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Particle Monitoring in Sterilizing Tunnels

Portable aerosol particle counters are designed to sample ambient air at 1 cubic foot per minute (1 cfm) and no greater than 35 °C. There are however applications which are based on ambient temperatures much greater than this, such as pharmaceutical sterilizing tunnels. Sterilizing tunnels are used to ensure sterility off glassware (vials, syringes, bottles) prior to their entry onto an aseptic filling line, where internal temperatures can reach up to 200ºC.

The question of monitoring particle levels within these class 100 (ISO Class 5) areas, to prove that the area remains within specification raises two separate issues: do we need to monitor in these areas? If so, how do we monitor in these areas?

Requirements for Monitoring within Sterilizing Tunnels

Sterilizing tunnels are typically classified as the first part of the aseptic environment, and, therefore, Class A (ISO 5).

As a classified environment it must be monitored on a regular basis to prove that it meets the requirements. However, one of the functions of a non-viable particle monitoring system is to act as a barometer to the potential of viable particles, and it is these which most of the legislation is designed to control. As the environment is sterile, the high temperatures confirming this, then this part of the particle counter function is negated.

The first critical part to monitor a sterilizer tunnel is therefore within the cooling zone, where temperatures drop to that which may support viable organisms.

Classification of a sterilizing tunnel should be based upon the cold classification of the filters and their installed integrity. This classification should be performed at regular intervals, during routine shutdowns and room classification exercises. This data is then used to support the stability of the tunnels in operation. The particle counter in the cold zone will identify if particles are migrating into the tunnel from the cleanroom and the pressure differential used to prove that particles did not ingress into the system from outside the tunnel.

If Sampling Must be done
If sampling must be performed, then the sample must be cooled to a temperature acceptable by the particle counter; this is typically less than 35ºC. The only method of cooling the sample down is to use a cooling probe. Various other methods exist but do not meet ideal criteria:

Dilution: The amplification of errors due to dilution dramatically affect the statistical value of the data being reviewed. Either long sample intervals should be used to ensure sufficient 'real' particles are being seen or very low dilution rates which may cause particle counter temperatures to rise.

Cooling loops: Cause significant losses due to particle entrainment in the loop mechanism.

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