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Bioburden Routine Determination - Medistri

🚀 Bioburden Routine Determination

Understanding and controlling the bioburden of a product is a prerequisite for any proper sterilisation. It is also a quality prerequisite in the medical and pharmaceutical industries.

Bioburden Routine Determination is a process used to measure the total microbiological population on a medical device or pharmaceutical article prior to sterilization. This process is crucial for ensuring the sterility of these products.

The routine determination of bioburden is important for several reasons:

1. **Quality Control:** It helps in maintaining the quality of medical devices and pharmaceutical products. By measuring the total microbiological population, manufacturers can ensure that their products are safe for use.
2. **Sterilization Effectiveness:** The bioburden count is used to validate the sterilization process. A high bioburden count may indicate that the sterilization process is not effective.
3. **Regulatory Compliance:** Routine bioburden testing is often a regulatory requirement for medical devices and pharmaceutical products. It helps manufacturers demonstrate that their products meet the necessary safety standards.
4. **Risk Management:** By identifying and quantifying the bioburden, manufacturers can take steps to manage and reduce the risk of contamination. This is particularly important in the production of sterile products.
5. **Product Stability:** Routine bioburden testing can also provide information about the stability of the product. Changes in the bioburden count over time can indicate issues with product stability.

The routine determination of bioburden must be performed using a documented sampling plan defining the sample size and the sampling frequency. The application of statistical methods to determine the sample size, sampling frequency, and/ or acceptable limits can be advised by Medistri.

This sampling plan is determined by factors such as the number of lots, the health risks associated with the use of products with a level of unacceptable contamination, product characteristics, and the degree of alleged contamination.

Bioburden testing is a regulatory requirement for medical devices as outlined in the international standard ISO 11737-1:2018 "Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products". This standard specifies the requirements and provides guidance for the determination of the bioburden on medical devices prior to sterilization.

Medistri's in-house laboratory possesses an in-depth comprehension of the Bioburden execution process. Our expertise and deliver precise results to meet your regulatory requirements.

🎯 To learn more about Medistri's Bioburden Routine Determination, visit on our website here or directly contact our team at contact@medistri.swiss.

- The Medistri Team

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