WickhamLaboratories
Contract Analytical Services

FACT SHEET - OVERVIEW OF ENVIRONMENTAL MONITORING

Description:

- Environmental Monitoring (EVM) is a process which is conducted to monitor the quality of the environment in areas where microbial contamination is of concern.
- Aseptic processing (particularly in facilities operating to Good Manufacturing Practice) relies on the prevention of microorganisms from entering products or test systems during testing or manufacturing.
- EVM is used as a monitoring strategy to establish the ongoing status of an environment in terms of any contamination that may be present.
- All EVM data should be analysed, reviewed and recorded.

Microbiological EVM:

- Microbiological EVM helps ensure pharmaceutical and medical device products meet the appropriate safety standards.
- Microorganisms can survive in water, on skin, in the air and other surfaces, therefore avoiding microbiological contamination can be difficult. This is why EVM is vital throughout all stages of testing and manufacturing.
- It is very important for manufacturers of pharmaceuticals and medical devices to understand the levels of microorganisms within the surrounding environment and identify them to reduce the risk of contamination.
- Regular cleaning procedures to relevant regulatory standards must be performed to ensure the facility is within specified limits for microbiological contaminants.
- It is required by most regulatory bodies that pharmaceutical companies have EVM operating procedures in place during the process of drug release to maintain public safety.

In the Lab / at Wickham Laboratories Ltd

- Assisting clients with environmental monitoring requirements starts by determining the level of background contamination.
- This can be done via surface monitoring to determine the microbial bioburden of any surfaces in the area being assessed, including equipment, as well as the monitoring of airborne particles via active air sampling.
- Surface monitoring can be accomplished by using contact plates, flexible film, swabs or the surface rinse method.
- Contact plates are common in environmental monitoring due to ease of use and the quantitative results they provide, but should only be used for flat, impervious surfaces.
- Swabbing and flexible film are similar to the contact plate method and can be used on irregular surfaces where contact plates are unsuitable.
- For surfaces where the interior bioburden must also be assessed, such as with porous materials, the surface rinse method can be utilised.
- In order to establish the type of microorganisms in the environment we use a Matrix Assisted Laser Desorption Ionisation-Time of Flight (MALDI-ToF) to accurately identify the microorganism to the species level.
- Consultancy is offered to help set up ongoing EVM of cleanrooms in compliance with ISO 14644 and the Orange Guide and we routinely assist clients with risk assessment, cleanroom commissioning and routine monitoring.