Aseptic Solutions Inc.

CONCLUSIONS

Media Fill Challenges

1. The level of environmental contamination can impact the sterility assurance of the product being filled.

2. Good aseptic technique can reduce the risk of product contamination, even in the presence of a contaminated environment.

3. Personnel are the main vectors of contamination in the aseptic filling facility, unless a contaminated aerosol is created.

4. A contaminated media-fill unit is a major event. In modern cleanrooms with basic facility design, including HEPA-filtered air and a knowledge of good aseptic techniques, a positive media-filled vial or product-filled vial should **NEVER** occur. ***Any positive media-filled unit, regardless of the number of vials filled, should be considered a failure and a major investigation should be initiated immediately.***

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