

A Contamination Control Strategy Gone Wrong



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ABSTRACT Warning letters and regulatory inspection observation reports (e.g., FDA 483) often provide useful information for assessing risks in your facility and preparing for upcoming inspections. Starting with the updates to the European Union's Annex 1 for the Manufacture of Sterile Drugs there has been an increased focus on contamination control strategies in facilities. A contamination control strategy is an integral part of pharmaceutical manufacturing, whether sterile or non-sterile. For this article we are going to look at a series of observations for a vaccine production facility and...

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