

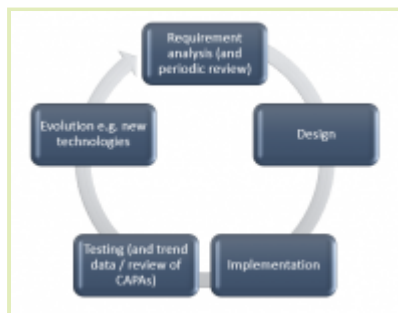
An Anatomy of a Contamination Control Strategy for Sterile Manufacturing



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By

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An effective strategy, depending on the type of pharmaceutical product being manufactured, considers (3, 4): Microbial contamination Sterility assurance Facility design Chemical contamination Particle contamination (visible and sub-visible) Viral control Other forms of contamination that can arise from mix-ups, damaging primary or secondary packaging, distribution problems, and environmental fluctuations. It is recognized that any contamination control strategy represents a cyclical process, designed to prompt the manufacturers to identify and resolve risk, and hence one that requires periodic...

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