

Summary - Overview of Trending of Environmental Monitoring Data for Aseptic Processing Areas

How should environmental monitoring data be trended to assure microbiological control of aseptic processing areas?

This article establishes the need for trending of environmental monitoring data and gives recommendations on aspects of trending such as categorization of data, frequency of trending, trend definition and content of trend reports.

From a microbiological perspective, this means review of environmental monitoring (EM) results from each batch supplemented with periodic review of EM data over extended periods of time.

EM data in isolation provides a snapshot of microbial control at a discrete time point, but does not provide information on adverse trends that may be developing.

How often should trend data be reviewed? For example, it may be sensible to examine Grade A and B data for both short and long term trends while analysing Grade C and D data only for long term trends.

The easiest form of trending is to consider a certain number of alert level excursions equivalent to an action level excursion. While alert level excursions will show adverse trends in the short term, more advanced statistical treatment is required for longer-term data analysis.

Once the upper control level is established, it can be compared to the percentage of EM data points that do not conform to the chosen attribute.

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