

The Environmental Monitoring Program in a GMP Environment

Scott Sutton

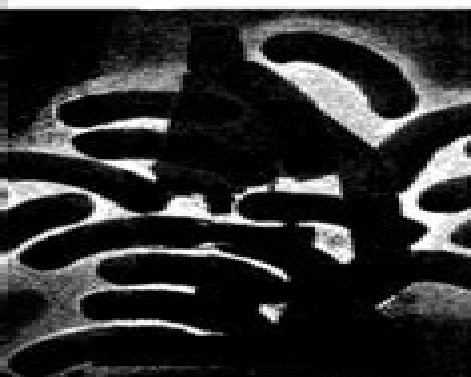


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"Microbiology Topics" discusses various topics in microbiology of practical use in validation and compliance. We intend this column to be a useful resource for daily work applications.

Reader comments, questions, and suggestions are needed to help us fulfill our objective for this column. Please send your comments and suggestions to column coordinator Scott Sutton at scott.sutton@microbiol.org or journal coordinating editor Susan Haigney at shaigney@advanstar.com.

KEY POINTS

The following key points are discussed in this article:

- 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 guidelines for the areas of an aseptic core region—a suggestion consistent with proposed revisions to *United States Pharmacopeia* chapter <1116> "Microbiological Control and Monitoring Environments Used for the Manufacture of Healthcare Products" is provided
- Explicit examples are provided from publically-available sources (FDA-483 observations and warning letters) of enforcement activities based on good manufacturing practice failures in the environmental monitoring program
- A discussion is provided on the relative values of 483 observations and warning letters as useful indicators of US Food and Drug Administration policy.

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between 1798 and 1800 and published in 1801 dedicated to joseph franz von lobkowitz although it is numbered third it was
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published in 1819 is an arrangement of the early c minor piano trio op 1 no 3 this work is scored for a string quintet with two
violas the work is referenced in vikram seth s 1999 novel an equal music structure

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