

## Recommendations from USP <1116> on “Contamination Recovery Rates”

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By **Scott Sutton, Ph.D.** Mar 23, 2016 7:00 am EDT

INTRODUCTION The USP <1116> “Microbiological Control and Monitoring of Aseptic Processing Environments” (1) marks a significant shift in regulatory thinking regarding microbiological monitoring of aseptic areas. This shift leads away from arbitrary numerical levels in these extremely clean environments to a more qualitative trending methodology. In addition to the important information in this chapter on new ways to set alert and action levels for environmental monitoring (EM) programs, this chapter also stresses the separate and

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