

## A Risk Matrix Approach for Media Simulation Trials

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**INTRODUCTION** Aseptic processing is generally regarded as the most "at risk" pharmaceutical process to conduct, primarily due to the possibility of microbial contamination, and because the product, often due to its inherent nature, cannot be subjected to a terminal sterilization process. A number of environmental controls, particularly in relation to cleanroom and clean air design, are built into the process to protect the product (1). Personnel are required to follow strict disciplines in relation to good aseptic technique. One of the periodic assessments undertaken to measure the likelihood of...

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