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monitoring data is only one of a And number of Listeria measures used to indicate the state of control in an aseptic manufacturing process. Besides, environmental monitoring is not a direct measure of product batch sterility due to the inherent variability Page 16/36

of environmental monitoring methods and more Listeria importantly; the lack of a correlation

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occurs (211.42 and 211.113)." Section X.A.2 of the Listeria gUidance states, "Environmen tal monitoring data will provide information on the quality of the manufacturing ...

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based on a formal risk analysis study and the results obtained

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