Scapa Healthcare

Most Common **Microbiology Testing Methods**

for Medical Devices and Pharmaceutical Products

Routine testing of medical devices and pharmaceuticals is required to ensure that the manufacturing process remains in control. The method of microbiological testing is dependent upon the type of product or component and the unique quality control standards that need to be met.

Bioburden Validation and Testing

- Bioburden validation ensures that the bioburden test method is effective in recovering microorganisms that are present on the device.
- Bioburden testing determines how many microbes are on the non-sterile medical device, component or container, and is performed on a product that requires control / monitoring of bioburden counts.

Sterility Validation and Testing

- Sterility test method validation ensures that microorganisms can be recovered in the presence of the product under the conditions of the test.
- The test of sterility is used to determine the presence or absence of viable microorganisms on medical devices (or portions thereof) and is used to confirm the appropriateness of the minimum sterilization dose in achieving the required Sterility Assurance Level (SAL).
- The test for sterility is specified within the pharmacopoeias and is performed on product following an aseptic process or exposure to a sterilization process.

Sterilisation Dose Audits, Substantiation and Setting

- Sterilization dose substantiation and setting studies confirm the minimum irradiation dose needed to achieve the required Sterility Assurance Level (SAL).
- Sterilization dose audits confirm the continued appropriateness of the minimum irradiation dose to achieve the required Sterility Assurance Level (SAL).

Environmental Monitoring

- Used to test for surface and airborne contaminants within pharmaceutical clean rooms and other controlled environments.
- Surface monitoring ensures microbial populations are at acceptable levels using contact, swabbing and rinsing techniques.
- Air monitoring involves the assessment of non-viable (non-living) and viable (living) airborne contamination that has the potential to settle, and therefore contaminate the products.

When seeking for Microbiology and Sterilisation consultancy services, it's important to ensure that the team has specific experience in the pharmaceutical and medical device industries and adheres to national standards committees for microbiology and sterilisation.

Learn more about how Scapa Healthcare can help to support your microbiology and sterilisation needs.

Scapa Healthcare

We are the trusted strategic partner of choice for the world's leading companies in Advanced Wound Care, Consumer Wellness and Medical Device Fixation. We partner with market leaders to design, develop and manufacture innovative medical device fixation and topical solutions to improve people's lives.

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