

The Environmental Monitoring Program in a GMP Environment

May 13, 2013 10:19 pm EDT



The routine environmental monitoring program is a critical aspect of documenting the state of control of the facility. Recommendations for the selection of sample sites to be used in the qualification program are provided. These recommendations are directed at providing data to allow creation of a program useful in determination of the state of control of the facility. The qualification study should provide data to allow determination of meaningful alert and action levels for that facility. It must be noted that there are significant technical and scientific issues with the regulatory...

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