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## **Particulates Reduction Efforts in Single Use Technologies: A Case Study**

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Single use technologies require a close collaboration between supplier and end-user with regards to cleanliness issues, primarily focused on particulate contamination. Since a large percentage of drug recalls relate to particulate contamination, and detection of a single visible particle in a dose of injectable drug is considered a critical issue and thus causes significant time and money to remedy, reduction of risk related to particulate contamination is of highest priority. Particulate detection is challenging in single use systems due to the complexity of the devices. As this presentation will show, concerted efforts to reduce particulate generation at all steps of the manufacturing process by using quality by design and risk reduction principles can bring large benefits.

This presentation will detail the method used jointly by two suppliers along the manufacturing supply chain for vial stoppers and syringe plungers to improve quality and to decrease the risk of particle contamination in injectable drug products. The stoppering of a vial or prefilled syringe is a critical process step during the manufacturing of drug products since particulates remaining on the stopper or plunger could potentially end up in the product and lead to a product recall. Therefore it is necessary for the stopper supplier to have process capabilities with regards to particle contamination under control. Control starts from the design phase for the stopper, where it is critical to follow quality by design principles. An adequate cleanroom environment and good manufacturing practices drive the final cleanliness of the product, and it is critical to have a continuous improvement program in place. A process fish bone analysis and FMEA is the approach chosen for this case study in order to identify the risk of contamination and in parallel to improve the stopper manufacturing process including the final packaging. Thus, particulate reduction methods were applied all along the supply chain in a successful effort to reduce particulate contamination risk.