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Providing Sterilisation & Laboratory Services for the World's Most Innovative Healthcare Companies.

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Bioburden Validation - Medistri

🚀 Bioburden Validation

Bioburden is a method that must be validated in order to assess the actual results of routine analysis. This determines a conversion factor indicative of the recovery of organisms of a particular device. The bioburden validation should be reviewed at regular intervals.

Bioburden, also known as microbial limit testing, is a quality control process that detects and quantifies microbial contamination of a product at different stages of production. It's performed on pharmaceutical products and medical products for quality control purposes.

Bioburden is normally defined as the number of bacteria living on a surface that has not been sterilized. The aim of bioburden testing is to measure the total number of viable micro-organisms (total microbial count) on a medical device prior to its final sterilization.

Bioburden validation is essential for the safety and efficacy of medical devices and pharmaceutical products, as it controls microbial presence in products and informs the sterilization process. It ensures patient safety by minimizing risk and is key for regulatory success. As part of quality control, it helps maintain laboratory standards and monitors changes in the microbiological load on a device.

Bioburden validation is a systematic process that involves several steps, and is typically followed by routine determination of bioburden using a documented sampling plan defining the sample size and the sampling frequency. The bioburden validation should be reviewed at regular intervals.

👉 In case of exceeding the limits of acceptance, actions are taken at the source of the problem.

Medistri SA has STS 0504 accreditation for the analysis of microbial load, analysis approaches and validation (determining the rate of recovery and conversion factor). Our procedures meet the requirements of appropriate and current versions of European and United States Pharmacopeia and ISO standard.

At Medistri, our experts can effectively manage microbial presence, inform sterilization processes, and ensure patient safety.

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

- The Medistri Team

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