

IN THEIR OWN WORDS

FDA, US Food and Drug Administration, Questions and Answers on Current Good Manufacturing Practices, Good Guidance Practices, Level 2 Guidance Production and Process Controls - August 4, 2004, updated November 19, 2009.

What is the acceptable media fill frequency in relation to the number of shifts? Normally, media fills should be repeated twice per shift per line per year. Is the same frequency expected of a process conducted in an isolator?

...Certain modern manufacturing designs (isolators¹ and "closed vial" filling) afford isolation of the aseptic process from microbiological contamination risks (e.g., operators and surrounding room environment) throughout processing. For such closed systems, if the design of the processing equipment is robust and the extent of manual manipulation in the manufacturing process is minimized, a firm can consider this information in determining its media fill validation approach...

¹This does not apply to RABS (Restricted Access Barrier Systems)

[Read more](http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm124782.htm) <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm124782.htm>