Regulatory Actions Taken in Response to Issues in Aseptic Processing and the Quality System

By 

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FDA has cited many issues with the requirements in 21CFR 211.113(b), which sites failures in appropriate written procedures to prevent microbiological contamination. This requirement is as follows: Your firm failed to follow appropriate written procedures that are designed to prevent microbiological contamination of drug products purporting to be sterile, and that include validation of all aseptic and sterilization processes (21CFR 211.113(b)). Examples of FDA Concerns Poor Aseptic Behavior The operators displayed poor aseptic practices during aseptic set-up and filling operations. Examples of...