents the growth of bacteria or fungi, which could result in false negatives during sterility testing, is determined by a bacteriostasis and fungistasis (B&F) test. In order to conduct the test, media must first include the device before being injected with less than 100 CFU of each of three separate organisms. The device passes the B&F test and sterility testing can start if the three organisms can make the media turbid.

Medical equipment sterility testing is often carried out utilizing media known as SCDM (Soybean-Casein Digest Medium). The device is actually put into the medium. Depending on the testing method selected, a different amount of sample is needed, but all require an incubation period of 14 days. After 14 days, the sample has failed the sterility test if the media has become turbid.

BIOBURDEN TEST RESULTS MAY BE USED TO:

- Using regular monitoring and trends, demonstrate microbiological quality control of the production process (ISO 11737)
- Calculate the radiation exposure for the final product (ISO 11137)
- Examine the underlying reasons for contaminated deviations from regular production (Alert and Action levels)
- Test raw materials and final goods for non-sterile products' microbiological safety (USP 61).
- Techniques for eliminating certain or unwanted microbes can be created. These techniques provide comprehensive, reliable test findings by identifying the presence or absence of specific microorganisms in addition to total viable counts. (USP 62; USP 60)

MAKING THE UNKNOWN KNOWN...

CMDC Labs, LLC I 105 S. Sunset St, STE O I Longmont I CO I 80501
info@CMDCLabs.com I +1 (720)-378-7387